641—41.4(136C) Mammography registration, certification, and general requirements. In addition to the rules of this chapter, mammography facilities shall comply with the requirements of 21 CFR 900.11.

41.4(1) *Registration and certificates.* Each radiation machine used to perform mammography shall be registered according to 641—subrule 37.8(2).

a. A certificate issued by the FDA or this department is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this department, facilities are required to meet the quality standards of this chapter and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for authorization by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for department-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

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

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually (within 10 to 14 months of previous occurrence) by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

41.4(2) *Inspections.* After initial mammography certification, the department will conduct an inspection of each radiation machine no later than every 14 months thereafter.

a. An application for authorization shall be submitted to the department and processed for department approval. A mammography authorization is effective for three years.

b. A phantom image taken with the authorized unit(s) will be reviewed at the time of annual inspection by the department.

41.4(3) *Review workstation (RWS) requirements.* RWS used for final interpretation of mammogram images shall meet the following criteria:

a. Have 5 megapixel resolution; or

b. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

c. The workstation shall have a quality control program substantially the same as that outlined by the mammography unit manufacturer's quality control manual, that outlined by the RWS monitor manufacturer's quality control manual, or the quality control program outlined by an FDA-approved accrediting body.

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