**4732.0870 REQUIREMENTS FOR STEREOTACTIC MAMMOGRAPHIC EQUIPMENT.**

Subpart 1. **Equipment requirements.** Radiation-producing equipment specifically designed to perform stereotactically guided breast biopsies must meet the requirements of this chapter and:

A. nationally recognized standards such as Code of Federal Regulations, title 21, section 1020;

B. the equipment manufacturer's specifications; or

C. part 4732.1100.

Subp. 2. **Registrant requirements.** The registrant must ensure that:

A. individuals operating the equipment meet the requirements of Minnesota Statutes, section 144.121, subdivision 5, or the Food and Drug Administration's Mammographic Quality Standards Act requirements;

B. individuals have completed equipment manufacturer's training or equivalent and initial site-specific training in the registrant's operating and emergency procedures;

C. the training in item B is documented and records kept; and

D. the entire system for stereotactic breast biopsies including the equipment performance, procedures, and records are evaluated annually by a diagnostic radiographic physicist.

Subp. 3. **Quality assurance and quality control procedures.** The registrant must ensure that:

A. all manufacturer's quality assurance or quality control procedures follow the test procedures established by the registrant, recommendations of a nationally recognized standard, or the manufacturer's specifications;

B. the frequency of the quality assurance or quality control procedures, and corrective actions as a result of quality control testing are followed and documented; and

C. the facility's operating and emergency procedures include quality assurance or quality control procedures.

Subp. 4. **Records.** Records must be maintained according to part 4732.0330.

**Statutory Authority:** *MS s 144.12*

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