Ohio Administrative Code

Rule 3701:1-66-02 General administration requirements for medical radiation-generating equipment.

Effective: December 13, 2024

As used in this rule, "radiation-generating equipment" means radiation-generating equipment used for dental, veterinary, or medical purpose but does not include therapeutic radiation-generating equipment.

(A) The director may, upon application thereof or upon his or her own initiative, grant a variance to the obligations 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 will 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) An individual will not expose any individual or animal to the useful beamunless ordered by a licensed practitioner acting within his or her scope-of-practice for dental, medicalor radiation therapy purposes. Exposing an individual for training, demonstration or other purposes is forbidden unless otherwise specified in rules promulgated under Chapter 4773 or 3748 of the Revised Code.

(C) The handler will assure:

(1) Every individual who performs radiologic procedures on human beings holds the appropriate radiologic license as obligated by Chapter 3701-72 of the Administrative Code and Chapter 4715. of the Revised Code.

(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 obligations of Chapter 3701:1-66 of the Administrative Code will 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 will 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 will meet the following standards:

(1) On battery-powered x-ray generators, visual means will 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 will 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 will 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 will 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 obligations of this paragraph will be determined with the system fully charged and a setting of ten milliampere-seconds (mAs) for each exposure; and

(b) The obligated minimal HVL of the useful beam will 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 will link the kVp selector with the filter and will prevent an exposure unless the minimum amount of filtration necessary to produce the HVL obligated by paragraph (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 will be clearly indicated prior to initiation of the exposure. This indication will 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 will 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 will be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure will be indicated. This obligation may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors will be visible from the operator's position except in the case of spot films taken during fluoroscopy procedures or dental intraoral or panoral films; and

(8) All position locking, holding, and centering devices on radiation-generating equipment components will 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 will meet the following radiation safety obligations:

(1) Software-based technique selections, a chart, or a combination of the two will 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 panoral radiography;

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

(a) All individuals will be positioned such that no part of the body will 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 needed for the medical procedure will 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 will be protected from the direct scatter

radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or will 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;

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

(a) Mechanical holding devices will 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 obligated by paragraph (B)(4) of rule 3701:1-66-04 of the Administrative Code will indicate the obligations for selecting someone to hold a patient or image receptor, and the procedure that will be followed. All individuals holding a patient or image receptor during radiation exposures will be at least eighteen years of age; and

(c) No individual will routinely hold patients or image receptors during radiologic procedures;

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

(5) Any radiation worker participating in fluoroscopic, veterinary, or mobile or portable x-ray procedures is obligated to wear an individual monitoring device unless the IRRP or radiation expert determines 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;

(6) The entrance air kerma resulting from the technique used for the specified average adult human patient for routine diagnostic radiography will not exceed the values listed in table 2. The entrance air kerma resulting from the technique used for routine intraoral bitewing exams will 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 will 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

Table 3.	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)

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

(a) For facilities utilizing radiographic film, the speed of the screen and film combinations used will be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens will 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 will 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 will 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;

(8) Except for radiation-generating equipment used for veterinary, portable, dental panoral, dental intraoral, lithotripsy, or bone densitometry applications, the operator will be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield and be able to see the patient without leaving the protected barrier; and

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

(a) Patient identification;

(b) Date of examination; and

(c) Operator identification.

(H) In addition to other applicable structural shielding obligations in Chapter 3701:1-66 of the Administrative Code, handlers of radiation-generating equipment will:

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

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

(i) Prior to new construction, or renovation; and

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

(b) Prior to patient use, use 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.

(c) 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) Obtain a written report of the shielding design and the area radiation survey. A copy of the report will be made available to the department's inspector upon request.

(2) 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 will 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) 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) Provide a window of lead equivalency affording protection equal to that obligated 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) Assure the stationary CT and mobile CT radiation-generating equipment used in a fixed location 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 obligate another area radiation survey as long as the previous documented area radiation survey is maintained and available for inspection.

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

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

(2) The handler will 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 will 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, will 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 will be constructed of mechanically rigid, corrosion resistant material; and

(ii) The temperature of solutions in the tanks will be maintained within the range of 15.6 to 26.7 degrees Celsius (sixty to eighty degrees Fahrenheit). Film will 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 will be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time needed;

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

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

Developer Temperature (Degrees)	Minimum Immersion Time[a/]	°C
°F	Seconds	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 will be posted in the darkroom, on the automatic processor, or be readily available to the operator;

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

(d) Film processing solutions will be prepared in accordance with the directions given by the film manufacturer, and will 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, will be so constructed as to exclude light from entering the darkroom when cassettes are placed in or removed from the boxes, and will incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

(5) The darkroom will 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 will:

(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 will provide a method to prevent accidental entry of light while undeveloped films are being handled or processed;

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

(8) Expired x-ray film will not be used for diagnostic radiographs;

(9) Cassettes, intensifying screens, and computed radiographic imaging plates will 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 will 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 will not be made during processing;

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

(c) Computed radiography plates will be adequately shielded from stray radiation. Registrants will 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 veterinarywill complete at least annually image quality evaluations appropriate for the equipment as established by a radiation expert or system manufacturer;

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

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

(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 will 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 will not contain the individual's name or any other information that could lead to the identification of the individual.