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Bone Density Rules DRAFT
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4732.0850 BONE DENSITOMETRY SYSTEMS.

Subpart 1. **Applicability.** Facilities using dedicated bone densitometry equipment or QCT (Quantitative Computed Tomography) systems must comply with the requirements in this part and other relevant requirements in this chapter.

Subpart 2. **Equipment requirements.** Facilities using ionizing radiation equipment to measure bone density must register the equipment with the Minnesota Department of Health, according to 4732.0200, and be responsible for maintaining the equipment in compliance with:

- A. nationally recognized standards, such as Code of Federal Regulations, title 21, section 1020; and
- B. the manufacturer's recommendations with a copy on site...a copy of installation, preventative maintenance, and serviced records must be maintained by the facility; or
- C. applicable calibration and performance evaluations in part 4732.1100; and
- D. systems with stepless collimators must be provided with the means to both size and align the x-ray field at the place of the image detector and the SID indicator accuracy is within +/- 2%.

Subp. 3. **Operating requirements for bone densitometry systems.** The registrant must ensure that:

- A. staff has site-specific training on all operating and emergency procedures;
- B. staff have additional training anytime there is a change in equipment of software that affects radiation output;
- C. all training is completed and documented according to 4732.0330;
- D. dose levels do not exceed doses in 4732.0410 to 4732.0430;

- E. bone density procedures are ordered and conducted according to 4732.0560, subpart 2;
- F. bone density study must be interpreted by a Licensed Practitioner of the Healing Arts;
- G. self-referral is prohibited under 4732.305, subpart 1, item B;

- H. the exposure of a human subject for the purpose of training is prohibited in part 4732.0305;
- I. the bone density equipment and operator are positioned at least six feet away from the patient, unless the requirements of 4732.0510 are met;
- J. only the patient, operator, required ancillary personnel, or nonmedical persons required for assistance for the bone density procedure, may be in the room during the radiographic exposure; and
- K. daily quality control tests are performed and documented. Equipment that does not pass the daily quality control tests can not be used except as provided for in 4732.0520, subpart 1, E.

Subp. 4. **Quality assurance or quality control procedures.** The registrant must implement a site-specific quality assurance program. The program must include:

- A. all quality control procedures must follow manufacturer's recommendations or a nationally recognized standard.
- B. the manufacturer's quality control procedures and any corrective actions must be performed prior to the first patient of the day and the results documented;
- C. the facility's operating and emergency procedures;
- D. repeat analysis must be done at intervals not to exceed 90 days and must include any scan site that is restarted after 50% of the study is completed; and
- E. annual audits and utilization logs are completed according to 4732.0540 and 4732.0545, subp. A., items 1-6.

Subp. 5. **Bone densitometry system operators.** The registrant must ensure that all operators of bone densitometry equipment:

- A. be a qualified x-ray operator having fulfilled the requirements of Minnesota Statutes, section 144.121; and
- B. complete specific manufacturer's training or equivalent training provided by :
 - (1) an ISCD or ARRT certified bone densitometer operator; or
 - (2) a licensed practitioner of the healing arts trained in bone densitometry; and
- C. receive a minimum of 16 hours of bone densitometry training, to be completed prior to examining their first patient. This may be a combination of manufacturer's training and additional training to meet the 16 hour requirement. Training must be documented and include the following items:
 - (1) bone physiology and anatomy as it pertains to bone density;
 - (2) methods used to test bone density including, Single and Dual Energy X-ray Absorptiometry (SXA and DXA,) Radiographic Absorptiometry (RA,) Quantitative CT (QCT,) and peripheral Quantitative CT (pQCT);
 - (3) basic statistics, including measuring bone density and reporting patient results using T and Z scores;
 - (4) the different types of DXA systems including pencil, fan and cone beam systems;
 - (5) quality control testing;
 - (6) factors in determining quality in bone mineral density;
 - (7) data acquisition;
 - (8) artifacts and disease processes that affect bones and possibly study outcomes;
 - (9) understanding the basic concepts of osteoporosis as a disease and its etiology.
- D. Equivalencies to meet the above requirement include:
 - (1) operators passing a nationally recognized bone density examination such as: an ARRT Bone Densitometry Exam; or
 - (2) an ISCD (International Society for Clinical Densitometry) certification in Bone Densitometry; or
 - (3) passing an equivalent examination approved by the commissioner.

Subp. 6. Precision Assessment. Facilities using quantitative comparisons for bone density, such as DXA, pDXA, QCT, pQCT that perform precision assessment, must do so according to a nationally recognized standard such as: the ISCD (International Society for Clinical Densitometry) and with these stipulations:

- A. Participation of subjects is voluntary and can not be performed on children under the age of 10 years.

- B. Each operator must keep a log of their precision study on file, with the name of the operator, name of the patients or medical record numbers, and the least significant change; and
- C. A patient must sign a consent form prior to the precision study. The following information must be included on the consent form:
 - (1) purpose of the study;
 - (2) areas to be scanned;
 - (3) information on the estimated amount of radiation dose to be received as compared to background radiation
 - (4) name of operator conducting the precision assessment
 - (5) date of the assessment exam;
 - (6) attestation that any female of child bearing age is not pregnant;
 - (7) precision assessment done on children between the ages of 11 and 18 must have a parent's consent prior to the examination being performed.

Subp. 7. **Records.** The registrant must ensure that the records are maintained according to part 4732.0330.

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