**3701:1-66-05 General diagnostic radiographic equipment.**

As used in this rule, "radiographic equipment" means radiation-generating equipment that is designed or used for diagnostic imaging. The requirements of this rule do not apply to radiation-generating equipment used for dental intraoral or panoral, mammography, bone densitometry, computed tomography, fluoroscopy or spot film imaging, and radiation therapy simulators. In addition to other applicable rules contained in Chapters 3701:1-38 and 3701:1-66 of the Administrative Code, handlers of radiographic equipment shall comply with the following:

(A) General purpose radiographic equipment shall meet the following equipment standards for field limitation and alignment:

(1) The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if:

(a) A positive beam limiting device (PBL) meeting manufacturer's specifications is installed and the requirements of paragraph (A)(5) of this rule have been met; or

(b) If evidence of collimation is shown on at least three sides or three corners of the film.

(2) Mobile, portable, and stationary radiographic equipment shall meet the following:

(a) Variable x-ray field limitation shall have means for independent stepless adjustment of both the length and width of the x-ray field; and

(b) Provide a method for visually defining the perimeter of the x-ray field. In the case of radiographic equipment that employs a light 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).

(3) In addition to the requirements of paragraph (A)(2) of this rule, field indication and alignment for stationary radiographic equipment shall have:

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

(b) 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) Means provided 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.

(4) For radiographic equipment, other than general purpose use, the following special field limitation requirements apply:

(a) In the case of radiographic equipment designed for only one image receptor size at a fixed SID:

(i) A means shall be provided 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

(ii) Shall be provided with 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.

(b) Radiographic equipment not specifically covered in paragraphs (A)(2), (A)(3), and (A)(4)(a) of this rule, or in rules 3701:1-66-07 or 3701:1-66-08 of the Administrative Code, and radiographic equipment in rule 3701:1-66-06 of the Administrative Code which are also designed for use with extraoral image receptors and when used with an extraoral image receptor:

(i) A means shall be provided 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;

(ii) A means shall be provided to align the center of the x-ray field with the center of the image receptor to within two per cent of the SID; and

(iii) Paragraphs (A)(4)(b)(i) and (A)(4)(b)(ii) of this rule may be met with a system that meets the requirements for a general purpose

x-ray system as specified in paragraph (A)(2) of this rule, or when alignment means are also provided, may be met with either:

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

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

(5) 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)(5)(c) of this rule;

(ii) The sum of the length and width differences as stated in paragraph (A)(5)(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)(5)(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; and

(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)(5)(a) of this rule, then any change of image receptor size or SID must cause an automatic return.

(e) When provided, the PBL system shall function as described in paragraph (A)(5) 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.

(B) Radiographic equipment shall meet the following for control and indication of technique factors:

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

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

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

(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;

(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 radiographic equipment.

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

(D) The coefficient of variation:

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

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

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

(E) 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.

(F) 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 (milliroentgen/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than ten per cent of their sum.

(G) The average exposure ratio for paragraphs (E) and (F) of this rule shall be expressed as follows:

$$|X1 - X2| \leq 0.1(X1 + X2)$$

Where the value of X1 and X2 are the average milliroentgen/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.

(H) Handlers of radiographic equipment shall comply with the structural shielding requirements in paragraph (I) of rule 3701:1-66-02 of the Administrative Code.

(I) Handlers of radiographic equipment shall comply with radiation safety rules in Chapter 3701:1-38 of the Administrative Code, and other applicable radiation safety requirements in rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code.

(J) Handlers of radiographic equipment shall comply with all applicable quality assurance requirements found in rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code.

(K) Handlers of mobile or portable radiographic equipment shall comply with all requirements of this rule, except paragraphs (A)(4) and (H) of this rule, and shall comply with the following:

(1) Mobile and portable systems 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 the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens per hour (0.5 microcoloumb per kilogram) or, 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.

(L) Handlers of radiographic equipment for veterinary use shall meet the following special requirements:

(1) Stationary veterinary radiographic 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;

(2) Mobile or portable veterinary radiographic equipment shall comply with all applicable requirements of this rule except paragraph (H) of this rule; and

(3) Stationary veterinary radiographic equipment shall comply with all requirements of this rule except paragraph (I)(3) of rule 3701:1-66-02 of the Administrative Code.

Replaces: 3701:1-65-05

Effective:

R.C. 119.032 review dates:

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Certification

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Date

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|---|---|
| Promulgated Under: | 119.03 |
| Statutory Authority: | 3748.04 |
| Rule Amplifies: | 3748.01, 3748.02, 3748.04, 3748.05, 3748.06, 3748.07, 3748.12, 3748.121, 3748.13, 3748.14, 3748.15, 3748.18, 3748.19, 3748.20, 3748.22, 3748.99 |
| Prior Effective Dates: | 2/15/2001, 2/10/06 |