Ohio Administrative Code

Rule 3701:1-66-05 General purpose radiographic equipment.

Effective: December 20, 2019

The requirements of this rule do not apply toradiation-generating equipment used for dental intraoral or panoral,mammography, bone densitometry, computed tomography, fluoroscopy or spot filmimaging, and equipment used in radiation therapy.

(A) General purpose radiographic equipment shall meet the following equipment standards:

(1) A means shall be provided for limiting the x-ray beam to the image receptor and area of clinical interest;

(2) For radiographic equipment having a variable x-ray field limitation device, the limitation device shall have means for independent stepless adjustment of both the length and width of the x-ray field;

(3) For radiographic equipment that employs a light field for visually defining the perimeter of the x-ray field, the light source shall be functional and the total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two per cent of the source-to-image distance (SID);

(4) In addition to the requirements of paragraphs (A)(1), (A)(2) and (A)(3) of this rule stationary radiographic equipment having a variable x-ray field limitation device shall have:

(a) A means provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(b) A means provided to align the center of the x-ray field with respect to the center of the image receptor to within two per cent of the SID, when the x-ray beam is perpendicular to the plane of the image receptor;

(c) A means to indicate the SID to within two per cent. If it is a fixed SID, the distance shall be

indicated with a permanent marking;

(d) The beam limiting device indicate numerically the field size in the plane of the image receptor to which it is adjusted and be accurate within two per cent of the SID; and

(e) Compliance measurements made to discrete SID's and image receptor dimensions in common clinical use, or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate;

(5) General purpose radiographic equipment designed with only one image receptor size at a fixed SID shall have:

(a) A means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor within two per cent of the SID; or

(b) A means to align the field such that the x-ray field at the plane of the image receptor shall not extend beyond any edge of the image receptor;

(6) General purpose radiographic equipment designed with multiple removable or selectable fixed apertures shall have:

(a) A means to limit the x-ray field in the plane of the receptor so that such field does not exceed each dimension of the image receptor by more than two per cent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(b) A means to align the center of the x-ray field with the center of the image receptor to within two per cent of the SID or for equipment uniquely designed where the beam axis is intended to be offset from the center of the image receptor, the x-ray field at the plane of the image receptor shall not extend beyond the image receptor; and

(c) Paragraphs (A)(6)(a) and (A)(6)(b) of this rule may be met with either:

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

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

(7) If a positive beam limitation (PBL) device is used, it shall meet the following additional requirements:

(a) The PBL shall prevent the production of x-rays when any of the following conditions are met:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three per cent of the SID, except as permitted by paragraph (A)(7)(c) of this rule;

(ii) The sum of the length and width differences as stated in paragraph (A)(7)(a)(i) of this rule without regard to sign exceeds four per cent of the SID; or

(iii) The beam-limiting device is at an SID for which PBL is not designed for sizing;

(b) Compliance with paragraph (A)(7)(a) of this rule shall be determined:

(i) When the equipment indicates that the beam axis is perpendicular to the plane of the image receptor; and

(ii) No sooner than five seconds after insertion of the image receptor;

(c) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of

the field size. The minimum field size at a SID of one hundred centimeters shall be equal to or less than five centimeters by five centimeters;

(d) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in paragraph (A)(7)(a) of this rule, then any change of image receptor size or SID must cause an automatic return; and

(e) The PBL system shall function as described in paragraph (A)(7) of this rule whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than fifty centimeters;

(iii) The x-ray beam axis is within plus or minus three degrees of vertical in any direction and the SID is ninety to one hundred thirty centimeters inclusive; or the x-ray beam axis is within plus or minus three degrees of horizontal and the SID is ninety to two hundred five centimeters inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus three degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed;

(8) A device shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses, or preset radiation exposure to the image receptor;

(9) For radiographic equipment that provides manual exposure control, the operator shall be able to terminate the exposure at any time unless:

(a) The exposure is 0.5 second or less; or

(b) During serial radiography, means are provided to permit completion of any single exposure of the series in progress;

(10) In the case of radiographic equipment that provides automatic exposure control:

(a) The control panel shall indicate when this mode of operation is selected;

(b) The density setting and automatic exposure control detector positions that are selected prior to the exposure shall be indicated; and

(c) A visible signal shall indicate when an exposure has been terminated at the back-up limit. Manual resetting shall be required before further automatic timed exposures can be made;

(11) The x-ray control panel shall provide visual indication when x-rays are produced and an audible signal shall indicate when the exposure has terminated;

(12) The exposure control switch shall meet the following requirements:

(a) The switch shall be a "dead-man switch;"

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

(c) The switch shall be permanently mounted in a protected area so that it cannot be operated outside the protected area except for portable, mobile, or veterinary radiation-generating equipment.

(B) In addition to the applicable quality assurance requirements of Chapter 3701:1-66 of the Administrative Code, handlers of general purpose radiographic equipment shall comply with the following:

(1) The kilovoltage peak (kVp) accuracy shall be within plus or minus ten per cent of the indicated value;

(2) 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;

(3) The coefficient of variation:

(a) Of the kVp reproducibility for at least four consecutive exposures shall not exceed 0.05;

(b) Of the timing device reproducibility for at least four consecutive exposures shall not exceed 0.05; and

(c) Of radiation exposure reproducibility for at least four consecutive exposures shall not exceed 0.05 for any specific combination of selected technique factors;

(4) For radiographic equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated mA-seconds (mAs) product obtained at any two consecutive tube current settings shall not differ by more than ten per cent of their sum;

(5) For radiographic equipment having a combined x-ray tube current-exposure time product, or mAs selector, but not a separate tube current, or mA selector, the average ratios of exposure to the indicated milliampere-seconds product (milligray/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than ten per cent of their sum;

(6) The average exposure ratio for paragraphs (B)(4) and (B)(5) of this rule shall be expressed as follows:

$$|X_1 - X_2| < 0.10(X_1 + X_2)$$

Where the value of X_1 and X_2 are the average milligray/mAs values obtained at each of the two consecutive tube mA or mAs settings, or at two settings differing by no more than a factor of two where the mA or mAs selector provides continuous selection.

(C) In addition to the applicable radiation safety rules in Chapter 3701:1-38 and rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, the operator of general purpose radiographic equipment shall limit the useful beam to the area of clinical interest, not to exceed the size of the

image receptor by more than two per cent of the source-to-image distance.

(D) Handlers of mobile or portable radiation-generating equipment shall not be required to comply with the requirements of paragraph (H) of rule 3701:1-66-02 of the Administrative Code, and shall comply with the following:

(1) Mobile and portable radiation-generating equipment which are:

(a) Used continuously for greater than one week in the same location, such as a room or suite, shall have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; or

(b) Used for less than one week at the same location shall be provided with either a protective barrier at least 6.5 feet high for operator protection during exposures, or means shall be provided to allow the operator to be at least six feet from the tube housing assembly during exposures and the operator shall wear a protective apron of not less than 0.25 millimeter lead equivalent when making exposures;

(2) Radiation emitted from the x-ray tube when a capacitor energy storage system is fully charged and the exposure switch, timer, or any discharge mechanism is not activated shall not exceed an air kerma of 0.26 microgray in one minute at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open; and

(3) A tube stand or other mechanical support shall be used so that the x-ray tube housing assembly shall not be hand-held during exposures.

(E) Handlers of stationary veterinary radiation-generating equipment shall not be required to comply with the requirements of paragraph (H)(4) of rule 3701:1-66-02 of the Administrative Code. However, stationary veterinary radiation-generating equipment shall be provided with either a 6.5 foot high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least six feet from the tube housing assembly during exposures. If the operator or assistant is not behind the protective barrier, a lead apron of not less than 0.25 millimeter lead equivalent shall be worn when making exposures.

(F) Handlers of mobile or portable veterinary radiation-generating equipment shall not be required to comply with the requirements of paragraph (H) of rule 3701:1-66-02 of the Administrative Code. However, mobile or portable veterinary radiation-generating equipment shall be provided with either a 6.5 foot high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least six feet from the tube housing assembly during exposures. If the operator or assistant is not behind the protective barrier, a lead apron of not less than 0.25 millimeter lead equivalent shall be worn when making exposures.

(G) Handlers of certified veterinary radiation-generating equipment specifically designed by the manufacturer to be hand-held during radiographic exposures shall not be required to comply with the requirements of paragraph (H) of rule 3701:1-66-02 of the Administrative Code. The handler 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 and document at least the following:

(1) Hand-held radiation-generating equipment shall be used for intraoral, extremity or small animal purposes only;

(2) Examination specific source-to-image distances shall be developed and implemented to assure the useful beam is limited to the area of clinical interest or no larger than the image receptor;

(3) Operators of the hand-held radiation-generating equipment and individuals participating in the x-ray procedure shall be protected from direct scatter radiation by protective aprons of not less than 0.25 millimeter lead equivalent material;

(4) If the hand-held radiation-generating equipment is designed with a back scatter shield, the backscatter shield shall be in place during all radiographic exposures;

(5) 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 handler;

(6) Hand-held radiation generating equipment shall not be used in hallways or waiting rooms; and

(7) Operator training shall include documented specific instruction to the x-ray operator regarding:

(a) The prohibition on placing any part of their body into the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

(b) The proper use of source-to-image distance for the examination to assure the size of the radiation beam is no larger than necessary;

(c) Ensure that all individuals required for the examination are wearing the appropriate lead equivalent aprons and no bystanders are in the vicinity;

(d) The areas of use, proper storage and security procedures for the hand-held radiation-generating equipment; and

(e) The use of the dead-man switch and software safety devices such as locks and sensors.