

## Guidance in Bold Text

Rule 3701:1-66-11 Effective Date: 02/01/14

### Bone densitometry radiation-generating equipment

For the purposes of this rule, “bone densitometry equipment” means radiation-generating equipment intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. In addition to the applicable rules in Chapters 3701:1-38 and 3701:1-66 of the Administrative Code, handlers of bone densitometry equipment shall comply with the following:

- (A) Handlers of bone densitometry equipment shall assure that the equipment is certified by the manufacturer in accordance with the requirements of 21 C.F.R. 1010.2, as published in the April 1, 2012, Code of Federal Regulations, and maintained in accordance with the manufacturer’s specifications.

**X-ray equipment manufactured after August 1, 1974 and used in the United States of America must be certified by the U.S. Food and Drug Administration. Each certified x-ray system will be affixed or inscribed with at least one certification label, readily accessible to view when the product is fully assembled for use, that contains a statement that the product complies with federal regulation 21 CFR 1020.30.**

**Inspectors will verify the equipment is certified by observing the required certification label.**

- (B) In addition to other applicable radiation safety requirements in Chapters 3701:1-38 and 3701:1-66 of the Administrative Code, handlers of bone densitometry equipment shall comply with the following:

- (1) The operator shall 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.

**If the operator is not behind an appropriate protective barrier, the operator’s position must be at least one meter from the primary beam of the x-ray tube.**

**Note: The safe operating procedures must indicate where this position is located to meet the requirements of rules 3701:1-66-04 of the Ohio Administrative Code.**

**Inspectors will observe the area and review the safe operating procedures to verify compliance.**

- (2) Operators of bone densitometry equipment shall possess an Ohio radiologic license in accordance with rules in Chapter 3701-72 of the Administrative Code.

**Stationary bone densitometry equipment may only be operated by:**

- **An Ohio licensed physician;**
- **An Ohio licensed radiographer; or**
- **An Ohio General X-ray Machine Operator (GXMO) licensed in the category of ‘Bone Densitometry’ (this category will be indicated on the individual’s license).**

## Guidance in Bold Text

Rule 3701:1-66-11 Effective Date: 02/01/14

Bone densitometry radiation-generating equipment

**Mobile or portable bone densitometry equipment may only be operated by:**

- **An Ohio licensed physician; or**
- **An Ohio licensed radiographer.**

**Inspectors will review the license documents to verify compliance.**

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

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

**Bone densitometer equipment manufacturers typically provide a phantom and a procedure for daily quality control testing which addresses the following items:**

- (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.
- (e) Maintain a readily available copy of the manufacturer's operating manual.

**Readily available means the facility is able to present the manufacturer's operating manual to the inspector at the time of the inspection.**

**Inspectors will observe the manufacturer's specifications and review documents to verify compliance.**

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

**The written safe operating procedures must clearly describe the method the facility uses to ensure the operator advises the patient that the bone densitometry examination is a type of x-ray procedure. Conspicuously posting this information in a patient area is not adequate to meet the requirements of this rule.**

**Inspectors will interview operators and review documents to verify compliance.**