

**New York State Department of Health
Bureau of Environmental Radiation Protection**

**Guide for Radiation Safety/Quality Assurance Programs in Bone Densitometer
Facilities**

Introduction

A. Purpose

This guide describes the type and extent of information and standards by which the New York State Department of Health will evaluate a bone densitometer facility's Radiation Safety/Quality Assurance Program.

Our Department has implemented this program to reduce radiation exposure and optimize the diagnostic quality of the scans. It is our goal to assist facilities to be more actively involved and responsible for Quality Assurance in their practices. It is important to review the overall program and not become enmeshed in the quality control tests. Facilities may substitute quality control tests if the Department prior to their implementation deems the tests equivalent.

This guide applies to bone densitometry equipment only. Facilities using other forms of diagnostic radiation equipment are referred to the Department's "Guide for Radiation Safety/Quality Assurance Programs" or "Guide for Radiation Safety/Quality Assurance Programs in Small Facilities."

B. ALARA (As Low As Reasonably Achievable)

The regulations in Part 16 and this guide have been established on the ALARA principle to assure that the benefits of the use of ionizing radiation exceed the risks to the individual and the public health and safety.

C. Control Limits and Standards

The control limits and standards used in this guide have been taken from the Federal Performance Standard for Diagnostic X-ray Equipment and Part 16. Equipment problems should be corrected and documented expeditiously and shall be corrected with appropriate documentation within sixty (60) days of discovery.

D. Authority

The statutory authority for these rules and regulations is found in the New York State Public Health Law, Section 225. While there are no specific regulations in Part 16 of Chapter 1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations pertaining to bone densitometry equipment, Section 16.63 of Part 16 allows the Department to establish special inspections procedures for equipment not specifically covered by Part 16. This guide is delineating that special inspection procedure. Please note that this program is in addition to and does not replace other sections of Part 16, which pertain to your installation.

Radiation Safety/Quality Assurance Program

A. Radiation Safety/Quality Assurance Responsibility

The installation's radiation safety officer (RSO) is responsible for radiation safety and quality assurance and the implementation of this program. The RSO must be a physician, an osteopath, a chiropractor, or a medical physicist who is certified as per Section 16.2(99)(i) of Part 16.

B. Records

1. Manual

If a Radiation Safety/Quality Assurance manual has been developed for other diagnostic radiation equipment used at your installation, a separate manual is not needed for any bone densitometer units. An addendum for the bone densitometer units can be added to your current manual. That addendum or manual must contain the following:

- a. a list of the tests to be performed;
- b. the frequency of performance;
- c. the acceptability limits for each test;
- d. a brief description of the procedures to be used for each test.

Proper reference to the operator's manual for those tests which can be performed by the operator will be sufficient to fulfill this requirement if the operator's manual is readily available for review.

2. Equipment Records

Records shall be maintained for each bone densitometer unit and include:

- a. the initial test results (acceptance testing and radiation safety survey as appropriate);
- b. the current year;
- c. outlying test results and the repairs made based on those results since the last inspection of the equipment.

If the results of operator initiated tests are automatically stored to a computer, the results must be readily available for review and provision must be made to protect the data in case of computer failure.

3. QC Records for Test Equipment

Records shall be maintained and available for review for QC test equipment requiring calibration.

4. Radiation Safety Policies and Procedures (Appendix A)

If written policies and procedures have been developed for other diagnostic radiation equipment used at your facility, it is not necessary to develop separate policies and procedures for any bone densitometer units. If policies and procedures have not been previously written, they must be developed for the holding of patients, pregnant operators, and personnel monitoring.

C. Equipment Monitoring

Before each day of operation the operator shall follow the manufacturer's procedure for checking the constancy of the bone densitometer's performance. With most units this will involve the scanning of a quality assurance/quality control or calibration phantom provided by the manufacturer with the unit in the calibration or quality control mode. If any of the test results fall outside the manufacturer's programmed

specifications, the test must be repeated. If the test result is again outside the manufacturer's specifications, the unit must not be used on patients and service must be called. A service ticket or its equivalent must document the correction of any outlying test result.

The preventive maintenance schedule provided by the manufacturer must be followed. Performance of preventive maintenance must be evidenced by a service ticket or its equivalent.

D. Log Book

Each facility shall maintain a log book or an equivalent record system containing the patient's name, date of the exam, type of scan, number of scans done, and when applicable the reason for holding the patient.

APPENDIX A-1

Policy and Procedures for Patient Holding

The facility shall include the following information in its Policy and Procedures Manual item for those situations where patient holding may be necessary:

1. A list of the scans where holding devices cannot be utilized;
2. Who will hold;
3. The existing restraining devices available;
4. The use of protective garments; and
5. Where to find the log of those individuals who hold. This log will include date, number of views, and the name of the holder, their exposure and the reason holding was necessary.

APPENDIX A-2

Policy and Procedures for Pregnant Workers

The facility must use the requirements in Part 16 of 10NYCRR to establish their Policy and Procedure Manual item regarding pregnant employees.

The following information shall be included:

1. The method of instructing workers as to the requirements of Sections 16.2(a)(29) and 16.6(h) of Part 16 with regard to voluntarily declaring a pregnancy.
2. The method of ensuring that the embryo/fetus does not receive a monthly total effective dose equivalent of more than 50 mrem and total dose for the gestation period of more than 500 mrem.
3. The method of informing workers of their monthly exposure and total exposure for the gestation period.
4. The facility policy regarding work assignments for declared pregnant workers.

APPENDIX A-3

Policy and Procedures of Personnel Monitoring

The facility using personnel monitoring shall include the following information in its Policy and Procedures manual:

1. The name of the person responsible for distribution, collection and records of badges;
2. The location of controls;
3. A prohibition against intentionally exposing the control or personnel badge; and
4. The location of records and policy regarding notification of personnel of exposures.