

Hand-held Dental X-Ray Units are Approved for Expanded Use

We changed our rule Radiation safety and diagnostic image quality standards for dental facilities, chapter 246-225A WAC, to allow dental facilities to use hand-held dental X-ray units. Previously we approved the use of hand-held dental X-ray units on a case-by-case basis. The requirements for using hand-held dental X-ray units are:

“WAC 246-225A-085 Hand-held X-ray system. The following requirements apply to hand-held X-ray systems:

- (1) Registrants using hand-held X-ray systems must provide for security and safe storage while not in use.
- (2) The image receptor used with hand-held dental X-ray systems must either be:
 - (a) A speed class of intra-oral film designated as "F," "E/F" or faster; or
 - (b) A digitally acquired image (CR or DR).
- (3) The hand-held X-ray system must be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that can be positioned to within 1 cm of the end of the position indicating device. The hand-held X-ray system must always be used with the backscatter shield in place.
- (4) Conditions and restrictions using the predicted whole body dose rate (effective dose) to the operator and shallow dose to the fingers:

If the predicted whole body dose rate (effective dose) is:	And the shallow dose rate to the fingers is:	The operator:
<100 mrem/yr	<1 rem/yr	Can operate equipment with no additional requirements
>100 mrem/yr	<1 rem/yr	Shall wear a leaded apron of 0.25 mm lead equivalent
>100 mrem/yr	>1 rem/yr	<ul style="list-style-type: none">• Shall wear a leaded apron of 0.25 mm lead equivalent; and• Shall use equipment for special needs patients outside of routine dental office settings only

ATTENTION!

It came to our attention that unlabelled (no-name) hand-held dental units from outside the United States are being sold online. The Food and Drug Administration (FDA) requires manufacturers of medical devices intended for use in the U.S. to [register annually with the FDA](#). Not all of these devices are registered or FDA approved. If you are in doubt about the approval status when buying a hand-held dental X-ray unit, please contact us at 1-800-299-9729, or check the [FDA website](#) before purchasing.