

3701:1-66-02 General administration requirements for handlers of 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. 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 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.
- (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.

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (millimeter of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems ¹	I- Other X-Ray Systems ²	II - Other X-Ray Systems ³
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

¹ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

² 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.

³ 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 milliamperes-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)(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 utilized for each;
 - (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 panoramic 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 rule 3701:1-38-14 of the Administrative Code.
- (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.

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

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

- (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 panoramic, 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 panoramic 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, 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.
- (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 patient and operator.
- (I) 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) shall be maintained in compliance with applicable requirements of 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 cqwelsius (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:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2.5
25.0	77	2.5
24.4	76	3
23.9	75	3
23.3	74	3.5
22.8	73	3.2
22.2	72	4
21.7	71	4
21.1	70	4.5
20.6	69	4.5
20.0	68	5
19.4	67	5.5
18.9	66	5.5
18.3	65	6
17.8	64	6.5
17.2	63	7
16.7	62	8
16.1	61	8.5
15.6	60	9.5

(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:

Developer Temperature (Degrees)		Minimum Immersion Time ^{a/} Seconds
°C	°F	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25

31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
^{a/} 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.
- (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 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 so as to produce diagnostic quality images.

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