

## Guidance in Bold Text

Rule 3701:1-66-02 Effective 05/15/2015

### 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.

**A request for a variance must be made in writing to the Director and must show good reason for the variance and that the variance will not result in any undue hazard or effect on public health and safety or environment.**

**Variations that are approved by the Director will set the terms, conditions and expiration of the variance. If the terms and conditions of the variance are not met, the variance may be revoked.**

**If the variance has expired or the effective date of the rule in which the variance was granted has changed, the variance is invalid and a new variance must be requested.**

**A copy of the approved variance must be maintained on site.**

**If a variance has been granted, it is best to provide the inspector with a copy of the variance before the inspection begins. The inspector will verify the expiration date and that the terms outlined in the variance are being met.**

- (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.

**Only a patient is to be exposed to the useful beam and the exposure must be authorized by a licensed practitioner. A licensed practitioner is one of the following:**

**A Dentist licensed in Ohio pursuant to Chapter 4715. of the Revised Code;**

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**A Physician licensed in Ohio to practice medicine or surgery or osteopathic medicine or surgery pursuant to Chapter 4731. of the Revised Code;**

**A Podiatrist licensed in Ohio pursuant to Chapter 4731. of the Revised Code;**

**A Veterinarian licensed in Ohio pursuant to Chapter 4741. of the Revised Code, can order x-ray on animals only;**

**A Chiropractor licensed in Ohio pursuant to Chapter 4734. of the Revised Code;**

**A Clinical nurse specialist licensed in Ohio pursuant to Chapter 4723. of the Revised Code can order x-ray procedures that are specified in the standards of care arrangement and under the scope of his or her collaborating physician; and**

**A physician assistant licensed in Ohio pursuant to Chapter 4730. of the Revised Code can order x-ray procedures that are specified in the standards of care arrangement and under the scope of his or her collaborating physician.**

**Exposing individuals for training, demonstration, or other non-dental or non-medical diagnostic purposes is prohibited.**

**Inspectors verify that procedures regarding ordering x-rays are in place and that x-rays were authorized by a physician through documentation or other verifiable means.**

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

**All inspectors carry identification cards to identify they are inspectors of the Ohio Department of Health. These inspectors may interview employees and use observation during inspections to assure compliance with the regulations. This is also authorized by rule 3701:1-38-09 of the Ohio Administrative Code.**

(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

**The inspectors will use interview and observation to verify that each x-ray machine operator has a current Ohio Department of Health radiologic license certificate; a copy must be available on site or accessed via internet within the office.**

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- (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.

**The inspector will use interview and observation to verify that handlers assure each operator is competent in the operation of each type of x-ray machine used. Selection of techniques, proper positioning, and knowledge of safe operating procedures are some of the items to be demonstrated. Documented sign-off on the safe operating procedures or using a check-off list showing the date of the competency checks and the signature of the operator and person conducting the competency test is acceptable.**

- (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.

**Each facility that is operating radiation-generating equipment for diagnostic purposes must meet the requirements of Chapter 3701:1-66, unless there is a variance from the director OR if a radiation expert has determined that the non-compliance will not pose a radiation risk or other safety hazard to workers or patients and arrangements have been made to correct the noncompliance**

**Inspectors verify that radiation-generating equipment meet the provisions of this rule. If the equipment does not, the inspector will request evidence of a Director approved variance (reviewing expiration date and terms) or documented evidence that the Radiation Expert has determined that the non-compliance will not pose a radiation risk or other safety hazards to workers or patients and arrangements have been made to correct the noncompliance.**

- (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.

**All radiation-generating equipment must have a warning label on the control panel. The use of universal symbols is acceptable for meeting the requirements of this rule.**

- (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.

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**All battery-powered generators must have an indicator on the control panel showing the amount of charge remaining on the battery for adequate operation, so that each operator knows the unit will operate properly during the x-ray exposure.**

- (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;

**All FDA compliant equipment will meet this requirement. It is the responsibility of the manufacturer to ensure that leakage radiation shall not exceed one hundred milliroentgens in one hour.**

- (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 <sup>1</sup>	I- Other X-Ray Systems <sup>2</sup>	II - Other X-Ray Systems <sup>3</sup>
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

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	150	4.1	4.1	5.4
<sup>1</sup> Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.				
<sup>2</sup> 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.				
<sup>3</sup> 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 milliamperere-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.

**The HVL must meet the required specifications. Inspectors use properly calibrated instruments to measure half-value layer. Radiation Experts performing measurements of half-value layers must use properly calibrated instruments.**

- (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.

**FDA compliant equipment will meet this requirement. Inspectors use properly calibrated instrument to measure half-value layer. Radiation Experts performing measurements of half-value layers will use properly calibrated instruments.**

- (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.

**If two or more x-ray tubes are controlled by one exposure switch, make sure there is a means to determine which tube is selected. This should be clearly marked at the control panel and near each tube head assembly.**

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- (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.

**When positioned for exposure, the tube housing assembly must remain in the position it was placed and not drift during exposure.**

**Tomography is an example where the tube housing is designed to move but it is still stable in regards to the equipment supports.**

- (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 panoral films.

**All technique factors must be visible from the operator position. For automatic exposure controls, the technique factors set prior to exposure must be indicated. For equipment having fixed technique factors, permanent markings on the equipment is acceptable.**

**Exceptions:**

**Spot films taken during fluoroscopy, dental intra-oral and dental panoral**

**Note: these exceptions do not mean that the technique factors are not required to be on the control panel. It only means that the technique factors do not need to be visible from operator position.**

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

**All locking, holding, and centering devices on the radiation-generating equipment must function as designed by the manufacturer. Check these components routinely to make sure they are working properly and document the checks as part of the quality assurance program.**

- (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:

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- (a) Patient's body part, radiographic projection, anatomical size or age, and the technique factors to be utilized for each;

**Example: Chest X-ray, Posterior-Anterior Projection, patient size 23cm, technique 120kVp, 400ma at 0.01seconds**

**Example: Dental intraoral techniques should be posted for both adult and child settings.**

- (b) Type and size of the image receptor to be used;

**Example: 14 X 17 inch film cassette**

- (c) Type and focal distance of the grid to be used, if any; and

**Example: 72 inch focal distance grid**

- (d) Source-to-image receptor distance (SID) to be used, except for fluoroscopy, and dental intraoral or panoral radiography.

**Example: 72 inch SID**

**A technique chart is required at the control of each x-ray unit on site and must address all applicable sections of this rule. If the facility is using both digital receptors and film (or multiple film speeds) each modality and/or film type(s) must be addressed separately on the technique chart(s).**

**A pre-programmed or software based x-ray console where the techniques are already installed are exempt from a technique chart.**

- (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.

**Gonadal shielding of at least 0.5 millimeter lead equivalent material must be used for human patients during all radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the radiologic procedure.**

**Full aprons, half aprons, gonad shields, and gloves with 0.5 millimeters of lead equivalent material may be used for shielding.**

- (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:

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- (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;

**If there is the potential to be struck by the useful beam then the individual must be provided with a minimum of 0.5 millimeter lead equivalent protection.**

- (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

**Any individuals required to be in the room for the medical procedure of a patient during the x-ray procedure of a patient must be protected from direct scatter radiation by protective aprons or whole body protective barriers of at least 0.25 millimeter lead equivalent material.**

- (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.

**Any patients, who cannot be removed from the room during the exposure, must be protected from direct scatter radiation by whole body protective barriers or aprons of 0.25 millimeter lead equivalency, or must be at least two meters from both the tube head and image receptor.**

**This is meant for patients in emergency rooms or intensive care unit settings. Otherwise, all other patients should be removed from the room.**

- (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;

**Auxiliary support equipment shall be available and considered before using a person to 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

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individuals holding a patient or image receptor during radiation exposures shall be at least eighteen years of age; and

**If all resources have been exhausted and another individual must be used to assist in holding during a radiographic procedure, there must be written safe operating procedures for how the individual is selected for holding the patient. The procedure must indicate that individual must be eighteen years of age and wear the appropriate lead equivalent aprons and gloves. The procedures shall indicate that no worker shall be dedicated as a routine holder of patients during radiation exposure. The procedures must not allow pregnant individuals to hold patients.**

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

**No individual in the office shall be dedicated as a routine holder of patients during radiation exposure.**

- (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.

**The facility shall have enough shielding devices to protect everyone involved with the x-ray procedures.**

- (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.

**All radiation workers participating in fluoroscopic, veterinary, mobile, or portable x-ray procedures must wear individual monitoring devices.**

**If a Radiation Expert has determined based on the workload and appropriate measurements and calculations that the radiation dose to an adult worker is unlikely to exceed 10% of 5rem annually, personnel badges can be discontinued. If the x-ray workload increases or geometry of the radiation source location changes in the room, then further evaluation or reinstatement of badges is required.**

**Or**

**If the registrant is using or has used individual monitoring devices and the records indicate minimum doses after wearing the monitoring devices for at least one year, the registrant can use this as evidence that the radiation dose to the adult worker is unlikely to exceed 10% of 5rem annually under the current use factors, and may discontinue using personnel monitoring devices. If the x-ray workload increases, there is a potential for an**

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**increase dose to the holders, then reinstatement of badges would be required.**

- (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.

**Inspectors use properly calibrated instruments to measure entrance air kerma values or entrance-skin-exposure (ESE) values. Radiation Experts performing measurements of entrance air kerma values or entrance skin-exposure values will use properly calibrated instruments.**

**Routine maintenance and quality assurance programs will help reduce problems with entrance air kerma values.**

**A high ESE reading can result from film processing related problems, calibration issues, the use of expired film and inadequate half value layers.**

**In regard to dental film/receptors: Insight (F speed) use the same criteria as E speed and digital receptors for determining the ESE acceptable limits and ranges.**

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)

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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)	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;

**The speed of the screen film combination shall be the fastest combination for the diagnostic objective. Film/screen manufactures should be able to help regarding their products**

**Diagnostic radiography procedures on human beings shall not be performed without intensifying screens.**

**Exceptions:  
Veterinary or 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;

**The Source-to-Skin (SSD) is not to be less than thirty centimeters for human use.**

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### **Veterinary units are exempt from this rule.**

- (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.

**When using a grid between the patient and image receptor, the correct SID, x-ray tube alignment and position must be 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.

**The operator is to remain behind a protective barrier at all times during the x-ray exposure and must be able to view the patient from behind the protective barrier while the exposure is being made.**

#### **Exceptions:**

**Veterinary, portable, dental panoramic, dental intraoral, lithotripsy, and bone densitometry are exempt from this rule.**

- (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.

**The radiographic image or a record linked to the radiographic image shall contain patient identity, examination date and operator identify.**

**Examples: labels, computer based identification, markers**

- (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:

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- (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.

**A radiation expert shall prepare a shielding design prior to new construction or renovation.**

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

**A radiation expert shall prepare a shielding design for new radiation-generating equipment installations which might cause a significant increase in radiation hazard.**

**Increase in radiation hazard from a new installation includes, change in geometrical location of unit or increased tube energy.**

**If the radiographic unit was installed after July 3, 2006, a shielding plan and an area radiation survey are required to be performed by a radiation expert.**

**If the radiographic room was already in existence and contained previous RGE and a new radiographic unit was installed for replacement after July 3, 2006, the shielding plan is not applicable, but an area radiation survey is still required by a radiation expert.**

**Dental Cephalometric and Dental CT units are NOT excluded from this rule.**

- (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.

**A radiation expert shall conduct an area radiation survey for new radiation-generating equipment installations prior to patient use.**

- (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.

**A radiation expert shall conduct an area radiation survey after any change in the radiation-generating equipment or its structural shielding which might cause a significant increase in radiation hazard.**

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**Increases in radiation hazard from changes in radiation-generating equipment or structural shielding may occur with increase tube energy, changes in geometrical location of equipment or changed in wall material.**

**If a written determination is provided by a radiation expert identifying the reinstallation or change will not cause a significant increase in radiation hazard, a new radiation survey is not necessary. However, the written determination and the initial radiation survey must be kept indefinitely (life of room) for review by inspectors.**

- (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.

**If there is a significant increase in the number of x-rays being taken at the facility that exceeds the assumptions used in and existing radiation survey, a re-calculation of the survey must be completed by a radiation expert to assure shielding is still appropriate.**

**If the radiographic unit was installed after July 3, 2006, a shielding plan and an area radiation survey are required to be performed by a radiation expert.**

**If the radiographic room was already in existence and contained previous RGE and a new radiographic unit was installed for replacement after July 3, 2006, the shielding plan is exempt, but an area radiation survey is still required by a radiation expert.**

**Dental Cephalometric and Dental CT units are NOT excluded from this rule.**

- (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.

**If the operating parameters, location and geometry of the new equipment installation is the same as those of the old equipment and the old survey documentation exist, a new survey does not need to be completed, but the old survey documentation must be kept indefinitely (life of room) for review by inspectors.**

- (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.

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**A written report of the shielding design shall be obtained from the radiation expert and kept on file for the duration of the installation. A copy of the report must be made available to the inspector upon request.**

## **SHIELDING PLAN DOCUMENT**

**Diagrams and Documentation of X-ray room and surroundings showing:**

- A. Location of X-ray unit, protected area for the control console, and patient viewing system**
- B. Room dimensions with window and door locations**
- C. All Beam orientations to be used**
- D. If applicable, location of wall cassettes**
- E. If applicable, location of Dark room and film storage areas**
- F. Adjacent location to the x-ray room (e.g. lounges, waiting rooms, exam rooms, offices, reception area, rest rooms, corridors etc...)**
- G. Location, type, and thickness of material required for each radiation barrier**
- H. Results of area radiation surveys performed outside each radiation barrier**
- I. Documentation of survey instrument used to include model, serial number, and copy of calibration certificate**

**Variations of any set or combination of documents containing the information above may be acceptable.**

- (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.

**The handler shall assure that all protective barriers are in place and provide proper shielding prior to individuals operating the equipment.**

- (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.

**The handler shall provide protective barriers for its operators.**

- (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.

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**The handler shall provide patient visualization mechanisms affording lead equivalencies of adjacent barriers so that operator can remain behind the protective barrier and see the patient 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.

**There must be ability for two-way aural communication between the operator and patient at all times.**

- (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.

**All certified equipment must be maintained in compliance with the certification standard.**

- (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.

**The handler must have all the items listed above available for inspection.**

- (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

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- (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:

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;

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### **Requirements for manual processing**

**Dark rooms must contain rigid and corrosion resistant tanks; the availability of a time/temperature chart, a temperature recording device and a timing device. These items are required for determining temperatures of the solutions and the immersion times for manual film processing.**

**NOTE: Normal wristwatches are not considered acceptable timing devices in dark rooms. They do not provide a method to preset the development time and do not signal the passage of that preset time.**

(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 <sup>a/</sup>
°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

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

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- (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

**Requirements for automatic processing:**

**The dark room must contain a film manufacturer time/temperature chart (or the chart contained in 66-02 (J)). A specified developer temperature and immersion time must be available (alternately, a 'drop' or 'transport' time is acceptable and usually found in the processor operator manual). The facility must document they are processing according to the recommended time-temperature relationship. If the processor does not have a built in temperature gauge the facility must provide documentation showing periodic temperature measurement (note: the facility should not use a glass thermometer to avoid mercury contamination). If the facility deviates from the temperature or immersion time, they must document the deviation and explain how this meets or exceeds time/temperature requirements.**

- (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.

**Improper preparation of film processing solutions can result in decreased life expectancy of clinical images due to retention of residual fixer (hypo); poor film quality including increased base + fog, decreased contrast and/or decreased speed; or high ESE readings. Check the chemical or processor manufacturer's recommendations and adhere to these recommendations for each processor. Documentation of processor maintenance to include replenishment and complete breakdown and cleanings must be recorded. If alternative processing procedures are used, documentation of compatibility with film type must be available**

- (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.

**Stand in the dark room with all lights off and look at the pass boxes. There should not be any light coming in around the edges.**

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(5) The darkroom shall be light tight and use proper safe lighting 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.

**There should be no light coming from around the door or ceiling panels. Other items to consider are that the wattage of the bulb and type of light filter agree with the film manufacturer's recommendations (yellow filters are not acceptable, unless registrant provides documentation that shows otherwise).**

(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.

**There must be a method to prevent accidental entry or a policy in the quality assurance program indicating the facilities plan to prevent accidental entry into the darkroom when used by more than one individual. A sign on the door or light outside the darkroom that comes on when the door is shut is acceptable.**

(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.

**Film must be stored as indicated in this rule. Film in sealed boxes should never be stored in x-ray rooms or where stray radiation from a radiation x-ray machine can strike the film.**

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

**Check film packages routinely to prevent the use of expired x-ray film.**

(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.

**The facility's film cassettes, intensifying screens and computed radiographic imaging plates must be cleaned according to manufacturer specification. The frequency, instruction for cleaning,**

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**list of cleaning materials, and criteria for cassette failure must be part of your quality assurance program including documented results of the cleaning. A log with signatures and dates to coincide with the facilities policy is acceptable.**

(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;

**When the computed radiography reader is in the same room as the radiation-generating equipment, no processing shall occur during radiation exposure. This should be identified in the safe operating portion of the quality assurance program.**

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

**Process the computed radiography plates as soon as possible after exposure and never allow processing to exceed eight hours after exposure.**

- (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.

**Document and implement a process to properly store and erase computed radiography plates frequently enough to assure diagnostic quality images. Follow manufacturer specifications.**