641—41.14(136C) Registration and application standards and requirements for stereotactic breast biopsy. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to the requirements set forth in 641—subrule 37.8(2).

41.14(1) Each facility wishing to perform stereotactically guided breast biopsies shall apply to the department for authorization by providing or verifying the following information for each machine:

a. The stereotactically guided breast biopsy equipment and facility meet the general requirements of the rules for radiation machines.

b. The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

c. The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

d. The radiation machine is operated by individuals meeting the requirements of this rule.

e. The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

f. The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

41.14(2) The department will conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]