

Guidance in Bold Text

Rule 3701:1-66-06 Effective Date: 02/1/2014

Dental radiation-generating equipment

As used in this rule, “dental equipment” means radiation- generating equipment used for dental radiography. In addition to other applicable rules adopted pursuant to Chapter 3748. of the Revised Code and Chapter 3701:1-66 of the Administrative Code, handlers of dental equipment shall comply with the following:

(A) Dental equipment for intraoral use shall meet the following equipment standards:

(1) A means shall be provided to limit the source-to-skin distance (SSD) to not less than:

(a) Eighteen centimeters if operable above fifty kVp; or

If the unit is capable of operating above 50 kVp, the minimum distance from the source (focal spot of the x-ray tube) to the end of the cone or spacer frame is 18 cm. Often this is indicated somewhere on the cone or spacer frame. This rule does not apply to x-ray intraoral equipment used for veterinary radiography.

Compliance verified by measuring from the point of the source on the x-ray tube head to the end of the collimator. The distance must equal at least 18 centimeters.

Inspectors will use a ruler or geometric triangulation to determine compliance with this requirement.

(b) Ten centimeters if operable at fifty kVp.

If operating at 50kVp, the minimum distance from the source (focal spot of the x-ray tube) to the end of the cone or spacer frame is 10 cm. Units that operate at this relatively low kVp maximum are often older and may not contain an indication of this distance. However, there is often an indication of the position of the focal spot on these older units (an indicator molded into the body of the tube housing). You may simply measure the distance from this indication to the end of the cone or spacer frame to determine compliance. This rule does not apply to x-ray intraoral equipment used for veterinary radiography.

Compliance verified by measuring from the point of the source on the x-ray tube head to the end of the collimator. The distance must equal at least 10 centimeters.

Inspectors will use a ruler or geometric triangulation to determine compliance with this requirement.

(2) The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.

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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, this 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.

Compliance verified by measuring the end of the collimator and a beam size test

Inspectors will determine compliance with this requirement using one of these 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).**

A timer accuracy test is used to verify compliance.

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

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

According to definition of ‘dead-man switch’ found in rule 3701:1-66-01(18), OAC, this means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Inspectors will observe the operation of the x-ray unit during the testing procedure to determine compliance with this requirement.

- (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.

The exposure must stop immediately after releasing the exposure control switch. In the case of intraoral equipment, premature termination of the exposure must cause the timer to reset to its initial setting. Specifically, the use of spring-timer style hand switches, which do not function in this manner, is prohibited.

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Inspectors will observe the operation of the x-ray unit during the testing procedure to determine compliance with this requirement.

- (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.

Inspectors will observe the operation of the x-ray unit during the testing procedure to determine compliance with this requirement.

- (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.

Inspectors will use calibrated test equipment to measure the output of the x-ray machine.

- (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.

Inspectors will use calibrated test equipment to measure the output of the x-ray machine.

- (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.

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

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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.

Inspectors will observe the operation of the x-ray unit during the testing procedure to determine compliance with this requirement.

- (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 parameters are the same, the output produced by the x-ray machine must be similar from exposure to exposure (reproducible) for kVp, the timer and the radiation exposure. 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 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.

Inspectors will use calibrated test equipment to measure the output of the x-ray machine.

- (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 x-ray field of both intraoral and panoral units will be intercepted by the patient. When equipment is used in this manner, no additional primary barrier considerations are necessary. 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.

However, exposures where the entire cross section of the x-ray field are not intercepted by the patient, consideration must be made such that the useful beam is otherwise attenuated to the allowable radiation levels.

Inspectors will evaluate the use of each x-ray unit to determine the adequacy of the primary barriers. In addition, using calibrated test

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equipment; inspectors may measure the amount of radiation in the areas surrounding the x-ray unit(s) to verify compliance with this rule.

- (2) When intraoral or panoral units are in adjacent 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 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.

Understand, 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.

Inspectors will evaluate the use of each x-ray unit to determine the adequacy of the protective barriers or documented safety procedures.

- (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.

The operator must view the patient during the entire exposure to monitor for patient motion and proper positioning. As long as the operator is at least six feet from the patient during the exposure, no additional physical barrier is necessary.

Inspectors will evaluate the use of each x-ray unit to determine compliance with this rule.

- (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.

Regardless of the distance from the patient, if the operator's position, as determined in paragraph (B)(3) of this rule is behind a protective barrier, a viewing system must be provided. While the Ohio Administrative Code provides no numerical size requirements, the viewing system must be large enough and so placed that the operator can view patient motion and verify proper positioning. Typical viewing systems include observation windows, mirrors or electronic viewing systems.

Inspectors will evaluate the use of each x-ray unit to determine compliance with this rule.

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- (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.

Compliance verified by manual and visual check of the tube housing stability when placed in position for examination.

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

Reference the guidance for quality assurance requirements in rules 3701:1-66-02 and 3701:1-66-04 of the Ohio Administrative Code.

- (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:

NOTE: Paragraphs (A)(1) and (A)(2) of this rule are appropriate for dental intraoral x-ray equipment only.

- (1) Dental panoral x-ray machines shall be certified pursuant to 21 C.F.R. part 1020 (as published in the April 1, 2008, Code of Federal Regulations).

X-ray 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.

Inspectors will verify the panoral equipment is certified by observing the required certification label.

- (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 porting of the image receptor.

In the case of conventional cassette based panoral x-ray equipment, the x-ray field can be no larger than the slit in the image receptor holder. In the case of digital x-ray equipment, that has no slit, the x-ray field size can be no larger than the active portion of the image receptor. Inquire with your service representative to ensure the x-ray unit is operating according to this standard.

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Inspectors will use specialized test equipment to determine compliance with this requirement.

- (F) Except for dental equipment used for panoramic use, handlers of radiographic equipment used for extra oral 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 must comply with the equipment and shielding requirements of rule 3701:1-66-05, OAC – *General purpose radiographic equipment*. Extraoral equipment includes any system in which the image receptor (digital or film) is positioned outside of the mouth during exposures. This requirement includes, but is not necessarily limited to, those units used for the following purposes:

- Cephalometric radiography
- TMJ radiography
- Bone age radiography

These requirements apply combination units (i.e. intraoral equipment that are also used for extraoral dental procedures).

Inspectors will evaluate all uses for each x-ray unit and inspect those units according to the appropriate Ohio Administrative Code rules.

- (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 and be included in the registrant's quality assurance program as specified in rule 3701:1-66-04 of the Administrative Code.

Fluoroscopy radiation-generating equipment must be used according to the requirements of rule 3701:1-66-07 of the OAC. Items of interest for dental offices include:

- **If the unit is stationary, a shielding design must be prepared by a radiation expert (prior to construction / renovation / installation).**
- **If the unit is stationary, an area radiation survey must be performed by a radiation expert after the installation is completed.**
- **Annual performance evaluations must be performed by a radiation expert; and**
- **Operator(s) must complete additional formalized training, as approved by a radiation expert.**

Inspectors will inspect these units according to the appropriate Ohio Administrative Code rules.

- (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 and be included in the registrant's quality assurance program as specified in rule 3701:1-66-04 of the Administrative Code.

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Dental cone-beam CT radiation-generating equipment includes any system provided with a full field detector and capable of planar (2D) or volumetric (3D) tomographic image reconstruction. Items of interest for dental offices include:

- **A shielding design must be prepared by a radiation expert (prior to construction / renovation / installation).**
- **An area radiation survey must be performed by a radiation expert after the installation is completed.**
- **Annual testing must be performed by a radiation expert, to include at least a radiation dose assessment and image quality evaluation;**
- **A quality control testing program must be developed and implemented under the guidance of a radiation expert;**

Inspectors will inspect these units according to the appropriate Ohio Administrative Code rules.

- (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:**

Inspectors will review the written quality assurance program to verify it appropriately addresses all applicable requirements described in this paragraph.

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

The written safe operating procedures must limit the use of hand-held x-ray units to intraoral purposes only.

- (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 written safe operating procedures must specify that the operator of hand-held x-ray units must wear a full lead apron and the procedure must be followed.

- (3) **If the hand-held radiation-generating equipment is designed with a back scatter shield, the backscatter shield shall be in place during all radiographic exposures;**

The written safe operating procedures must specify that the back scatter shield must be in place during all exposures and the procedure must be followed.

- (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;**

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The 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.

The 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. This procedure must be followed.

- (J) Dental equipment with a nominal fixed kVp of less than fifty kVp shall not be used to make diagnostic dental radiographs of human beings.

If the unit is designed with only one (fixed) kVp, it must be at least 50 kVp for human use.

Inspectors will verify that the fixed kVp on units used to exposure humans is at least 50 kVp.

- (K) Dental equipment used by veterinarians shall comply with all requirements of this rule except paragraphs (A)(1), (E), 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 fix kVp requirements.**

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

Inspectors will evaluate all uses for each x-ray unit and inspect those units according to the appropriate Ohio Administrative Code rules.

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

Any x-ray equipment used for veterinary extraoral dental procedures must comply with the applicable requirements of rule 3701:1-66-05, OAC – *General purpose radiographic equipment.*

Inspectors will evaluate all uses for each x-ray unit and inspect those units according to the appropriate Ohio Administrative Code rules.