

**3701:1-66-06      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
    - (b) Ten centimeters if operable at fifty kVp.
  - (2) The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.
  - (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.
  - (4) The exposure control switch shall meet the following requirements:
    - (a) The switch shall be of the "dead-man" type.
    - (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.
    - (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.
  - (5) The kVp accuracy shall be within plus or minus ten per cent of the indicated value.
  - (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.
  - (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.
  - (8) The coefficient of variation for reproducibility of kVp, timing, and radiation exposure shall not exceed 0.05 for four consecutive exposures
- (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.

- (2) When intraoral or panoramic 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.
  - (3) Intraoral and panoramic 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.
  - (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.
- (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.
- (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.
- (E) Handlers of dental panoramic 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:
- (1) Dental panoramic x-ray machines shall be certified pursuant to 21 C.F.R. part 1020 (as published in the April 1, 2012, Code of Federal Regulations).
  - (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.
- (F) Except for dental equipment used for panoramic 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.
- (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.
- (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.
- (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;
  - (2) Operators of the hand-held radiation-generating equipment shall wear a full lead apron of not less than 0.25 millimeter lead equivalent;
  - (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;
  - (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;
  - (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.
- (J) Dental equipment with a nominal fixed kVp of less than fifty shall not be used to make diagnostic dental radiographs of human beings.
- (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.
- (L) Extraoral dental equipment used by veterinarians shall follow the requirements of paragraph (F) of rule 3701:1-66-05 of the Administrative Code.

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CERTIFIED ELECTRONICALLY

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Certification

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Date

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