



Ohio Administrative Code

Rule 3701:1-66-11 Medical bone densitometry radiation-generating equipment.

Effective: December 13, 2024

(A) Handlers of bone densitometry equipment will assure that the equipment is certified by the manufacturer in accordance with the obligations of 21 C.F.R. part 1010.2, (as effective on the effective date of this rule), and maintained in accordance with the manufacturer's specifications.

(B) In addition to other applicable radiation safety obligations in Chapters 3701:1-38 and 3701:1-66 of the Administrative Code, the operator of bone densitometry equipment will be positioned at least one meter (3.3 feet) from the primary beam or behind a protective barrier containing a minimum of 0.25 millimeter of lead equivalent materials.

(C) In addition to other applicable quality assurance obligations in rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, handlers of bone densitometry equipment will comply with the following:

(1) The quality assurance program will include quality control test records which will be maintained between inspections and will include the following:

(a) A list of the tests to be performed as specified by the manufacturer;

(b) The frequency of performance as specified by the manufacturer;

(c) The acceptability limits for each test as specified by the manufacturer; and

(d) A brief description of the procedures and test equipment to be used for each test;

(2) Maintain a readily available copy of the manufacturer's operating manual; and

(3) The operator will advise the patient that the bone densitometry examination is a type of x-ray procedure.



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