

641—40.7(136C) General requirements for dental intraoral, panoramic, cephalometric, and volumetric dental imaging equipment.

1. In addition to the applicable requirements of this chapter, all dental intraoral, panoramic, cephalometric, and volumetric imaging X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.31, as well as the requirements of this chapter, unless otherwise specifically authorized by the department.

2. Dental facilities using CBCT technology shall follow applicable provisions of this chapter.

40.7(1) X-ray systems used for dental imaging. In addition to the applicable requirements of rule 641—40.5(136C), X-ray systems used for dental imaging must meet all of the following:

a. Intraoral dental units. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm.

(1) The X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm.

(2) Intraoral dental X-ray machines cannot be operated at less than a measured 51 kVp.

b. Extraoral, panoramic, and cephalometric units. X-ray systems designed for use with extraoral image receptors, and when used with an extraoral image receptor, shall:

(1) Be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(2) Be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

1. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

2. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

40.7(2) Operators of dental X-ray systems. Operators of dental X-ray machines must meet the requirements of rule 481—575.3(153) and be trained in the appropriate use of the radiation machines in operation at the registered dental facility.

40.7(3) Exposure control location and operator protection. Except for units designed to be handheld, the exposure control shall allow the operator to be:

a. Behind a protective barrier at least 6.5 feet (2 meters) tall; or

b. At least 6.5 feet (2 meters) from the tube housing assembly, outside the path of the useful beam, while making exposures.

40.7(4) Administrative controls. Patient and image receptor holding devices shall be used when the techniques permit.

a. Except for units designed to be handheld and allowed by these rules, the tube housing and position indicating device (PID) cannot be handheld during an exposure.

b. Dental fluoroscopy without image intensification cannot be used.

40.7(5) Handheld intraoral equipment. Only equipment specifically designed by the manufacturer to be held by the operator for intraoral dental X-ray exposures is allowed to be operated. In addition to the applicable requirements in this chapter, the following apply specifically to handheld devices:

a. The handheld X-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 6 inches (15.2 cm) in diameter that is positioned as close as practicable to the distal end of the position indication device.

b. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer. Records of training shall be kept at the facility until the operator is no longer an employee or until the equipment is removed from the facility.

c. The facility shall adopt and follow protocols provided by the manufacturer regarding the safe operation of the device.

d. Protective aprons of not less than 0.25 mm lead equivalent shall be available for operators to wear while operating a handheld intraoral dental radiographic unit at the discretion of the facility's policy and procedures.

e. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

f. The equipment cannot be operated in hallways, waiting rooms, or other areas where access for individuals of the general public cannot be controlled.

g. When not in use, the equipment shall be stored in a manner that would prevent inadvertent exposures or use by unauthorized individuals.

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