

Bone Densitometry X-ray Equipment Operation in Pennsylvania

A bone densitometer is an essential tool in osteoporosis management. Osteoporosis is a condition that is characterized by a gradual loss of calcium, causing the bones to lose mass and become porous, more fragile, and susceptible to breaking. Standard diagnostic X-ray images cannot detect mild bone loss or quantitatively measure bone loss. An enhanced form of X-ray technology using a bone mineral density (BMD) test is the most efficient way to diagnose osteoporosis and evaluate bone for future fracture risk. A BMD measurement involves scanning and analyzing the lower spine or hip. Peripheral analysis of bone in the finger, heel, or forearm may be used for quick screening. Bone densitometry utilizes radiation-producing machines that vary from small peripheral bench-top units to table-size full-body scanners. Bone densitometry X-ray equipment used in the healing arts must be operated by or under the supervision of an appropriately credentialed physician or a qualified radiologic technologist. Specific requirements for determination of competence and for continuing education are addressed by regulation under 25 Pa. Code § 221.11(b) and § 221.16.

Operation of Bone Densitometers

Specialized X-ray equipment for the measurement of BMD is commonly used in two types of healing arts facilities: 1) doctor's offices (licensed practitioners) or clinics and 2) health care facilities, such as hospitals. The Department of Environmental Protection's (DEP) Bureau of Radiation Protection (BRP) works in conjunction with the Departments of State and Health in regulating auxiliary personnel that perform radiological procedures.

Unrestricted Scanning of the Whole Body

Typically, whole body scans with bone densitometry X-ray equipment are not performed for clinical evaluation of osteoporosis; rather, a hip or spine scan is used to determine the bone density value. The operation of X-ray equipment in these facilities must be conducted by or under the supervision of a physician. Operators or auxiliary personnel who use bone densitometry equipment must meet the BRP radiological requirements of 25 Pa. Code § 215.24(b) and Department of State (DOS) requirements of 49 Pa. Code, Part I, Subpart A, Chapter 18, Subchapter E, relating to Radiologic Procedures by Auxiliary Personnel. These regulations require the operator to be currently registered and certified by the American Registry of Radiologic Technologists (ARRT) in Radiography or by the International Society for Clinical Densitometry (ISCD) or must have passed the Limited Examination in Radiography administered by the ARRT.

Peripheral Testing

To operate bone densitometry equipment only for peripheral testing, auxiliary personnel must be ARRT or ISCD qualified, as stated above, or have passed the ARRT Limited Examination in Radiography for the thorax and extremities.

Precision Testing

Precision is the ability to reproduce a quantitative measurement when a test is repeated under identical circumstances. Some of the ways that a lack of reproducibility enters into the determination of BMD are through differences between operators and patient positioning. Precision testing involves a small additional radiation exposure to a few patients to improve reproducibility and minimize statistical errors for the diagnostic benefit of all patients. DEP supports the use of precision testing as a necessary component for calibration and quality control in bone densitometry. DEP will permit 30 volunteers to receive one additional BMD test each for precision measurement following their diagnostic scan for each operator of a bone densitometer X-ray unit at a facility. This will help ensure that the exposure to any one patient is minimized and that the diversity of patient types and operators affecting precision is taken into account. Informed consent of the patient must be obtained for participation in the additional BMD test

for precision, and there must be no charge to the volunteer for that additional test. Any facility that believes it cannot secure 30 volunteers and wishes to expose each volunteer to more than one additional BMD test per operator for precision must seek prior approval of DEP.

Registration of Bone Densitometers

Since most bone densitometers utilize X-rays by regulation under 25 Pa. Code § 216.2, they must be registered as radiation-producing machines with BRP within 30 days of acquisition.

Devices that measure BMD using ultrasound do not produce ionizing radiation and are not subject to BRP registration or regulation.

Bone Densitometry Use in Screening

In addition to measuring the progression of osteoporosis in patients who have already been diagnosed or are under treatment, BMD tests are also used to screen “at risk” populations to identify those who may be developing osteoporosis. Regulations in 25 Pa. Code § 221.11(g) require that any healing arts use of X-rays on humans shall be performed only for diagnosis or treatment and only upon the written order or valid prescription from a physician responsible for the individual’s care. Otherwise, the procedure is considered “Healing Arts Screening” and a written request for approval must be obtained from BRP prior to conducting the screening procedure. The process for obtaining Healing Arts Screening approval is addressed in 25 Pa. Code § 221.13.

References

The American Registry of Radiologic Technologists, 2003 Bone Densitometry Certification Handbook and Application Materials.

Pennsylvania Code Titles 25, 28, and 49 Regulations, www.pacodeandbulletin.gov.

For more information, visit www.dep.pa.gov or call the BRP at 717-787-3720.