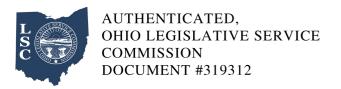


Ohio Administrative Code

Rule 3701:1-66-06 Dental radiation-generating equipment.

Effective: December 13, 2024

- (A) Dental equipment will meet the following equipment standards:
- (1) For dental intraoral equipment, a means will be provided to limit the source-to-skin distance (SSD) to not less than eighteen centimeters;
- (2) For dental intraoral equipment, the x-ray field at the minimum SSD will be containable in a circle having a diameter of no more than seven centimeters;
- (3) A means will 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 will meet the following obligations:
- (a) The switch will be of the "dead-man" type;
- (b) The operator will 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 will cause automatic resetting of the timer to its initial setting or to zero; and
- (c) It will 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 will be within plus or minus ten per cent of the indicated value;
- (6) For manual exposures, the accuracy of the timing device will be within plus or minus ten per cent of the indicated setting. The timing device will be tested at a minimum of two settings within the operative range of fifty milliseconds to one thousand milliseconds;

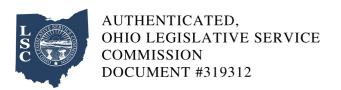


- (7) Visual indication will be provided whenever x-rays are produced. Certified equipment also will provide audible indication to the operator while x-rays are produced or on termination of the exposure; and
- (8) The coefficient of variation for reproducibility of kVp, timing, and radiation exposure will not exceed 0.05 for four consecutive exposures.
- (B) Handlers of dental intraoral and panoral equipment are exempt from paragraph (H) of rule 3701:1-66-02 of the Administrative Code and will comply with the following:
- (1) All areas struck by the useful beam will be provided with primary barriers;
- (2) When intraoral or panoral units are in adjacent human patient occupied rooms or areas, protective barriers will be provided between the rooms or areas, unless safety procedures are documented and implemented to obligate that no human patients will be present in the adjacent rooms or areas while exposures are being made;
- (3) Intraoral and panoral units will be provided with a protective barrier for the operator or will 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 will be arranged so that the operator views the patient during the entire exposure; and
- (4) When the operator is behind a protective barrier, a viewing system will 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 obligations listed in rule 3701:1-66-02 of the Administrative Code, handlers of dental equipment will 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) In addition to the quality assurance obligations of rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, handlers of dental radiation-generating equipment, with the exception of dental equipment used in hospitals, will conduct annual evaluations of x-ray operators to include the



following:

following:
(1) Positioning of the x-ray tube;
(2) Image processing;
(3) Operator location during x-ray exposure;
(4) Appropriate radiologic protocol; and
(5) Applicable regulatory obligations.
(E) Handlers of dental panoral equipment will comply with all obligations of paragraphs (A) to (D) of this rule, except for paragraphs (A)(1) and (A)(2) of this rule, and will comply with the following:
(1) Dental panoral x-ray machines will be certified pursuant to 21 C.F.R. part 1020 (as effective on the effective date of this rule); and
(2) The x-ray field will 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 panoral use, handlers of radiographic equipment used for extraoral dental procedures will comply with the obligations of paragraphs (A) and (B) of rule 3701:1-66-05 of the Administrative Code.
(G) Fluoroscopy without image intensification will not be used for dental examinations. Handlers of image intensified fluoroscopic equipment will comply with the applicable obligations of rule 3701:1-66-07 of the Administrative Code.
(H) Handlers of dental cone-beam CT radiation-generating equipment will comply with the applicable obligations of rule 3701:1-66-10 of the Administrative Code, except paragraph (H)(3) of 3701:1-66-02 if a radiation expert has determined that the public dose limit specified in 3701:1-38-13 of the Administrative Code are not exceeded.



- (I) Handlers of hand-held radiation-generating equipment used for dental procedures will meet the obligations of paragraphs (A), (B), and (D) of this rule, and will 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 will address at least the following:
- (1) Hand-held radiation-generating equipment will be used for intraoral purposes only;
- (2) Operators of the hand-held radiation-generating equipment will wear a full lead apron of not less than 0.25 millimeter lead equivalent;
- (3) Hand-held radiation-generating equipment will 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;
- (4) Storage and security procedures will 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 obligated in paragraph (B)(5) of rule 3701:1-66-04 of the Administrative Code, will include documented specific instruction to the x-ray operator regardingnot 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
- (6) Hand-held radiation-generating equipment will not be used in hallways or waiting rooms.
- (J) Dental equipment will not be operated at less than a measured fifty-one kVp.
- (K) Dental equipment used by veterinarians will comply with all obligations of this rule except paragraphs (A)(1), (D), (E), (I) and (J) of this rule. Additionally, the useful beam will be limited to the area of clinical interest.
- (L) Extraoral dental equipment used by veterinarians will follow the obligations of paragraph (F) of



rule 3701:1-66-05 of the Administrative Code.