

## Guidance in Bold Text

Rule: 3701:1-66-06      Effective: 12/20/2019

### Dental Radiation-Generating Equipment

(A) Dental equipment shall meet the following equipment standards:

- (1) For dental intraoral equipment, a means shall be provided to limit the source-to-skin distance (SSD) to not less than eighteen centimeters;

**Source-to-skin distance means the distance between the source and the skin of the patient.**

**For dental intraoral equipment, the minimum distance from the source (focal spot of the x-ray tube) to the end of the cone or spacer frame must be 18 cm. Often the focal spot is indicated somewhere on the cone or spacer frame.**

- (2) For dental intraoral equipment, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters;

**For dental intraoral equipment, the diameter of the x-ray field measured at the end of the cone or spacer frame can be no larger than 7 cm. On newer units, the diameter is often indicated somewhere on the cone or spacer frame. On older units, this diameter may have to be verified. Check with your service representative for proper verification methods.**

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

**The exposure must terminate at the end of:**

- **A pre-set time interval (mA & time or mAs selected by the operator);**
- **A preset number of pulses (number of pulses selected by the operator); or**
- **A preset radiation exposure (automatic exposure selected by the operator).**

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

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

**The exposure shall terminate when the exposure switch is released. Example of verification: Select a time of 1.0 second. Start the exposure and immediately let off the exposure switch prior to completion. The exposure should terminate prior to the full 1.0 seconds of exposure.**

- (b) The operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic radiography, termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero; and

**Terminating an exposure of greater than one-half second on a radiographic unit, other than a panoramic, shall cause automatic resetting of the timer to its original setting or zero.**

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

**When the timer is set to "zero" or "off", the equipment must prohibit exposures.**

- (5) The kVp accuracy shall be within plus or minus ten per cent of the indicated value;

**The difference between the kVp set on the x-ray equipment control panel and the kVp measured using a calibrated testing device must be within 10%. This should be checked at intervals suggested by the equipment manufacturer as part of the periodic equipment evaluation (calibration/preventive maintenance) required by rule 3701:1-66-04(B)(1) of the Ohio Administration Code.**

- (6) For manual exposures, 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;

**When exposure timing parameters are manually set by the operator, the difference between the time set on the x-ray control panel and the time measured using a calibrated testing device must be within 10%. This should be checked at intervals suggested by the equipment manufacturer as part of the periodic equipment evaluation (calibration/preventive maintenance) required by rule 3701:1-66-04(B)(1) of the Ohio Administration Code.**

**The x-ray unit's timing device shall be tested at a minimum of two timer settings that are between 50 to 1000 milliseconds.**

- (7) Visual indication shall be provided whenever x-rays are produced. Certified equipment also shall provide audible indication to the operator while x-rays are produced or on termination of the exposure; and

**All x-ray equipment must provide a visual indication whenever x-rays are produced. Commonly, a bulb will light during the exposure, however, the movement of a dial or other visual indication is acceptable to meet compliance with this rule. If the unit is certified by the FDA (any x-ray equipment manufactured after August 1, 1974), an audible indication must also sound whenever x-rays are produced. Commonly, a beep of some kind will sound during an exposure. Inquire with your service representative if appropriate exposure indicators are not available or functioning properly.**

- (8) The coefficient of variation for reproducibility of kVp, timing, and radiation exposure shall not exceed 0.05 for four consecutive exposures.

**When the set technique factors are the same, the output produced by the x-ray machine must be similar from exposure to exposure (reproducible) for the kVp, time and radiation output. The standard to which this reproducibility is held is known as a coefficient of variation (COV), which is to say the ratio of the standard deviation to the mean value of the exposure results (see COV definition in rule 3701:1-66-01 of the**

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**OAC). This should be checked at intervals suggested by the equipment manufacturer as part of the periodic equipment evaluation (calibration/preventive maintenance) required by rule 3701:1-66- 04(B)(1) of the Ohio Administration Code.**

**The x-ray unit must provide a kVp, time, and radiation output consistency for at least four consecutive exposures that does not exceed a coefficient of variation of 0.05.**

(B) In addition to other structural shielding requirements in rule 3701:1-66-02 of the Administrative Code, handlers of dental equipment shall comply with the following:

- (1) Intraoral and panoral units shall be provided with primary barriers at all areas struck by the useful beam. Consideration may be given to the attenuation provided by the patient as a result of direct interaction with the useful beam;

**Under normal conditions of operation, the entire cross section of the xray field of both intraoral and panoral units will be intercepted by the patient. Regular building materials are usually sufficient as primary barriers for intraoral or panoral units due to the small source-to-skin distances and technique factors involved.**

- (2) When intraoral or panoral units are in adjacent human patient occupied rooms or areas, protective barriers shall be provided between the rooms or areas, unless safety procedures are documented and implemented to require that no human patients shall be present in the adjacent rooms or areas while exposures are being made;

**If a barrier cannot be placed between adjacent patient occupied rooms, it must be stated in the safe operating procedures of the quality assurance program that while a patient is being x-rayed no other patient can be in the adjacent room or area during the x-ray exposure.**

**For intraoral and panoral units, a solid counter large enough to intercept any scatter radiation can be used as a protective barrier as long as the exposure on the other side is within public dose limits.**

- (3) Intraoral and panoral units shall be provided with a protective barrier for the operator or shall be so arranged that the operator is located at a minimum distance of six feet from the patient and out of the useful beam. The operator's position shall be arranged so that the operator views the patient during the entire exposure; and

**If a protective barrier for the operator cannot be provided for intraoral or panoral radiation-generating equipment, the operator's position must be out of the direct beam coming from the x-ray equipment and at least six feet from the patient, and so arranged that the operator can view the patient during the radiation exposure.**

- (4) When the operator is behind a protective barrier, a viewing system shall be provided 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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**If the operator's position is behind a protective barrier as determined by paragraph (B)(3) of this rule for intraoral or panoral units and the position is less than 6 feet away, a viewing system must be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure.**

**When using cephalometric and cone beam computed tomography radiation-generating equipment the operator must be behind the protective and a viewing system large enough and so placed that the operator can see the patient without having to leave the protective barrier.**

- (C) In addition to the radiation safety requirements listed in rule 3701:1-66-02 of the Administrative Code, handlers of dental equipment shall not permit any individual to hold any part of the x-ray tube housing, cone, or mechanical support of the x-ray tube during exposure.

**Dental x-ray units must be installed and maintained such that the x-ray tube is stable and remains motionless during exposures. If the x-ray tube of an intraoral unit is found to drift when in positions appropriate for exposures, the x-ray unit must be repaired or adjusted.**

- (D) In addition to the quality assurance requirements of rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, handlers of dental radiation-generating equipment shall conduct annual evaluations of x-ray operators to include the following:

**Handlers shall conduct annual evaluations of x-ray operators. This can be accomplished through observation and check-off. The evaluation results must be in an auditable format and list all the topics that were evaluated.**

- (1) Positioning of the x-ray tube;

**The handler must evaluate the x-ray operator for proper positioning of the x-ray tube for examinations.**

- (2) Image processing;

**The handler must evaluate the x-ray operator for proper image processing.**

- (3) Operator location during x-ray exposure;

**The handle must evaluate the x-ray operator for proper operator position during x-ray exposure.**

- (4) Appropriate radiologic protocol; and

**The handle must evaluate the x-ray operator for appropriate radiologic protocol (ie. following age, size, exposure technique charts).**

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(5) Applicable regulatory requirements.

**The handle must evaluate the x-ray operator to see if s/he knows or understands where to find the applicable Ohio Administrative Code regulations base on the direction from the handler's written quality assurance program.**

(E) Handlers of dental panoral equipment shall comply with all requirements of paragraphs (A) to (D) of this rule, except for paragraphs (A)(1) and (A)(2) of this rule, and must comply with the following:

**Dental panoral equipment is exempt from paragraphs (A)(1) and (A)(2) of this rule, as these two rules only apply to dental intraoral equipment. Dental panoral equipment must also comply with the following:**

(1) Dental panoral x-ray machines shall be certified pursuant to 21 C.F.R. part 1020 (as effective on the effective date of this rule); and

**Dental panoral equipment manufactured after August 1, 1974 and used in the United States of America must be certified by the U.S. Food and Drug Administration. Each certified x-ray system will be affixed or inscribed with at least one certification label, readily accessible to view when the product is fully assembled for use, that contains a statement that the product complies with federal regulation 21 CFR 1020.30.**

(2) The x-ray field shall be limited to the dimensions of the slit in the image receptor holder or limited to the dimensions of the active portion of the image receptor.

**The x-ray field size on conventional cassette-film panoral x-ray equipment can be no larger than the slit in the image receptor holder. The x-ray field size on digital panoral x-ray equipment, that has no slit in image receptor holder, can be no larger than the active portion of the image receptor.**

(F) Except for dental equipment used for panoral use, handlers of radiographic equipment used for extraoral dental procedures shall comply with the requirements of paragraphs (A) and (B) of rule 3701:1-66-05 of the Administrative Code.

**Any x-ray equipment used for extraoral dental procedures, except for panoral x-ray equipment, must comply with the x-ray equipment and quality assurance requirements of paragraphs (A) and (B) of Ohio Administrative Code 3701:1-66-05. Extraoral dental procedures is where the image receptor (digital or film) is positioned outside of the mouth. This includes, but not limited to, the following:**

- **Cephalometric X-ray Equipment**
- **Cone Beam Computed Tomography**
- **Combination units (Ceph/Panoral, Ceph/Intraoral, etc.)**

(G) Fluoroscopy without image intensification shall not be used for dental examinations. Handlers of image intensified fluoroscopic equipment shall comply with the applicable requirements of rule 3701:1-66-07 of the Administrative Code.

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**Fluoroscopy radiation-generating equipment must be imaged intensified and used according to the requirements of rule 3701:1-66-07 of the OAC.**

(H) Handlers of dental cone-beam CT radiation-generating equipment shall comply with the applicable requirements of rule 3701:1-66-10 of the Administrative Code.

**Cone Beam Computed Tomography (CBCT) radiation-generating equipment includes any system provided with a full field detector and capable of planar (2D) or volumetric (3D) tomographic image reconstruction. The handler must comply with the following:**

- **Develop and implement a written quality control testing program under the guidance of a radiation expert to include test procedures, test frequencies, and tolerance limits.**
- **The written quality control testing program must have an annual testing component that is performed by a radiation expert upon installation and annually thereafter. This testing by the radiation expert must include assessment of radiation dose and an image quality evaluation.**
- **Records of the annual testing must be documented and retained between inspections.**

**Note: CBCT radiation-generating equipment is subject to the shielding design and radiation survey requirements of Ohio Administrative Code 3701:1-66-02(H).**

(I) Handlers of hand-held radiation-generating equipment used for dental procedures shall meet the requirements of paragraphs (A), (B), and (D) of this rule, and shall develop and implement safe operating procedures as part of the quality assurance program specified in rule 3701:1-66-04 of the Administrative Code, which shall address at least the following:

(1) Hand-held radiation-generating equipment shall be used for intraoral purposes only;

**The handler's written safe operating procedures must indicate that hand-held radiation-generating equipment can only be used for intraoral procedures.**

(2) Operators of the hand-held radiation-generating equipment shall wear a full lead apron of not less than 0.25 millimeter lead equivalent;

**The handler's written safe operating procedures must indicate that operators of hand-held radiation-generating equipment must wear a full lead apron.**

(3) Hand-held radiation-generating equipment shall be equipped with a backscatter shield of not less than 0.25 millimeters lead equivalent and 15.2 centimeters in diameter that is positioned as close as practicable to the distal end of the device;

**The handler's written safe operating procedures must indicate that hand-held radiation-generating equipment must be equipped with a backscatter shield of not less than 0.25 millimeters lead equivalent with a diameter of 15.2 centimeters positioned at the distal end of the device.**

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- (4) Storage and security procedures shall be developed and implemented to assure hand-held radiation-generating equipment is secured against unauthorized use or removal when not under the control and constant surveillance of the registrant;

**The handler's written safe operating procedures must contain storage and security procedures to be followed when a hand-held x-ray unit is not under the control and constant surveillance of the registrant.**

- (5) Operator training, as required in paragraph (B)(5) of rule 3701:1-66-04 of the Administrative Code, shall include documented specific instruction to the x-ray operator regarding the prohibition on placing any part of their body into the useful beam and ensuring there are no bystanders within a radius of at least six feet from the patient being examined during exposure; and

**The handler's written safe operating procedures must specify the prohibition of placing any part of the operator's body into the useful beam; and ensure there are no bystanders within a radius of at least six feet from the patient being examined during exposure.**

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

**The handler's written safe operating procedures must specify that the hand-held radiation-generating unit will not be used in hallways or waiting rooms.**

- (J) Dental equipment shall not be operated at less than a measured fifty-one kVp.

**Dental radiation-generating equipment operating at less than a measured 51 kVp shall not be used on human patients.**

- (K) Dental equipment used by veterinarians shall comply with all requirements of this rule except paragraphs (A)(1), (D), (E), (I) and (J) of this rule. Additionally, the useful beam shall be limited to the area of clinical interest.

**Dental equipment used by veterinarians does not have to meet the following:**

- **Minimum source-to-skin distance requirements;**
- **Panoral equipment requirements; or**
- **Minimum kVp requirements.**

**Dental equipment used for veterinary purpose shall be limited to area of clinical interest, no larger the film size being used.**

- (L) Extraoral dental equipment used by veterinarians shall follow the requirements of paragraph (F) of rule 3701:1-66-05 of the Administrative Code.

**Extraoral dental equipment used by veterinarians must comply with the requirements of Ohio Administrative Code 3701:1-66-05(F) which means:**

- **Does not need to meet the requirements of paragraph (H) of Ohio**

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**Administrative Code 3701:1-66-02 but does need to be provided with either:**

- **A 6.5-foot high protective barrier for the operator protection during radiation exposure, or**
- **A means to allow the operator, and if applicable the assistant, to be at least 6 feet from the tube housing assembly and wear a lead apron of not less than 0.25-millimeter lead equivalent during exposures.**