

**Radiology Compliance Branch**  
RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

## BONE DENSITOMETER GUIDELINES

### **Rule .0603(b) Plan Reviews**

Plan reviews are not required for bone density units.

### **Rule .0603(c) Radiation Surveys**

For installations of X-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section.

### **Bone Densitometer Guidelines:**

#### **1) Mobile units used in different locations:**

- (a) A qualified expert must perform an initial radiation survey of the unit. The survey will demonstrate radiation levels near the unit. When the unit is moved to different locations, information from the survey will aid the operator when determining the use of procedures and engineering controls based upon sound radiation principles, to achieve occupational dose limits and doses limits to members of the public that are as low as reasonably achievable (ALARA). The survey must be available for review. (Manufacturer output specifications do not meet the rule requiring a radiation survey.)  
[.0603(c)][.1601(a)(7)(8)(15)]
- (b) The registrant must establish a restricted area for the operator, prior to operating the bone density unit, to assure compliance with occupational dose limits and ALARA. The restricted area is to be established based on the information from the radiation survey. **[.0603(a)(1)(I)(iii)]**  
**[.1601(a)(7)(8)]**
- (c) The registrant must establish an area control plan. This will explain how the operator is to conduct operations to assure dose limits for individual members of the public do not exceed the limits and ALARA. **[.1601(a)(15)]**
- (d) An unattended machine must be secured to prevent unauthorized operation.  
**[.0603(A)(1)(B)]**

#### **2) Mobile units used in only one location:**

- (a) A qualified expert must perform an initial radiation survey of the unit. The survey will demonstrate radiation levels near the unit. Information from the survey will aid the operator when determining the use of procedures and engineering controls, based upon sound radiation principles to achieve

occupational dose limits and dose limits to members of the public that are ALARA. The survey must be available for review.  
**[.0603(c)][.1601(a)(7)(8)(15)]**

- (b) The registrant must establish a restricted area for the operator, to assure compliance with occupational dose limits and ALARA. The restricted area is to be established based on the information from the radiation survey.  
**[.1601(a)(7)(8)]**
- (c) The registrant must establish an area control plan to explain how the area will be monitored to assure that the area is restricted. **[.1601(a)(15)]**

**(3) Permanently fixed units:**

- (a) A qualified expert must perform an initial radiation survey of the unit. The survey will demonstrate radiation levels near the unit. **[.0603(c)]**
- (b) The registrant must establish a restricted area for the operator, to assure compliance with occupational dose limits are ALARA. The restricted area is to be established based on the information from the radiation survey.  
**[.1601(a)(7)(8)]**

**The registrant must maintain the following documents:**

- 1) Copy of the post installation room(s) survey **[.0603(a)(2)(B)] [.0603(c)]**
- 2) Copy of the Food and Drug Administration Report of Assembly 2579 form **[.0115]**
- 3) Current copy of the Notice of Registration **[.0603(a)(2)(A)]**
- 4) Records of maintenance or modification which affect the useful beam **[.0603(a)(2)(c)]**
- 5) Technique chart – the program on the computer monitor is acceptable; however, the operator must know and understand the technique factors used. **[.0603(a)(1)(C)]**
- 6) Doctor's authorization/order for exam **[.0603(a)(1)(G)]**
- 7) Current copy of the State Regulations **[.1001(a)(5)]**
- 8) Current copy of the Notice to Employees **[.1001(a)(5)(A)(B)(C)]**
- 9) Current copy of the Radiation Safety Program **[.1601(a)(7)(49)]**
- 10) RSO review annually **[.1601(a)(7)(49)]**
- 11) Proper radiation caution signs **[.1601(a)(34)(35)]**
- 12) Personnel Exposure Records **[.1601(a)(53)(56)]**
- 13) Previous inspection reports and correspondence regarding X-ray inspections.
- 14) Monitoring of occupational dose records **[.1601(a)(24)(53)]**