**Section 370.170 Mammography Units Used for Localization or Biopsy Procedures**

a) Personnel. The following requirements apply to all personnel involved in localization or biopsy procedures performed with mammography units:

1) The mammography unit shall be operated by or under the direction of a physician licensed under the Medical Practice Act of 1987 [225 ILCS 60].

2) Radiologic technologists operating mammography units for localization or biopsy procedures shall meet the general requirements, mammography requirements and continuing education and experience requirements as specified in Section 370.70(b) of this Part.

3) Medical physicists who perform and provide oversight of quality assurance programs for mammography units used for biopsy procedures shall meet the requirements of Section 370.70(c) of this Part.

b) Equipment. Mammography units used for localization or biopsy procedures shall meet the requirements of Section 370.80 of this Part, except that digital output mammography systems that do not use screen-film image receptors are exempt from the requirements of Section 370.80 of this Part as they relate to screen-film image receptors.

c) Quality assurance. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity and accuracy of mammography localization or biopsy procedures performed at the facility.

1) Each facility shall have the services of a medical physicist available to survey mammography equipment and to oversee the equipment-related quality assurance practices of the facility.

2) The quality assurance program shall be in writing and shall have been developed by a medical physicist. The program shall include, but need not be limited to, the following:

A) Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

B) Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

3) The medical physicist shall conduct a review of the quality assurance program each year. Such review shall include evaluation of the results of quality assurance testing.

d) Each facility shall maintain written records of the radiation dose measurements and quality assurance testing performed, as required in this Section, for inspection by the Agency for a period of at least one year. Such records shall include, but need not be limited to, the following:

1) The date of the test and identification of the person performing the test;

2) Identification of the type of testing that was performed; and

3) Notation of whether the results of the testing were within the parameters established by the medical physicist.

AGENCY NOTE: The Agency recommends that facilities performing interventional mammography seek accreditation through the Stereotactic Breast Biopsy Program of the American College of Radiology.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)