MEMORANDUM

Date: January 14, 2019

To: Interested Parties

From: James Castle, Bureau of Environmental Health and Radiation Protection, Ohio Department of Health

Subject: Draft Amendments to Ohio Administrative Code (OAC) Rules 3701:1-66-01, 02, 04, 06, 07, 08, and 10


The proposed amendments are being posted for a second public comment period after receiving comments from the August 8, 2018 public comment period. The Ohio Department of Health and Radiation-Generating Equipment Committee reviewed the public comments and revised the rules based on some of the public comments at a public meeting on September 21, 2018. Please see the attached summary of amendments.

Please review the draft rule amendments and provide any comments you may have by February 14, 2019 to the address below. Please include the words “Comments to Proposed Amendments to “Draft Radiation-Generating Equipment Rules” in the subject line of all comments sent via regular mail or e-mail. The Ohio Department of Health will review and consider the comments received before the rule is submitted for formal rule proposal and adoption proceedings. Thank you.

Office of the General Counsel [Draft Radiation-Generating Equipment Rules]
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Columbus, Ohio 43215
ODHRules@odh.ohio.gov

(A) Terms defined in this rule are intended to be used only within this chapter of the Administrative Code.

(B) As used in this chapter:

(1) "Air kerma" means the sum of the initial kinetic energy of all charged ionizing particles liberated by uncharged ionizing radiation in a given mass of air. The unit for air kerma is joules per kilogram which is given the special name of gray (Gy). To determine air kerma in Gy from exposure in units of roentgens (R) multiply exposure by the conversion factor 0.00876 Gy/R.

(2) "Air kerma rate", or "(AKR)" means the air kerma per unit time.

(3) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

(4) "Annual" means at least once a year, not to exceed fourteen months.

(5) "Automatic exposure control", or "(AEC)" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation.

(6) "Beam-limiting device" means a collimator which provides a means to restrict the dimensions of the x-ray field.

(6) "Bone densitometry equipment" means radiation-generating equipment used for the medical purpose of quantifying bone density and mineral content by x-ray measurements through the bone and adjacent tissues.

(7) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

(8) "Calibration" means the determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or the radiation output of a source of radiation relative to a standard.

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

(10) "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

(11) "Computed radiography" means a system that utilizes a photostimulable phosphor (PSP) plate for capturing radiographic images. The components of the system include, at a minimum, the PSP plate and a computed radiography reader which laser scans the exposed plate, collects the stimulated light and ultimately creates the digital image.

(12) "Computed tomography", or "(CT)" means an imaging procedure that uses multiple x-ray transmission measurements and computer programs to generate tomographic images.

(13) "Control panel" means that part of the radiation-generating equipment used for setting the technique factors.
(14) "CT conditions of operation" means all selectable parameters governing the operation of CT radiation-generating equipment including, but not limited to, nominal image thickness, filtration, milliampere (mA), kilovoltage peak (kVp), and scan time.

(15) "CT noise" means the per cent standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.

(16) "CT number" or "(CTN)" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

(17) "Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

(18) "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.

(19) "Dental equipment" means radiation-generating equipment used for dental radiography.

(20) "Digital radiography" or "(DR)" means an x-ray imaging method which produces a digital rather than analog image.

(21) "Direct scattered radiation" means scattered radiation which has been deviated once in direction only by materials irradiated by the useful beam.

(22) "Enclosed system" means industrial radiation-generating equipment operated in an enclosure or cabinet and may include, but is not limited to, cabinet radiography, irradiation devices, and other equipment.

(23) "Executive administration" means individuals employed in the hospital's administration and having the authority to expend capital funds, approve personnel actions, and implement changes to hospital policy and procedure.

(24) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.

(25) "Fluoroscopic equipment" means radiation-generating equipment used for real time imaging of internal structures for medical purposes.

(26) "Fluoroscopically-guided interventional (FGI) procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy. This statement is focused on the FGI subset of potentially high-dose procedures.

(27) "Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

(28) "Full time training in medical physics" means having been engaged in the practice of clinical medical physics for a minimum of eighteen hundred hours within twelve consecutive months, under the supervision of a board-certified medical physicist.
"Full time work experience" means a minimum of eighteen hundred hours of work experience earned within twelve consecutive months.

"General purpose radiographic equipment" means stationary, mobile, and portable radiation-generating equipment used for medical purpose, but does not include dental intraoral, panoral, mammography, bone densitometry, computed tomography, fluoroscopy or spot film imaging and equipment used in radiation therapy.

"Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced by one-half of its original value.

"Hand-held radiation-generating equipment" means x-ray equipment that is specifically designed to be held in the hand during operation.

"Handle" means receive, possess, use, store, transfer, install, service, or dispose of radiation-generating equipment unless possession is solely for the purpose of transportation.

"Handler" means a facility that handles radiation generating equipment unless possession is solely for the purpose of transportation.

"Hybrid imaging system" means a combination of systems that separately produce anatomic and functional images in very close temporal proximity without the need for patient repositioning and allow images to be co-registered and fused. These systems may be used for purposes including, but not limited to, attenuation correction, localization, registration, or fusion, but not used independently for diagnosis.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device that transforms incident x-ray photons into either a visible image or another form that can be made into a visible image by further transformation. In those cases, where means are provided to preselect a portion of the image receptor, the term "image receptor" means the preselected portion of the device.

"Individual responsible for radiation protection (IRRP)" means an individual designated by the registrant who has the knowledge and responsibility for overall radiation safety and the quality assurance program at the facility, to include daily radiation safety operations and compliance with the rules.

"Interventional procedure" means an invasive procedure that utilizes radiation-generating equipment for diagnostic or therapeutic purposes.

"Kilovoltage peak (kVp)" means the maximum value of the electrical potential difference between the cathode and the anode of the x-ray tube during an exposure.

"Last image hold" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Lateral fluoroscope" means the portion of a biplane system consisting of an x-ray tube housing
assembly and an image receptor that are fixed in position to produce a horizontal x-ray beam.

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

(35)-(43) "Leakage radiation" means all radiation coming from within the x-ray tube housing except the useful beam.

(36)-(44) "Licensed practitioner" means an individual licensed by the state of Ohio pursuant to:
(a) Chapter 4715. of the Revised Code to practice dentistry;
(b) Chapter 4731. of the Revised Code to practice medicine or surgery or osteopathic medicine or surgery;
(c) Chapter 4731. of the Revised Code to practice podiatry;
(d) Chapter 4741. of the Revised Code to practice veterinary medicine;
(e) Chapter 4734. of the Revised Code to practice chiropractic medicine; and
(f) Chapter 4723. of the Revised Code to practice as a clinical nurse specialist within the scope of practice of his or her collaborating physician and in accordance with the standard care arrangement.
(g) Chapter 4730. of the Revised Code to practice as a physician assistant within the scope of practice of his or her supervising physician and in accordance with the utilization plan approved by the state medical board.

(37)-(45) "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.

(46) "Medical event" means one or more of the following criteria have occurred to a human patient:
(a) Unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rad);
(b) Unintended dose other than skin dose in a single procedure greater than:
   (i) 0.5 Gy (50 rad) to any organ; or
   (ii) 0.05 Sv (5 rem) effective dose;
(c) Wrong patient or wrong site for entire procedure when the resultant dose is:
   (i) Greater than 0.5 Gy (50 rad) to any organ; or
   (ii) Effective dose greater than or equal to 0.05 Sv (5 rem).

(38)-(47) “Medical use” or “Medical purpose” means using radiation-generating equipment to irradiate human beings or animals for diagnostic, localization, or other healing arts purposes.

(39)-(48) "Milliampere (mA)" means the measurement of tube current which reflects the number of electrons flowing from the cathode to the anode of an x-ray tube during x-ray production.
(40)-(49) "Mobile radiation-generating equipment" means x-ray equipment permanently mounted on a base with wheels or castors for moving while completely assembled and is not used in a fixed location.

(41)-(50) "Patient" means an individual or animal subjected to radiation for the purposes of examination or therapy.

(42)-(51) "Portable radiation-generating equipment" means radiation-generating equipment designed to be hand-carried.

(43)-(52) "Primary protective barrier" means a barrier sufficient to attenuate the useful beam to the required radiation level.

(44)-(53) "Protective apron" means an apron made of radiation-attenuating materials used to reduce radiation exposure.

(45)-(54) "Protective barrier" means a barrier of radiation-attenuating materials used to reduce radiation exposure.

(46)-(55) "Protective glove" means a glove made of radiation-attenuating materials used to reduce radiation exposure.

(47)-(56) "Radiation expert" means an individual who meets the qualifications of:

(a) Applicable paragraphs of rule 3701:1-66-03 of the Administrative Code;

(b) Paragraph (D) of rule 3701-83-45 of the Administrative Code for any facility providing radiation therapy services;

(c) Paragraph (C)(3) of rule 3701-83-52 of the Administrative Code for CT equipment, or paragraph (F)(3) of rule 3701-83-52 of the Administrative Code for fluoroscopy at any facility providing CT or fluoroscopy services; or

(d) 21 C.F.R. 900.12(a)(3) (as published in the April 1, 2013, Code of Federal Regulations effective on the effective date of this rule) for any facility providing mammography services.

(48) "Radiation-generating equipment (RGE)" means any manufactured product or any component of such a product or device, or any machine or system that during operation can generate or emit ionizing radiation, except those that emit ionizing radiation only from radioactive material. The system 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. "Radiation-generating equipment" does not include either of the following:

(a) Diathermy machines; or

(b) Microwave ovens including food service microwave ovens used for commercial and industrial uses, television receivers, electric lamps, and other appliances and products such as computer monitors that generate very low levels of radiation.

(49)-(57) "Radiation worker" means an individual engaged in activities registered by the department and controlled by the registrant.
"Reference plane" means a plane which is displaced from and parallel to the computed 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 sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

"Secondary protective barrier" means a barrier sufficient to attenuate stray ionizing radiation to a required level.

"Source" means the point of origin of the useful radiation beam.

"Source-to-image receptor distance" or "(SID)" means the distance from the source to the center of the input surface of the image receptor.

"Source-to-skin distance" or "(SSD)" means the distance between the source and the skin of the patient.

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

"Stationary radiation-generating equipment" means equipment which is installed in a fixed location.

"Stray radiation" means leakage radiation or scattered radiation.

"Table 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.

"Technique factors" means any combination of the following which determines the exposure rate: kVp, mA, time, x-ray pulses, or the product of tube current and exposure time in mAs.

"Tomogram" means the depiction of the radiation attenuation properties of a section through a body.

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

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

"Unintended Dose" or "Unintended Skin Dose" means a patient radiation dose resulting from an error or equipment malfunction during procedure.

"Useful beam" means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the source housing.

"Veterinary radiation-generating equipment" means radiation-generating equipment used for veterinary
radiography.

(66)-(77) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

(67)-(78) "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 air kerma rate is one-fourth of the maximum in the intersection.

(B) Terms appearing in this chapter, which are not defined in this rule, may be defined in rule 3701:1-38-01 of the Ohio Administrative Code
General administration requirements for handlers of medical radiation-generating equipment.

As used in this rule, "radiation-generating equipment" means radiation-generating equipment, other than therapeutic radiation-generating equipment, used for dental, veterinary, or medical purpose but does not include therapeutic radiation-generating equipment. Handlers of this equipment shall comply with the following:

(A) The director may, upon application thereof or upon his or her own initiative, grant a variance to the requirements of rules in this chapter as he or she determines is authorized by law, provided that the registrant shows to the satisfaction of the director that there is good cause for the variance, and that the variance will not result in any undue hazard or effect on the public health and safety or environment. The terms, conditions, and expiration of the variance shall be set forth in writing by the director. Failure to comply with the terms of the variance may result in immediate revocation of the variance.

(B) Except as specified in rule 3701:1-66-17 of the Administrative Code, no individual shall be exposed to the useful beam except a patient for dental or medical radiologic procedures and unless such exposure has been authorized by a licensed practitioner within his or her scope of practice. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or any other non-medical purpose; and
2. Exposure of an individual for the purpose of self-referred screening except as authorized by the department in accordance with paragraph (A) of rule 3701:1-66-17 of the Administrative Code.

(C) The department may use interview or observation to determine that the handler assures:

1. Every individual who performs radiologic procedures on human beings holds the appropriate radiologic license as required by Chapter 3701-72 of the Administrative Code and Chapter 4715. of the Revised Code; and
2. Every individual who is licensed to perform radiologic procedures is adequately instructed in the registrant's safe operating procedures and can demonstrate competency in the safe use of the equipment.

3. The individual responsible for radiation protection (IRRP) is qualified as one of the following:
   
   a. Ohio licensed to operate radiation-generating equipment;
   b. Dental assistant certified to operate dental radiation-generating equipment;
   c. Registered veterinary technician and trained to operate veterinary radiation-generating equipment;
   d. Certified by the American Registry of Radiologic Technologists in a pathway involving ionizing radiation or certified by the Nuclear Medicine Technologist Certification Board;
   e. A radiation expert as defined in rule 3701:1-66-01 of the Administrative Code;
   f. A health physicist certified by the American Board of Health Physics; or
   g. An associate's degree or higher in health physics, radiologic science, nuclear medicine or nuclear engineering.
(D) Any radiation-generating equipment that does not meet the provisions set forth in this rule or any other applicable equipment requirements of Chapter 3701:1-66 of the Administrative Code shall not be used to irradiate patients unless the director or a radiation expert determines that the non-compliance will not pose a radiation risk and arrangements have been made to promptly correct the non-compliance.

(E) Radiation-generating equipment shall bear a warning label on the control panel, by the exposure switch or by the main power switch which cautions individuals that radiation is produced when it is energized.

(F) Unless otherwise specified in this paragraph, radiation-generating equipment shall meet the following standards:

(1) 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.

(2) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 0.88 milligray air kerma (one hundred milliroentgen exposure) 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 one hundred square centimeters with no linear dimension greater than twenty centimeters.

(3) Except for mammographic radiation-generating equipment, the half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in table 1. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1, linear interpolation or extrapolation may be made.

Table 1.

<table>
<thead>
<tr>
<th>X-Ray Tube Voltage (kilovolt peak)</th>
<th>Minimum HVL (millimeter of aluminum)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Specified Dental Systems¹</td>
</tr>
<tr>
<td>Designed Operating Potential</td>
<td>Measured Operating Potential</td>
</tr>
<tr>
<td>Below 51</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>50</td>
</tr>
<tr>
<td>51 to 70</td>
<td>51</td>
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<tr>
<td></td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>70</td>
</tr>
<tr>
<td>Above 70</td>
<td>71</td>
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<tr>
<td></td>
<td>80</td>
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<tr>
<td></td>
<td>90</td>
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<td></td>
<td>100</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>130</td>
</tr>
<tr>
<td></td>
<td>140</td>
</tr>
<tr>
<td></td>
<td>150</td>
</tr>
</tbody>
</table>
Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

(a) For capacitor energy storage equipment, compliance with the requirements of this paragraph shall be determined with the system fully charged and a setting of ten milliampere-seconds (mAs) for each exposure; and

(b) The required minimal HVL of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(4) For x-ray systems which have variable kilovolt peak (kVp) setting and variable filtration for the useful beam, a device shall link the kVp selector with the filter and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by paragraph (G)(F)(3) of this rule is in the useful beam for the given kVp which has been selected.

(5) Where two or more x-ray tubes are controlled by one exposure switch, the tube that has been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and for dental equipment at or near the selected tube housing assembly.

(6) The x-ray tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the radiation-generating equipment.

(7) 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. This requirement may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films taken during fluoroscopy procedures or dental intraoral or panoramic films.

(8) All position locking, holding, and centering devices on radiation-generating equipment components shall function as designed by the manufacturer.

(G) In addition to other applicable radiation safety rules in Chapter 3701:1-66 of the Administrative Code, handlers of radiation-generating equipment shall meet the following radiation safety requirements:

(1) Software-based technique selections, a chart, or a combination of the two shall be provided in the vicinity of the radiation-generating equipment's control panel which specifies, for examinations performed with that system, the following information:

(a) Patient's body part, radiographic projection, anatomical size or age, and the technique factors to be
(b) Type and size of the image receptor to be used;
(c) Type and focal distance of the grid to be used, if any; and
(d) Source-to-image receptor distance (SID) to be used, except for fluoroscopy, and dental intraoral or panoral radiography.

(2) Gonadal shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiologic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the radiologic procedure.

(3) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiologic procedure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body shall be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

(b) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; and

(c) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters (6.5 feet) from both the tube head and the nearest edge of the image receptor.

(4) If performing a radiologic procedure requires auxiliary support for holding a patient or an image receptor, the handler shall ensure the following:

(a) Mechanical holding devices shall be used when the procedure permits their use in lieu of having an individual hold the patient or image receptor;

(b) Written safe operating procedures required by paragraph (B)(4) of rule 3701:1-66-04 of the Administrative Code shall indicate the requirements for selecting someone to hold a patient or image receptor, and the procedure that shall be followed. All individuals holding a patient or image receptor during radiation exposures shall be at least eighteen years of age; and

(c) No individual shall routinely hold patients or image receptors during radiologic procedures.

(5) The facility shall have protective aprons and gloves available in sufficient numbers to provide protection to anyone who is involved with x-ray operations.

(6) Any radiation worker participating in fluoroscopic, veterinary, or mobile or portable x-ray procedures shall be required to wear an individual monitoring device unless the registrant demonstrates it is unlikely the radiation worker will receive in excess of the doses specified in paragraphs (B)(1)(a) to (B)(1)(c) of
(7) The entrance air kerma resulting from the technique used for the specified average adult patient for routine diagnostic radiography shall not exceed the values listed in table 2. The entrance air kerma resulting from the technique used for routine intraoral bitewing exams shall not exceed the values listed in table 3. All values of entrance air kerma are specified as free-in-air, without backscatter. The corresponding entrance exposure in milliroentgens is listed in parentheses. Linear extrapolation or interpolation shall be used for an x-ray tube potential (kVp) not listed in table 3.

Table 2.

<table>
<thead>
<tr>
<th>Radiographic technique</th>
<th>Adult thickness cm</th>
<th>Entrance air kerma mGy (mR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest (pa), (non-grid)</td>
<td>23</td>
<td>0.26 (30)</td>
</tr>
<tr>
<td>Chest (pa), (grid)</td>
<td>23</td>
<td>0.35 (40)</td>
</tr>
<tr>
<td>Abdomen (kub)</td>
<td>23</td>
<td>5.26 (600)</td>
</tr>
<tr>
<td>Lumbo-sacral spine (ap)</td>
<td>23</td>
<td>6.13 (700)</td>
</tr>
<tr>
<td>Thoracic spine (ap)</td>
<td>23</td>
<td>3.50 (400)</td>
</tr>
<tr>
<td>Full spine</td>
<td>23</td>
<td>3.50 (400)</td>
</tr>
<tr>
<td>Cervical spine (ap)</td>
<td>13</td>
<td>1.75 (200)</td>
</tr>
<tr>
<td>Skull (lateral)</td>
<td>15</td>
<td>1.75 (200)</td>
</tr>
<tr>
<td>Foot (dp)</td>
<td>8</td>
<td>0.88 (100)</td>
</tr>
</tbody>
</table>

Table 3.

<table>
<thead>
<tr>
<th>Tube Voltage kVp</th>
<th>D-Speed Film mGy (mR)</th>
<th>F-Speed Film Digital Receptor mGy (mR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>4.82 (550)</td>
<td>2.45 (280)</td>
</tr>
<tr>
<td>55</td>
<td>4.56 (520)</td>
<td>2.19 (250)</td>
</tr>
<tr>
<td>60</td>
<td>4.12 (470)</td>
<td>1.93 (220)</td>
</tr>
<tr>
<td>65</td>
<td>3.64 (415)</td>
<td>1.66 (190)</td>
</tr>
<tr>
<td>70</td>
<td>3.15 (360)</td>
<td>1.45 (165)</td>
</tr>
<tr>
<td>75</td>
<td>2.72 (310)</td>
<td>1.23 (140)</td>
</tr>
<tr>
<td>80</td>
<td>2.28 (260)</td>
<td>1.01 (115)</td>
</tr>
<tr>
<td>85</td>
<td>2.06 (235)</td>
<td>0.92 (105)</td>
</tr>
<tr>
<td>90</td>
<td>1.84 (210)</td>
<td>0.83 (95)</td>
</tr>
<tr>
<td>95</td>
<td>1.71 (195)</td>
<td>0.74 (85)</td>
</tr>
<tr>
<td>100</td>
<td>1.58 (180)</td>
<td>0.61 (70)</td>
</tr>
</tbody>
</table>

(8) Procedures and auxiliary equipment designed to minimize patient and radiation worker exposure shall be utilized as follows:

(a) For facilities utilizing radiographic film, 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 shall not be used for any routine diagnostic radiography, with the exception of
veterinary and specimen radiography;

(b) Radiation-generating equipment subject to rule 3701:1-66-05 of the Administrative Code shall not be utilized in procedures where the source-to-skin distance (SSD) is less than thirty centimeters, except for veterinary x-ray systems;

(c) If grids are used between the patient and the image receptor to decrease scatter to the image receptor and improve contrast, the grid shall be:

(i) Properly aligned, with the x-ray tube side facing the correct direction, and the grid centered to the central ray; and

(ii) The proper focal distance for the SID being used.

(9) Except for radiation-generating equipment used for veterinary, portable, dental panoral, dental intraoral, lithotripsy, or bone densitometry applications, the operator shall stand behind a protective barrier, either in a separate room, in a protected booth, or behind a shield.

(10) Each radiographic image, or a record linked with each radiographic image, shall contain the following:

(a) Patient identification;

(b) Date of examination; and

(c) Operator identification.

(H) In addition to other applicable structural shielding requirements in Chapter 3701:1-66 of the Administrative Code, handlers of radiation-generating equipment shall comply with the following:

(1) For all units, except those used for bone densitometry, mammography, dental panoral or dental intraoral radiography:

(a) Handlers shall utilize a radiation expert to prepare a shielding design to include specifications for all structural radiation barriers:

(i) Prior to new construction, or renovation;

(ii) For new radiation-generating equipment installations which might cause a significant increase in radiation hazard.

(b) Prior to patient use, handlers shall utilize a radiation expert to determine compliance with exposure levels in accordance with rule 3701:1-38-14 of the Administrative Code by performing:

(i) An area radiation survey for new installation of radiation-generating equipment.

(ii) An area radiation survey for reinstallation or after any change in structural shielding unless, in the documented determination of a radiation expert, the reinstallation or change will not cause a significant increase in radiation hazard.

(iii) A re-calculation of an area radiation survey results after an increase in the clinical workload that
exceeds the assumptions used in the existing radiation survey.

(c) Notwithstanding paragraph (I)(1)(b)(ii) of this rule, reinstallations of radiation-generating equipment of the same operating parameters, location and geometry does not require another survey as long as the previous documented area radiation survey is maintained and available for inspection. Use a radiation expert to perform a re-calculation of area radiation survey results after any increase in clinical workload that exceeds the assumptions used in the existing radiation survey.

(d) The individual responsible for radiation protection shall obtain a written report of the shielding design and the area radiation survey. A copy of the report shall be made available to the department's inspector upon request.

(2) Handlers shall assure that no individual operates or permits the operation of radiation-generating equipment unless structural shielding and protective barriers are used such that no person other than the patient being examined shall receive a total effective dose equivalent in excess of the limits prescribed in rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code.

(3) Handlers shall provide a protective barrier either in a separate room, in a protected booth, or use a mobile barrier that will intercept the useful beam and any direct scattered radiation.

(4) Handlers shall provide a window of lead equivalency affording protection equal to that required by the adjacent barrier, a television monitoring system, or a mirror system large enough and so placed that the operator can see the patient without having to leave the protected area during exposure.

(5) Handlers of stationary CT and mobile CT radiation-generating equipment used in one place shall assure the facility design provides for two-way aural communications between the human patient and operator.

(I) Notwithstanding paragraph (H)(1)(b)(ii) of this rule, reinstallation of radiation-generating equipment of the same operating parameters, location and geometry does not require another area radiation survey as long as the previous documented area radiation survey is maintained and available for inspection.

(I)(J) In addition to all applicable rules in Chapter 3701:1-66 of the Administrative Code, handlers of radiation-generating equipment shall meet the following quality assurance requirements:

(1) X-ray systems and associated components used on humans and certified pursuant to 21 C.F.R. part 1020 (as published in the April 1, 2013 Code of Federal Regulations, effective on the effective date of this rule) shall be maintained in compliance with applicable requirements of that standard, any modifications to the original components or systems must comply with that standard, and handlers shall maintain documentation of compliance between inspections.

(2) The handler shall maintain the following information for all radiation-generating equipment for inspection by the department:

(a) User's manuals;

(b) Records of surveys, calibrations, maintenance, and modifications performed on the
radiation-generating equipment which shall be maintained between inspections; and

(c) A copy of all correspondence with the department regarding each piece of radiation-generating equipment;

(3) Unless otherwise specified in another rule in this chapter, each installation using a piece of radiation-generating equipment and using analog image receptors, such as radiographic film, shall have available suitable equipment for handling and processing radiographic images in accordance with the following provisions:

(a) For manually processing film:

   (i) Developer and fixer tanks shall be constructed of mechanically rigid, corrosion resistant material; and

   (ii) The temperature of solutions in the tanks shall be maintained within the range of 15.6 to 26.7 degrees Celsius (sixty to eighty degrees Fahrenheit). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in absence of such recommendations, with the following time-temperature chart:

<table>
<thead>
<tr>
<th>Thermometer Reading (Degrees)</th>
<th>Minimum Developing Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>°C</td>
<td>°F</td>
</tr>
<tr>
<td>26.7</td>
<td>80</td>
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<td>26.1</td>
<td>79</td>
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<td>25.6</td>
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<td>16.7</td>
<td>62</td>
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<tr>
<td>16.1</td>
<td>61</td>
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</tbody>
</table>
(iii) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required;

(b) For automatic processors and other closed processing systems:

(i) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

<table>
<thead>
<tr>
<th>Developer Temperature (Degrees)</th>
<th>Minimum Immersion Time&lt;sup&gt;a/&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>°C</td>
<td>°F</td>
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<tr>
<td>35.5</td>
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<td>30</td>
<td>86</td>
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<tr>
<td>29.5</td>
<td>85</td>
</tr>
</tbody>
</table>

<sup>a/</sup>Immersion time only, no crossover time included.

(ii) The specified developer temperature and immersion time shall be posted in the darkroom, on the automatic processor, or be readily available to the operator; and

(c) Processing deviations from the requirements listed above shall be documented by the handler in such manner that the requirements of this rule are shown to be met or exceeded, such as with extended processing, and special rapid chemistry;

(d) Film processing solutions shall be prepared in accordance with the directions given by the film manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer; and

(4) Pass boxes, if provided, shall be so constructed as to exclude light from entering the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

(5) The darkroom shall be light tight and use proper safelighting such that any film which would produce an optical density between one and two when exposed in a cassette to x-radiation and then processed shall:
(a) Not suffer an increase in optical density greater than 0.1 when exposed in the darkroom for two minutes with all safelights on; and

(b) Not suffer an increase in optical density greater than 0.05 for mammography when exposed to the darkroom for two minutes with all safelights on.

(6) Darkrooms typically used by more than one individual shall provide a method to prevent accidental entry of light while undeveloped films are being handled or processed.

(7) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light-tight container. If used, daylight film handling boxes shall preclude fogging of the film.

(8) Expired x-ray film shall not be used for diagnostic radiographs.

(9) Cassettes, intensifying screens, and computed radiographic imaging plates shall be:

   (a) Cleaned according to manufacturer's specifications or an alternate frequency approved and documented by a radiation expert in the quality assurance program;

   (b) Inspected for damage; and

   (c) Replaced as necessary to assure radiographs of good diagnostic quality.

(10) For those registrants employing computed and digital radiography imaging systems, the following shall apply:

   (a) If the computed radiography reader is located in the same room as the radiation-generating equipment and it is not behind a protective barrier, x-ray exposures shall not be made during processing;

   (b) Computed radiography plates shall be processed as soon as possible after exposure, not to exceed eight hours under any circumstances; and

   (c) Computed radiography plates shall be adequately shielded from stray radiation. Registrants shall develop a process that will ensure that computed radiography plates are used frequently enough or erased at least weekly so as to produce diagnostic quality images; and

   (d) Facilities other than dental, podiatric, and veterinary, shall complete quarterly phantom image evaluations using a phantom approved by a radiation expert or system manufacturer. The analysis at a minimum shall include artifacts, spatial resolution, contrast/noise, work station monitors, and exposure indicator constancy;

(11) Annual evaluation of the integrity of all required protective apparel.

(K) Upon discovery of a medical event, the handler shall:

   (1) Contact the department regarding the medical event within one business day;

   (2) Provide a written report, including the analysis of the medical event, by a radiation expert to the department within fifteen business days of the medical event. The written report must include:
(a) The handler or registrant's name;

(b) The name of the prescribing physician;

(c) A brief description of the event including the body site, dose delivered and any critical structures involved;

(d) Why the event occurred;

(e) The effect, if any, on the individual who received the medical event;

(f) Actions, if any, that have been taken, or are planned, to prevent recurrence; and

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

(3) Provide a clinical summary to the prescribing physician and patient within fifteen business days; and

(4) Maintain record of the medical event as part of the patient's permanent medical record.

(L) The written report in paragraph (K)(2) of this rule shall not contain the individual's name or any other information that could lead to the identification of the individual.
3701:1-66-04 Quality assurance program for medical radiation-generating equipment.

(A) Each registrant shall develop, implement and maintain a written quality assurance program in the form of a readily available manual or manuals, either in hard copy format or electronic format. For purposes of this chapter and Chapter 3701:1-67 of the Administrative Code, quality assurance program means a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities.

(B) The written quality assurance program of each registrant shall address and include records to verify implementation of at least the following:

1. The intervals of and procedures for the evaluation of all radiation-generating equipment to ensure compliance with all applicable rules of this chapter;
2. Procedures for maintaining compliance with occupational and public exposure limits;
3. Procedures for notifying the director when individuals are occupationally over-exposed to radiation, pursuant to Chapter 3701:1-38 of the Administrative Code;
4. Safe operating procedures for each type of radiation-generating equipment to be handled;
5. Training of operators of each type of radiation-generating equipment to be handled in order to assure competency in the operating procedures;
6. In addition to the requirements of paragraph (B)(1) of rule 3701:1-38-10 of the Administrative Code, individuals likely to receive an annual occupational dose in excess of one millisievert (one hundred millirem) shall be instructed in the following:
   a. The location, boundaries, and purpose of restricted areas; and
   b. A description of the radiation-generating equipment and its location;
7. The quality control tests to be performed, the frequency of the quality control tests to be performed and the personnel responsible for the performance of the quality control tests as applicable to the radiation-generating equipment type and use;
8. Policies regarding the state licensure or certification of each person operating radiation-generating equipment as required by Chapters 4773. and 4715. of the Revised Code;
9. The dissemination of quality assurance policies and a method to educate affected workers on those policies and any policy changes;
10. Radiation workers' role and responsibility for following and supporting the quality assurance program;
11. Policies regarding personnel protection, including time, distance, and shielding;
12. Policies regarding occupational exposure of pregnant workers;
13. Policies regarding radiation safety training for ancillary personnel;
(14) Policies regarding training for personnel with quality control responsibilities; and

(15) Policies regarding human patient protection, including screening for pregnancy, exposure of pregnant patients, patient shielding, patient education, patient identity verification.

(16) Policies regarding verification of human patient identity and exam to be performed, including identification of the appropriate body part;

(17) Policies to only permit licensed practitioners to order radiographic examinations;

(18) An inventory of radiation-generating equipment, including the location and description of each unit.

(C) In addition to the requirements of paragraphs (A) and (B) of this rule, the quality assurance program of hospital registrants shall comply with the following:

(1) A certified radiation expert shall conduct oversight and maintenance of quality assurance programs for hospital registrants, by:

   (a) Auditing the quality assurance program on an annual basis;

   (b) Performing quarterly reviews of the quality assurance program each quarter;

   (c) Completing and submitting all required information with the annual audit form in accordance with paragraph (C)(6) of this rule; and

   (d) Serving on the quality assurance committee;

(2) Employees working in the radiation areas shall be made aware of the identity, scope of authority, and a method for contacting the certified radiation expert and the individual responsible for radiation protection. This information, or a specific location where this information may be obtained, shall be conspicuously posted in each area where radiation-generating equipment is used.

(3) Each hospital registrant shall establish a quality assurance committee for the management of the quality assurance program. The members of the quality assurance committee shall be approved by an executive administrator. Committee meetings may be attended by the members or similarly qualified, designated alternates. The quality assurance committee shall include at least the following members:

   (a) A member of the hospital's executive administration;

   (b) The individual responsible for radiation protection;

   (c) A radiologist or radiation oncologist;

   (d) A certified radiation expert representing each of the following as applicable in each hospital;

      (i) Radiation therapy services,

      (ii) Mammography, or

      (iii) Diagnostic radiography other than mammography; and
(e) A management representative of each department of the hospital which has responsibilities involving the handling of radiation-generating equipment;

(4) The quality assurance committee shall meet as often as is deemed necessary to carry out its duties, but at least on a quarterly basis once each quarter. To establish a quorum at least one-half of the committee's membership must be present either in person or by telecommunication means, and must include the individual responsible for radiation protection for the hospital, and the member of the executive administration of the hospital. In addition, each member must attend at least one quarterly meeting each calendar year. A record of each meeting shall be maintained and distributed to each member which shall include the following:

(a) The date of the meeting;
(b) An indication of members present; and
(c) A summary of meeting including any recommended actions and ALARA reviews;

(5) Each quarter, the certified radiation expert shall submit, to each appointed quality assurance committee member, a review of the quality assurance program, which shall contain, as applicable:

(a) Radiation safety policy revisions proposed by the certified radiation expert;
(b) A review of occupational exposure records by the certified radiation expert;
(c) Radiation safety incidents;
(d) Radiation-generating equipment performance evaluation summaries to include for radiation-generating equipment including a description of any issues found; and
(e) Any corrective actions recommended by the certified radiation expert that are necessary to comply with the requirements of this chapter;

(6) The quality assurance program shall be audited at least annually as defined in paragraph (A)(18) of rule 3701:1-38-01 of the Administrative Code by a certified radiation expert. The certified radiation expert shall develop a written report of the audit findings on forms prescribed by the director and submit the report to the quality assurance committee within thirty days of completing the audit. The quality assurance committee shall review the audit report and implement any corrective actions determined to be necessary. The certified radiation expert shall file the audit report with the director within ninety days of completing the audit. Every audit report shall include a determination of whether the quality assurance program properly addresses the matters described in this rule and whether it is being carried out in accordance with the written quality assurance program, and any corrective actions to be taken to comply with the requirements of this chapter. The audit report shall become a part of the inspection record.

(D) At the time of the state inspection the following items shall be readily available for review: In addition to the requirements of paragraphs (A) and (B) of this rule, the quality assurance program of registrants performing...
fluoroscopically-guided interventional other than veterinary procedures, and computed tomography (CT) other than veterinary and cone beam CT procedures shall establish a radiation dose review committee in accordance with the following:

(1) A complete listing of the inventory of radiation-generating equipment, including the location and description of each unit. The registrant may establish a system-wide committee if the registrant has more than one site;

(2) The written quality assurance program as required by this rule shall be maintained in the form of a readily available manual or manuals, either in hard copy printed format or electronic format. If the registrant is a subsidiary of a hospital, the requirements of paragraph (D) of this rule may be delegated to the hospital quality assurance committee provided its members meet the requirements of paragraph (D)(3) of this rule;

(3) Data and test results of the evaluation of each unit of radiation-generating equipment and its shielding and surroundings. The radiation dose review committee shall include at least the following members:

(a) The individual responsible for radiation protection;

(b) A diagnostic radiation expert;

(c) As applicable, a physician that performs fluoroscopically-guided interventional and/or computed tomography procedures; and

(d) As applicable, a technologist that performs fluoroscopically-guided interventional and/or computed tomography procedures;

(4) Maintenance logs and incident reports for each radiation-generating equipment system. A quorum of the radiation dose review committee shall meet as often as necessary to carry out its duties, but at least annually. To establish a quorum at least one-half of the committee's membership must be present either in person or by telecommunication, and must include the individual responsible for radiation protection. A record of each meeting shall be maintained and include the following:

(a) The date of the meeting;

(b) An indication of members present; and

(c) A summary of meeting including any recommended actions;

(5) Current copies of department's licensure verification web page for each individual who is required to possess a license at the facility; and The radiation dose review committee for fluoroscopically-guided interventional procedures shall establish and implement written protocols that include but are not limited to the following:

(a) Identification of individuals who are authorized to use fluoroscopic systems for interventional purpose;

(b) A method to be used to monitor patient radiation dose during fluoroscopically-guided interventional
procedures;

(c) Dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety;

(d) Substantial radiation dose level values following nationally recognized standards;

(e) Actions to be taken for cases when a substantial radiation dose level is exceeded which may include patient follow-up; and

(f) Reviewing established protocols at least annually;

(6) Instrumentation used to perform area radiation surveys, calibrations and evaluations, as appropriate for each type of radiation-generating equipment, including at least biennial calibration certificates or cross-calibration documentation done within the biennium. The radiation dose review committee for computed tomography shall determine and review written protocols to improve image quality and minimize patient dose. The review shall include acquisition and reconstruction protocols, image quality, and radiation dose. At a minimum, the review shall be performed annually and include the following clinical protocols, if performed:

(a) Pediatric head;

(b) Pediatric abdomen;

(c) Adult head;

(d) Adult abdomen;

(e) Adult chest; and

(f) Brain perfusion.

(E) Records required by this chapter and Chapter 3701:1-67 of the Ohio Administrative Code shall be maintained in accordance with the following:

(1) Data and test results of evaluations and calibrations of all radiation-generating equipment for no less than five years;

(2) Data and test results of evaluations of shielding and surroundings of all radiation-generating equipment until the director terminates the registration;

(3) Maintenance logs for radiation-generating equipment for five years;

(4) Incident reports involving radiation exposure to individuals for all radiation-generating equipment until the director terminates the registration;

(5) Copies of current licenses or the department's licensure verification web page for everyone who is required to possess a license at the facility; and

(6) Biennial calibration certificates or cross calibration documentation for all instruments used to perform area radiation surveys, calibrations, and evaluations for five years.
As used in this rule, "dental equipment" means radiation-generating equipment used for dental radiography. In addition to other applicable rules adopted pursuant to Chapter 3748. of the Revised Code and Chapter 3701:1-66 of the Administrative Code, handlers of dental equipment shall comply with the following:

(A) Dental equipment for intraoral use shall meet the following equipment standards:

1. A means shall be provided to limit the source-to-skin distance (SSD) to not less than eighteen centimeters;
   (a) Eighteen centimeters if operable above fifty kVp; or
   (b) Ten centimeters if operable at fifty kVp.

2. The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.

3. A means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

4. The exposure control switch shall meet the following requirements:
   (a) The switch shall be of the "dead-man" type.
   (b) The operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic radiography, termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero; and
   (c) It shall not be possible to make an exposure when the timer is set to "zero" or "off" position if either position is provided.

5. The kVp accuracy shall be within plus or minus ten per cent of the indicated value.

6. For manual exposures, the accuracy of the timing device shall be within plus or minus ten per cent of the indicated setting. The timing device shall be tested at a minimum of two settings within the operative range of fifty milliseconds to one thousand milliseconds.

7. Visual indication shall be provided whenever x-rays are produced. Certified equipment also shall provide audible indication to the operator while x-rays are produced or on termination of the exposure.

8. The coefficient of variation for reproducibility of kVp, timing, and radiation exposure shall not exceed 0.05 for four consecutive exposures.

(B) In addition to other structural shielding requirements in rule 3701:1-66-02 of the Administrative Code, handlers of dental equipment shall comply with the following:
(1) Intraoral and panoral units shall be provided with primary barriers at all areas struck by the useful beam. Consideration may be given to the attenuation provided by the patient as a result of direct interaction with the useful beam.

(2) When intraoral or panoral units are in adjacent human patient occupied rooms or areas, protective barriers shall be provided between the rooms or areas, unless safety procedures are documented and implemented to require that no human patients shall be present in the adjacent rooms or areas while exposures are being made.

(3) Intraoral and panoral units shall be provided with a protective barrier for the operator or shall be so arranged that the operator is located at a minimum distance of six feet from the patient and out of the useful beam. The operator’s position shall be arranged so that the operator views the patient during the entire exposure.

(4) When the operator is behind a protective barrier, a viewing system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure.

(C) In addition to the radiation safety requirements listed in rule 3701:1-66-02 of the Administrative Code, handlers of dental equipment shall not permit any individual to hold any part of the x-ray tube housing, cone, or mechanical support of the x-ray tube during exposure.

(D) Handlers of dental equipment shall comply with all applicable quality assurance requirements. In addition to the quality assurance requirements of rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, handlers of dental radiation-generating equipment shall conduct annual evaluations of x-ray operators to include the following:

(1) Positioning of the x-ray tube;

(2) Image processing;

(3) Operator location during x-ray exposure;

(4) Appropriate radiologic protocol; and

(5) Applicable regulatory requirements.

(E) Handlers of dental panoral equipment shall comply with all requirements of paragraphs (A) to (D) of this rule, except for paragraphs (A)(1) and (A)(2) of this rule, and must comply with the following:

(1) Dental panoral x-ray machines shall be certified pursuant to 21 C.F.R. part 1020 (as published in the April 1, 2012, Code of Federal Regulations effective on the effective date of this rule).

(2) The x-ray field shall be limited to the dimensions of the slit in the image receptor holder or limited to the dimensions of the active portion of the image receptor.

(F) Except for dental equipment used for panoral use, handlers of radiographic equipment used for extraoral dental procedures shall comply with the requirements of paragraphs (A) and (B) of rule 3701:1-66-05 of the Administrative Code.
(G) Fluoroscopy without image intensification shall not be used for dental examinations. Handlers of image intensified fluoroscopic equipment shall comply with the applicable requirements of rule 3701:1-66-07 of the Administrative Code and be included in the registrant's quality assurance program as specified in rule 3701:1-66-04 of the Administrative Code.

(H) Handlers of dental cone-beam CT radiation-generating equipment shall comply with the applicable requirements of rule 3701:1-66-10 of the Administrative Code and be included in the registrant's quality assurance program as specified in rule 3701:1-66-04 of the Administrative Code.

(I) Handlers of hand-held radiation-generating equipment used for dental procedures shall meet the requirements of paragraphs (A), (B), and (D) of this rule, and shall develop and implement safe operating procedures as part of the quality assurance program specified in rule 3701:1-66-04 of the Administrative Code, which shall address at least the following:

1. Hand-held radiation-generating equipment shall be used for intraoral purposes only;
2. Operators of the hand-held radiation-generating equipment shall wear a full lead apron of not less than 0.25 millimeter lead equivalent;
3. If the hand-held radiation-generating equipment is designed with a backscatter shield, the backscatter shield shall be in place during all radiographic exposures and equipped with a backscatter shield of not less than 0.25 millimeters lead equivalent and 15.2 centimeters in diameter that is positioned as close as practicable to the distal end of the device;
4. Storage and security procedures shall be developed and implemented to assure hand-held radiation-generating equipment is secured against unauthorized use or removal when not under the control and constant surveillance of the registrant;
5. Operator training, as required in paragraph (B)(5) of rule 3701:1-66-04 of the Administrative Code, shall include documented specific instruction to the x-ray operator regarding the prohibition on placing any part of their body into the useful beam and ensuring there are no bystanders within a radius of at least six feet from the patient being examined during exposure; and
6. Hand-held radiation-generating equipment shall not be used in hallways or waiting rooms.

(J) Dental equipment with a nominal fixed kVp of less than fifty shall not be used to make diagnostic dental radiographs of human beings operated at less than a measured fifty-one kVp.

(K) Dental equipment used by veterinarians shall comply with all requirements of this rule except paragraphs (A)(1), (D), (E), (I) and (J) of this rule. Additionally, the useful beam shall be limited to the area of clinical interest.

(L) Extraoral dental equipment used by veterinarians shall follow the requirements of paragraph (F) of rule 3701:1-66-05 of the Administrative Code.
3701:1-66-07  **Medical Fluoroscopic radiation-generating equipment.**

For the purposes of this rule, "fluoroscopic equipment" means a type of radiation-generating equipment that is used for real-time imaging of internal structures for medical purposes. In addition to other applicable rules adopted pursuant to Chapter 3748. of the Revised Code, handlers of fluoroscopic equipment shall comply with the following:

(A) Fluoroscopic equipment shall meet the following standards:

   (1) Unless the United States food and drug administration (FDA) has granted a variance for the specific fluoroscopic equipment, the source-to-skin distance (SSD) for fluoroscopy equipment shall not be less than:

      (a) Thirty-eight centimeters on stationary fluoroscopic equipment unless a particular procedure application prohibits that distance, in which case the SSD shall not be less than twenty centimeters.;

      (b) Thirty centimeters on mobile fluoroscopic equipment unless a particular procedure prohibits that distance, in which case it shall not be less than twenty centimeters.; and

      (c) Nineteen centimeters for c-arm type fluoroscopic equipment having a maximum source-to-image distance (SID) less than forty-five centimeters unless a particular procedure prohibits that distance, in which case it shall not be less than ten centimeters. Such systems shall be used for extremity or dental purposes only.

   (2) For c-arm fluoroscopic equipment equipped with a removable spacer cone, the spacer cone shall be attached to the x-ray source during use at all times unless it interferes with the clinical procedure.

   (3) 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 and shall prevent further exposures when the primary barrier is not in the path of the entire x-ray beam.

   (4) All fluoroscopic equipment shall provide intensified imaging. As used in this rule "intensified imaging" will include the use of digital image receptors.

   (5) Fluoroscopic equipment shall meet the following field limitation specifications:

      (a) For fluoroscopic equipment manufactured before June 10, 2006, the following applies:

         (i) 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 per cent of the SID. The sum of the excess length and the excess width shall be no greater than four per cent of the SID.;

         (ii) For rectangular 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.

      (b) For fluoroscopic equipment with a circular image receptor manufactured on or after June 10, 2006,
the maximum area of the x-ray field in the plane of the circular image receptor shall conform with one of the following requirements. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is:

(i) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty-four centimeters in any direction, at least eighty per cent of the area of the x-ray field shall overlap the visible area of the image receptor; or

(ii) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty-four centimeters in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the edge of the visible area of the image receptor by more than two centimeters.

(c) For fluoroscopic equipment with a rectangular image receptor manufactured on or after June 10, 2006, the following applies:

(i) 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 per cent of the SID. The sum of the excess length and the excess width shall be no greater than four per cent of the SID; and

(ii) 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.

(d) If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

"For X-ray Field Limitation System Failure"

(e) Beam-limiting devices shall be provided with a means for stepless adjustment of the x-ray field; and

(f) Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters or less.

(6) Timers shall meet the following specifications:

(a) A means shall be provided to preset the cumulative on-time timer of the fluoroscopic tube. The maximum cumulative time of the timer shall not exceed five minutes without resetting; and

(b) The timer shall terminate the exposure or emit a signal audible to the operator when the exposure time reaches a maximum of five minutes. The signal shall continue to sound while x-rays are produced until the timer is reset.

(c) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:
(i) A display of the fluoroscopic irradiation time at the operator's working position. This display shall function independently of the audible signal described in paragraph (A)(6)(c)(ii) of this rule. The following requirements apply:

(a) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds.;
(b) The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.; and
(c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.;

(ii) A signal audible to the operator shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.;

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

(8) Fluoroscopic systems shall meet the following air kerma rate limits:

(a) Fluoroscopic equipment provided with only automatic exposure rate control, or provided with both automatic exposure rate control and manual mode capabilities, shall not exceed an air kerma rate of eighty-eight milligray per minute (ten roentgens per minute exposure rate) in either mode at any combination of tube potential and current, at the point where the center of the useful beam enters the patient;
(b) Fluoroscopic equipment provided with only manual mode capabilities shall not exceed an air kerma rate of forty-four milligray per minute (five roentgens per minute exposure rate) at any combination of tube potential and current, at the point where the center of the useful beam enters the patient; and
(c) For fluoroscopic equipment that is provided with high-level control, and the high-level control is activated, the air kerma rate shall not exceed one hundred seventy-six milligray per minute (twenty roentgens per minute exposure rate) at any combination of tube potential and current, at the point where the center of the useful beam enters the patient;

(i) For all fluoroscopy equipment that is provided with high-level control, special means of activation of high level control, such as manual pressure applied continuously by the operator, shall be required to avoid accidental use; and

(ii) A continuous signal audible to the operator shall indicate that high level control is being employed.

(9) During fluoroscopy and cinefluorography the x-ray tube potential and current shall be continuously indicated.
(10) For undertable fluoroscopic equipment, a shielding device of at least 0.25 millimeter lead equivalent shall cover the bucky-slot.

(11) For undertable fluoroscopic equipment, protective drapes, or other devices, at least 0.25 millimeter lead equivalent shall be provided between the patient and the individual operating the fluoroscopic equipment to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the x-ray unit, except when such drapes or other devices would compromise the sterile field. Such devices shall not substitute for wearing required protective apparel.

(12) Radiography using the fluoroscopic imaging assembly shall meet the following specifications:

(a) A means shall be provided between the source and the patient which will automatically limit the x-ray field at the time the exposure is initiated to no more than the portion of the image receptor selected by the operator for spot films or radiographic images. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected such a mode of operation;

(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 per cent of the SID when adjusted for full coverage of the selected portion of the image selector;

(c) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two per cent of the SID; and

(d) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor. The minimum field size at the greatest SID shall not exceed five centimeters by five centimeters.

(13) Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the operator's working position the air kerma rate (AKR) and cumulative air kerma in accordance with the following requirements:

(a) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in milligrays per minute shall be continuously displayed and updated at least once every second;

(b) The cumulative air kerma in units of milligrays shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds;

(c) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma;

(d) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope:

(i) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in paragraph (C)(6)(a), (C)(6)(b) or (C)(6)(d) of this rule.
(ii) For C-arm fluoroscopes, the reference location shall be fifteen centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient’s skin.

(e) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure; and

(f) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than plus or minus thirty-five per cent.

(14) Fluoroscopic equipment manufactured on or after June 10, 2006 shall be equipped with means to display a last image hold (LIH) image following termination of the fluoroscopic exposure:

(a) For a LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure;

(b) For a LIH image obtained by initiating a separate radiographic exposure at termination of the fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure; and

(c) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of the fluoroscopic exposure unless separate displays are provided.

(B) In addition to other applicable radiation safety rules adopted pursuant to Chapter 3748. of the Revised Code, handlers of fluoroscopic radiation-generating equipment shall comply with the following:

(1) Any individual who is in the room during the fluoroscopic procedure shall be adequately protected by standing behind a whole body protective barrier or shall be required to wear a protective lead apron of not less than 0.25 millimeter lead equivalent.

(2) Protective lead or lead equivalent gloves shall be used by individuals who are required to have their hands in or near the useful beam; and

(3) In accordance with Chapter 3701-72 of the Administrative Code, individuals who perform fluoroscopic procedures on human beings shall hold a radiographer license or shall be a licensed practitioner, except for those individuals identified in paragraph (D) of rule 3701-72-04 of the Administrative Code who are limited to performing only the radiologic tasks related to cardiac catheterization procedures as specified in paragraph (D) of rule 3701-72-04 of the Administrative Code. Personnel working for veterinarians that use radiation generating equipment are not required to comply with this paragraph.

(4) Handlers of fluoroscopic equipment used for interventional or cardiac procedures or on pediatric or pregnant patients shall maintain a record of:

(a) Cumulative air kerma or dose area product used for each examination, if the display of either is
available on the fluoroscopic equipment; or

(b) The following items if the cumulative air kerma or dose area product is not displayed on the fluoroscopic equipment:

(i) Mode of operation such as high-level or pulsed mode;

(ii) Cumulative fluoroscopic exposure time; and

(iii) Number of radiographs and number of acquisitions.

(C) In addition to other applicable quality assurance requirements of Chapter 3701:1-66 of the Administrative Code, handlers of fluoroscopic equipment shall comply with the following:

(1) Handlers shall designate and utilize a radiation expert who shall develop in writing and perform fluoroscopic image quality evaluations appropriate for the fluoroscopic equipment including written procedures to include time intervals and system conditions for the evaluation of image quality.

(2) On new installations or reinstallations of existing equipment prior to patient exposure, handlers shall utilize a radiation expert to perform the following:

(a) Radiographic device tests to determine compliance with allowable limits as specified in paragraph (A)(12) of this rule;

(b) Fluoroscopic image quality evaluations as specified in paragraph (C)(1) of this rule; and

(c) Air kerma rate tests as specified in paragraph (C)(6) of this rule;

(d) High contrast and low contrast resolution evaluations in both fluoroscopic and radiographic modes;

(e) Five minute timer evaluations; and

(f) Evaluation of the accuracy of technique indicators and integrated radiation dose displays;

(3) After initial evaluations of fluoroscopic equipment have been performed, the test and evaluations in paragraph (C)(2) of this rule shall be performed by a radiation expert annually within periods not to exceed fourteen months.

(4) After repair or replacement of any component of the fluoroscopic equipment which may alter the radiation output or image quality, prior to patient use, a radiation expert shall perform and document measurements of air kerma rates as specified in paragraph (C)(6) of this rule and image quality as specified in paragraph (C)(1) of this rule unless in the documented determination of a radiation expert, the repair or replacement will not cause a significant change in radiation output or significant degradation of image quality as specified in the quality assurance program.

(a) The radiation expert may designate qualified individuals to perform and document the measurements specified in paragraphs (C)(6) and (C)(1) of this rule;

(b) The radiation expert shall provide the criteria for qualifying these designees in the quality assurance program; and
(c) The radiation expert's approval of the designee's test results shall be documented within thirty days.

(5) The results of all tests performed in accordance with paragraphs (C)(2) to (C)(4) of this rule shall:

(a) Include the technique factors used in determining such results;

(b) Include the name of the individual performing the measurements;

(c) Include the date the measurements were performed; and

(d) Be maintained by the IRRP between inspections for review by the department.

(6) Compliance with air kerma rate allowable limits in paragraph (A)(8) of this rule shall be determined as follows:

(a) If the source is below the x-ray table, the air kerma rate shall be measured at one centimeter above the tabletop or cradle.

(b) If the source is above the x-ray table, the air kerma rate shall be measured at thirty centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.

(c) For c-arm type fluoroscopic equipment, the air kerma rate shall be measured at thirty centimeters from the input surface of the image receptor with the source positioned at any SID.

(d) For fixed SID lateral fluoroscopes attached to the x-ray table, the maximum air kerma rate shall be measured at a point fifteen 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 closely as possible to the point of measurement. If the table top 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 fifteen centimeters to the centerline of the table.

(e) For c-arm type fluoroscopic equipment having a SID less than forty-five centimeters, the air kerma rate shall be determined at the minimum SSD.

(f) The maximum air kerma rate shall be determined with the kVp, mA and/or other selectable parameters adjusted to those settings which give the maximum air kerma rate. X-ray systems that incorporate automatic exposure control shall have sufficient attenuative material placed in the useful beam to produce the maximum exposure rate of the system.

(D) Handlers of mobile fluoroscopic equipment shall not be required to comply with the requirements of paragraphs (A)(10), and (A)(11) of this rule and paragraph (I)(H) of rule 3701:1-66-02 of the Administrative Code.

(E) Handlers of c-arm fluoroscopic equipment having a maximum SID less than forty-five centimeters shall not be required to comply with the requirements of paragraphs (A)(5)(e), (A)(5)(f), (A)(10), (A)(11), and (A)(12) of this rule and paragraph (I)(H) of rule 3701:1-66-02 of the Administrative Code. In addition, if a radiation expert has specified in the registrant's quality assurance program that an individual is unlikely to
receive a total effective dose equivalent of greater than two millirem in any one hour or one hundred millirem in a year, the handler shall not be required to comply with the requirements of paragraph (B)(1) of this rule.

(F) All individuals operating fluoroscopic equipment, and individuals likely to receive an annual effective dose-equivalent in excess of one millisievert (one hundred millirem) from participating in fluoroscopic procedures, licensed practitioners supervising the fluoroscopic procedure shall receive at least two hours of radiation protection training specific to fluoroscopy in addition to the training required by rule 3701:1-38-10 of the Administrative Code prior to performing or participating in fluoroscopic procedures. Additionally, each individual shall receive one hour of re-training whenever the individual receives in excess of thirty percent of the allowable occupational dose measured over one calendar year.:

(1) Have completed:

(a) Prior to June 1, 2020, a minimum of two hours training. In addition, shall complete one hour of re-training whenever any individual participating in the fluoroscopy procedure receives in excess of thirty per cent of the allowable occupational dose measured over one calendar year;

(b) Beginning June 1, 2020:

(i) For diagnostic and localization fluoroscopic procedures, a minimum of four hours training; and

(ii) For fluoroscopically-guided interventional procedures, a minimum of eight hours of training, of which one hour shall be hands-on fluoroscopic equipment training.

(2) Assure adequate radiation protection to the patient and staff participating in the fluoroscopic procedure.

(G) The training required by paragraph (F) of this rule shall be provided by an Ohio registrant, approved by the registrant's designated radiation expert, and be specific to the type of fluoroscopic equipment used. Previous documented fluoroscopy training approved by the registrant's designated radiation expert may be used to meet the training requirements of paragraph (F)(1)(a) and (F)(1)(b) of this rule. Documentation of receiving the training required by paragraph (F) of this rule shall be retained by the registrant and be available for review upon inspection. At a minimum, training topics shall include, but not be limited to:

(1) Principles and operation of the fluoroscopic equipment to be used;

(2) Fluoroscopic and radiographic outputs of each mode of operation, including high-level control options as applicable clinically used;

(3) Dose management, including dose reduction techniques for fluoroscopic equipment; and

(4) A review of the safe operating procedures of each piece of fluoroscopic equipment that may be used by each individual.

(5) Units of measurement and dose, including dose-area product values and air kerma;

(6) Radiation protection methods for patient and staff;
(7) Basic properties of radiation; and

(8) Biological effects of radiation.

(H) Beginning June 1, 2020, in addition to the training requirements of paragraph (F)(1)(b) of this rule, individuals operating or supervising the operation of fluoroscopy equipment shall receive, once every two years, a minimum of two hours in-service training every two years or continuing education covering the topic of fluoroscopy.

(H)(I) Fluoroscopic equipment used for radiation therapy simulation procedures is regulated pursuant to rule 3701:1-67-09 of the Administrative Code.

(H)(J) Computed tomography scanners equipped with fluoroscopic capabilities are regulated pursuant to rule 3701:1-66-10 of the Administrative Code.
This rule provides standards for radiation-generating equipment used for screening and diagnostic mammography, and mammography equipment used for invasive localization and stereotactically-guided breast biopsy purposes, except as provided by paragraphs (E) and (F) of this rule. In addition to Chapters 3701:1-38 and 3701:1-66 of the Administrative Code, a handler of mammography radiation-generating equipment that uses either stationary or mobile installations, shall comply with all applicable standards in 21 C.F.R. part 1020 (as published in the April 1, 2012, Code of Federal Regulations effective on the effective date of this rule) and the following:

(A) In addition to meeting the applicable equipment standards in rule 3701:1-66-02 of the Administrative Code, a facility handler performing screening or diagnostic mammography shall have a valid certificate issued by the U.S. department of health and human services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900 (as effective on the effective date of this rule).

(B) A handler of all types of mammography radiation-generating equipment shall comply with the shielding requirements in paragraphs (I)(2)(H)(2) to (I)(4)(H)(4) of rule 3701:1-66-02 of the Administrative Code.

(C) In addition to applicable radiation safety requirements in rules adopted pursuant to Chapter 3748. of the Revised Code and rule 3701:1-66-02 of the Administrative Code, a handler of all types of screening and diagnostic mammography radiation-generating equipment shall comply with the following:

1. When a film/screen mammography system is used, clinical films shall be processed as soon as possible, but not to exceed twenty-four hours from the time the first clinical image is taken. Facilities utilizing batch processing shall:
   (a) Use a container to transport clinical films that will protect the film from exposure to light, excessive heat and radiation; and

   (b) Maintain a log to include date and identification of each patient, time of first exposure of each batch, and date and time of each batch processing.

2. An individual, other than a licensed practitioner, operating any type of mammography equipment on human beings shall possess an Ohio radiographer license in accordance with rules in Chapter 3701-72 of the Administrative Code and meet at least one of the following initial qualifications:

   (a) Documented evidence of having completed sixteen hours of structured education in mammography which was university-awarded or approved by a recognized continuing education evaluation mechanism as accepted by the "American Registry of Radiologic Technologists" or

   (b) Proof of advanced certification in mammography issued to the operator by the "American Registry of Radiologic Technology Technologists."

(D) In addition to all applicable quality assurance requirements in rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, the facility shall maintain phantom and quality control images for three months.
(E) Radiation-generating equipment designed for mammography, but used exclusively for radiography of tissue from a biopsy, shall be exempt from paragraphs (A) to (D) of this rule, and shall comply with the requirements set forth in paragraphs (A), (F)(E), (H)(1), (I)(2)(H)(2), (I)(3)(H)(3) and (J) of rule 3701:1-66-02 of the Administrative Code.

(F) Radiation-generating equipment used for radiography of tissue from a biopsy and equipped with an x-ray tube enclosure designed to exclude personnel from its interior during x-ray generation shall be exempt from paragraphs (A) to (E) of this rule, and shall comply with the requirements set forth in paragraph (H)(2) of rule 3701:1-68-03 of the Administrative Code.

(G) Quality control testing by a medical physicist shall be conducted on mammography radiation-generating equipment used for invasive localization or having stereotactically-guided breast biopsy capability. Quality control testing for stereotactically-guided breast biopsy equipment shall follow the "American College of Radiology (ACR) Practice Guideline for the Performance of Stereotactically-Guided Breast Interventional Procedures" (as revised in 2009). This document is available from the "American College of Radiology, 1891 Preston White Drive, Reston, Virginia 20191, telephone (703) 648-8900."

(1) The medical physicist shall meet the requirements of the aforementioned ACR guideline; and

(2) The medical physicist shall document and verify that the facility is taking proper corrective actions when results of the quality control tests indicate the need.
3701:1-66-10  **Medical Computed tomography radiation-generating equipment.**

As used in this rule, “applies to mobile and stationary computed tomography (CT) radiation-generating equipment” means CT units as defined in paragraph (B)(12) of rule 3701:1-66-01 of the Administrative Code and used for medical purpose, except for fluoroscopy units with CT capability, CT units used exclusively for radiotherapy simulation, and CT units integrated with linear accelerators. In addition to other applicable rules adopted pursuant to Chapter 3748. of the Revised Code and Chapter 3701:1-66 of the Administrative Code, handlers of CT radiation-generating equipment that includes either mobile or stationary installations shall comply with the following:

(A) CT radiation-generating equipment shall be maintained to meet the following equipment standards:

1. The operator shall be able to terminate x-ray exposure at any time during a scan or series of scans under CT radiation-generating equipment control of greater than 0.5 second duration.

2. In the case of premature termination of the x-ray exposure by the operator, the CT radiation-generating equipment shall require the operator to reset CT conditions of operation prior to the initiation of another scan.

3. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced.

4. If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Visual 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.

5. Each emergency button or switch shall be clearly labeled as to its function.

6. The CT radiation-generating equipment shall be designed such that the CT conditions of operation are indicated prior to the initiation of a scan or a scan sequence.

7. The indicated table increment shall not deviate from the actual table increment by more than one millimeter.

8. Means shall be provided to permit visual determination of the location of the tomographic plane or a reference plane. A reference plane may be offset from the location of the tomographic plane(s).

9. If a device using a light source is used to satisfy paragraph (A)(8) 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 five hundred lux.

10. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

11. Mobile CT radiation-generating equipment permanently mounted on a base with wheels or castors for moving while completely assembled shall be provided with curtains of not less than 0.25 millimeter lead equivalent that completely surrounds the gantry bore during exposures.
(B) In addition to paragraph (H)(G) of rule 3701:1-66-02 of the Administrative Code, handlers of CT radiation-generating equipment shall meet the following radiation safety requirements:

1. Techniques shall be provided in the vicinity of the control panel or on a pre-programmed menu, based on patient age, weight, body mass index, or patient dimensions, as appropriate, that specifies for each routine examination the CT conditions of operation, including techniques specific to pediatric patient examinations, if applicable.

2. The limits of radiation dose shall not exceed a volume computed tomography dose index (CTDIvol):
   - Eighty milligray (eight rad) for the facility's routine adult head scan;
   - Thirty milligray (three rad) for the facility's routine adult or seventy kilogram (one hundred fifty-four pound) abdomen scan;
   - Twenty milligray (two rad) for the facility's routine pediatric five-year old or eighteen kilogram (forty pound) abdomen scan; and
   - Forty milligray (four rad) for the facility’s routine (one-year old) pediatric head scan.

3. If the results of the quality control tests, the image quality evaluations, or the radiation dose measurements exceed a tolerance limit established by a radiation expert, use of the CT radiation-generating equipment on patients shall be limited to those uses permitted by written instruction of a radiation expert.

4. Operators of CT radiation-generating equipment used on humans shall possess an Ohio radiologic license in accordance with Chapter 3701-72 of the Administrative Code or hold an appropriate license or certificate in accordance with Chapter 4715. of the Revised Code for dental imaging. Mobile CT radiation-generating equipment, except for stationary CT radiation-generating equipment installed in a van, trailer, or mobile vehicle and operator behind a protective control booth, shall be provided with protective curtains of not less than 0.25 millimeter lead equivalent that completely surrounds the gantry bore during exposures, unless the protective curtains interfere with the sterile field of a surgical procedure; and

5. Any individual who is in the room during a CT exposure shall stand clear of the gantry bore, and shall stand behind a whole body protective barrier or wear a protective lead apron of not less than 0.25 millimeter lead equivalent.

(C) In addition to other applicable quality assurance requirements in rule 3701:1-66-04 of the Administrative Code, handlers of CT radiation-generating equipment shall comply with the following quality assurance requirements:

1. The registrant handler shall designate and utilize a radiation expert who shall:
   - Perform measurements of the radiation dose and image quality prior to medical use:
     - Upon installation;
     - After repair or replacement of any component of the CT equipment which may alter the radiation
output or image quality, prior to patient medical use, a radiation expert shall perform and document measurements of radiation output, using a method specified by a radiation expert in the quality assurance program, and image quality as specified in paragraph (C)(1)(c) of this rule unless in the documented determination of a radiation expert, the repair or replacement will not cause a significant change in radiation output or significant degradation of image quality as defined in the quality assurance program according to paragraph (C)(1)(c) of this rule.

(a) The radiation expert may designate qualified individuals to perform and document the measurements specified in paragraph (C)(1)(a)(ii) of this rule;

(b) The criteria for qualifying the designees specified in paragraph (C)(1)(a)(ii)(a) of this rule shall be specified by a radiation expert in the quality assurance program; and

(c) The radiation expert’s approval of the designee's test results shall be documented within thirty days.

(b) Perform measurements of radiation dose annually, not to exceed a fourteen month period.

(c) Develop written procedures to include system conditions and tolerance limits for the evaluation of image quality. The procedures shall incorporate the use of a CT phantom which has the capability of providing an indication of CT number accuracy for at least three materials, noise, image thickness, alignment light accuracy, and the resolution capability of the system for low and high contrast objects. Perform evaluations of image quality at least annually using a CT phantom which has the capability of providing an indication of CT number accuracy for at least three materials. The evaluation of image quality shall include CT number accuracy and uniformity, noise, artifacts, radiation beam width, resolution for low and high contrast, alignment light accuracy, and table travel accuracy; and

(d) Perform evaluations of image quality according to the written procedures upon installation and prior to scanning patients and at least annually, not to exceed a fourteen month period, thereafter. Develop the written quality control program conducted by the CT technologist appropriate for the evaluation of the CT system that includes the tests and allowable tolerance limits. The quality control evaluation for image quality shall include the use of a water equivalent phantom, and at a minimum, the evaluation of artifacts, noise, CT number accuracy and uniformity. The evaluation of image quality shall not exceed intervals of one week;

(e) Approve the quality control program conducted by the CT technologist including the image quality evaluations appropriate for the system and allowable variations for the indicated parameters.

(2) Written records of all image quality evaluations and radiation dose measurements shall be maintained between inspections for review by the department's inspector.

(3) The images for quality shall be retained until a new image quality evaluation is performed as follows:

(a) Photographic copies of the images obtained from the image display device; or
(b) Images stored in digital form on a storage medium compatible with the CT x-ray system.

(4) In consultation with a radiation expert, develop and implement a written program for radiation dose optimization and scan protocol review. The protocol review must include perfusion studies, if performed. The written program shall be audited by a radiation expert on an annual basis, not to exceed a fourteen month period.

(5) Radiation dose measurements shall be performed using clinical protocols representative of the utilization of the CT unit. If protocols are estimated, measurements must be based on a sample of actual patient data. The specific CT conditions of operation shall be documented for each protocol:

(a) Radiation dose measurements shall be expressed in terms of CTDI_{vol};

(b) Radiation dose measurements shall be performed using a CT dosimetry phantom that meets the following specifications and conditions of use:

(i) The CT dosimetry phantom shall be a right circular cylinder of a material having approximate tissue equivalence of one gram per cubic centimeter. The phantom shall be at least fourteen centimeters in length and shall have diameters of thirty-two centimeters for measuring radiation dose from the adult abdomen scan protocol and sixteen centimeters for measuring radiation dose from the head and pediatric abdomen scan protocols;

(ii) The CT dosimetry phantom shall provide a means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation on the outer surface or within one centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(iii) 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; and

(iv) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present; and

(c) Radiation dose measurements shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard, or cross-calibrated with a dosimetry system whose calibration is traceable to a national standard. Records of these calibrations shall be readily available for review upon inspection. The dosimetry system shall have been calibrated within the preceding two years; and

(d) Requirements of paragraphs (C)(5)(a) and (C)(5)(b) of this rule may be satisfied by an alternative nationally-recognized standard for CT dosimetry. If an alternate dosimetry method is used, a radiation expert shall document the procedures in the written quality assurance program.

(D) Cone beam computed tomography (CBCT) scanners and hybrid imaging systems, with the exception of CBCT units, integrated with linear accelerators shall comply with the following rules:

(1) Under the guidance of a radiation expert, handlers of CBCT units shall develop and implement a written
quality control testing program to include test procedures, test frequencies, and tolerance limits.

(2) The written quality control testing program must include an annual testing component to be performed by a radiation expert. This annual testing component must be performed upon installation of new CBCT units and annually thereafter, not to exceed fourteen months.

(3) The annual tests to be performed by a radiation expert must include an assessment of radiation dose and an evaluation of image quality.

(4) Records of all quality control tests shall be documented and retained between inspections.

(5) CBCT scanners are exempt from paragraphs (B)(2) and (C)(5) of this rule; and

(6) SPECT/CT and PET/CT units used exclusively for hybrid imaging shall be in compliance with paragraph (B)(2) of this rule if protocols used to scan the head satisfy the limits of paragraph (B)(2)(a) of this rule and protocols used to scan the abdomen satisfy the limits of paragraph (B)(2)(b) of this rule.

(E) Micro-CT units equipped with an x-ray tube enclosure designed to exclude personnel from its interior during x-ray generation shall be exempt from paragraphs (A) to (D) of this rule, and shall comply with the requirements set forth in paragraph (H)(2) of rule 3701:1-68-03 of the Administrative Code.

(F) Mobile CT radiation-generating equipment permanently mounted on a base with wheels or castors for moving while completely assembled and not used in one place are exempt from paragraphs (I)(4)(H)(4) and (I)(5)(H)(5) of rule 3701:1-66-02 of the Administrative Code.

(G) Handlers of CT radiation-generating equipment used for veterinary purposes are exempt from the requirements of paragraphs (B)(2) and (C)(4) of this rule.
Agency Name: Ohio Department of Health

Regulation/Packaage Title: Radiation Generating Equipment Requirements and Quality Assurance Standards


Date: 01/14/2019

Rule Type:
- New
- Amended
- 5-Year Review
- Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.
Regulatory Intent

1. Please briefly describe the draft regulation in plain language.
   Please include the key provisions of the regulation as well as any proposed amendments.

   These regulations provide the quality assurance and radiation safety requirements that facilities must follow to ensure medical radiation-generating equipment is controlled and operated properly to ensure radiation safety to the operator, patient and other members of the public.

   Please see attachment for a listing of the specific changes.

   Please list the Ohio statute authorizing the Agency to adopt this regulation.

   **RC 3748.04**

2. Does the regulation implement a federal requirement? NO 
   Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? NO

   If yes, please briefly explain the source and substance of the federal requirement.

3. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

   N/A – While the federal government does not require the State of Ohio to regulate medical radiation-generating equipment, Ohio law (RC 3748.04) given the potential health and safety issues, does require the Ohio Department of Health, as the radiation control agency (RC 3748.02), to set forth the requirements governing the registration and inspection of entities using radiation-generating equipment.

4. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

   These regulations are in place to ensure the proper functioning of radiation-generating equipment for controlled delivery of radiation to patients for diagnosing disease and injury. These regulations include radiation safety measures to protect the operator, staff and other members of the public. The regulations help reduce unnecessary radiation and the likelihood of radiation induced health issues and injury to Ohio citizens.

5. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

   The Agency measures success of facilities meeting and maintaining compliance with regulatory requirements through inspecting facilities with medical radiation-generating equipment.
equipment. In turn, facilities meeting safe operational and quality assurance requirements demonstrate few incidents of radiation induced health effects.

**Development of the Regulation**

6. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

   *If applicable, please include the date and medium by which the stakeholders were initially contacted.*

   The Radiation-Generating Committee (REC), a subcommittee of the Governor Appointed Radiation Advisory Committee, provides significant technical input on rulemaking actions regarding radiation protection, and advises the Director of Health on radiological issues. This committee is comprised of experts in the field of radiation who represent medical, nonmedical, academic and dental stakeholders of radiation-generating equipment. The REC meetings are open to the public for further stakeholder input. The stakeholders involved in drafting the amendments to medical radiation-generating equipment rules are medical physicists, physicians, oncologists, radiation therapists, radiographers and other members of the public attending the REC meetings on September 15, 2017 and November 3, 2017.

   The first draft of these regulations was posted for public comment on August 8, 2018. On September 21, 2018, the REC and ODH reviewed the public comments received from this comment period. Revisions were made based on public comment. Therefore, these rules are being posted for a second public comment period.

7. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

   The overall input provided by the medical physicists, physicians, radiation therapists, radiographers and other members of the public included technical and clinical expertise to help make the regulations representative of current practices while focusing on radiation safety. This input included explicit qualifications for the individual responsible for radiation protection and the time frame of the radiation expert’s approval of his/her designee’s test results.

8. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

   The regulations are comparable with the State Suggested Regulations from the Conference of Radiation Control Program Directors and Title 21 of the Code of Federal Regulations developed by scientific professionals in the field of radiation safety. This includes having medical physicists, physicians, oncologists, radiation therapists and radiographers at the REC meetings to support and further provide scientific input regarding radiation safety.
9. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?

These regulations are devised around the national standards from the Conference of Radiation Control Program Directors and Title 21 of the Code of Federal Regulations which are developed by professionals in the field. There are no alternative provisions with as much profession knowledge behind them.

10. Did the Agency specifically consider a performance-based regulation? Please explain.

Performance-based regulations define the required outcome, but don’t dictate the process the regulated stakeholders must use to achieve compliance.

These regulations are mostly performance based because they define the acceptable results without describing the processes for achieving compliance.

11. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Ohio Department of Health (ODH) is designated as Ohio’s radiation control agency in RC 3748.02 and solely implements and administers all Ohio regulations concerning the possession and use of radiation-generating equipment as they pertain to radiation protection and safety.

12. Please describe the Agency’s plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The regulations are implemented through registration and inspection of facilities where medical radiation-generating equipment is used. The registration reviewers and inspectors of medical facilities are given extensive training to ensure that regulations are applied consistently and predictably to the regulated community.

**Adverse Impact to Business**

13. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

   a. Identify the scope of the impacted business community;

      There are currently 9,000 businesses with medical radiation-generating equipment in Ohio affected by these regulations. The businesses vary from small doctor offices to large medical facilities. These regulations provide standards that businesses must follow to assure radiation safety to all members of the public.
b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

These regulations provide standards that businesses must follow to assure radiation safety to all members of the public. Inspectors look to see how well the registrants adhere to radiation safety and quality assurance practices. There are hourly costs involved to set-up and maintain the radiation safety/quality assurance program. Also, registration and inspection fees.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

These regulations provide standards that businesses must follow to assure radiation safety to all members of the public. The estimated annual costs of complying with Chapters 3701:1-66 and 3701:1-38 of the Ohio Administrative Code range from $850.00 for small single x-ray unit facilities to $488,000 annually for the largest medical facilities. This range begins with the smallest of facilities and ends with the largest of corporations with multi-registrations, numerous large hospitals and clinics throughout Ohio. The source of this cost analysis comes from medical physicists working in Ohio medical facilities.

14. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

These regulations are in place to assure that medical radiation-generating equipment functions properly to deliver controlled doses of radiation to patients for diagnosing injury and disease. In addition, these regulations require that facilities follow quality assurance and safe operating procedures for radiation protection to the patient, operator and members of the public. The goal is to assure that radiation exposure from medical procedures is kept as low as possible to reduce the likelihood of radiation induced health effects and injury.

Regulatory Flexibility

15. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The regulations allow registrants to apply for variances (alternative means to meet the regulations) if the variances do not pose a health and safety risk to operators, patients or other members of the public.
16. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Department of Health may and often does utilize settlements facilitated by the Ohio Attorney General’s office to effectuate the intent of section 119.14 of the Revised Code. In addition, Ohio Revised Code 3748.17(A) requires the Director of Health to provide facilities with notice of any violation of Ohio Revised Code 3748, or any rules adopted under that Chapter. Facilities have thirty days to cover their violations before the Department assesses any fines or penalties not otherwise required by law. And further, the Bureau of Environmental Health and Radiation Protection does not, as a matter of course assess fines and penalties for paperwork violations.

17. What resources are available to assist small businesses with compliance of the regulation?

Health Physicists and administrative staff at the Ohio Department of Health are available to provide technical advice to registrants. The Ohio Department of Health, X-ray Program’s website provides instruction for completing applications and regulatory guidance for facilities.