641—41.19(136C) Quality assurance program for stereotactic breast biopsy. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems to ensure high-quality images with minimum patient exposure.

41.19(1) The facility shall name a supervising stereotactic breast biopsy physician who shall be responsible for all of the following:

a. Quality assurance activities including the medical audit;

b. Oversight and review of the quality control program at least annually;

c. Supervision of the radiologic technologist(s) and the medical physicist.

41.19(2) Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program.

a. The program shall include equipment performance monitoring conducted at installation and at least annually thereafter. Performance monitoring shall include the following:

(1) Evaluation of biopsy unit assembly. Any failed items shall be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

(2) Collimation.

1. X-ray field cannot extend beyond the image receptor by more than 5 mm on any side.
2. Any failures shall be corrected within 30 days of the survey.

(3) Evaluation of focal spot. Focal spot cannot degrade from initial measurement. If reduction in lp/mm is found, focal spot shall be corrected within 30 days of survey.

(4) kVp accuracy/reproducibility. kVp accuracy/reproducibility shall be accurate to within +/- 5 percent of nominal kVp setting. Failures shall be corrected before further procedures are performed.

(5) Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures shall be corrected before further procedures are performed.

(6) Automatic Exposure Control System Assessment.

(7) Digital receptor uniformity. The SNR in each corner shall be within +/- 15 percent of the SNR in the center. Failures shall be corrected within 30 days of the survey.

(8) Breast entrance exposure, average glandular dose and exposure reproducibility. Exposure shall be reproducible to within +/- 15 percent of mean exposure. Average glandular dose shall be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.2 centimeter breast. Failures shall be corrected before further procedures are performed.

(9) Image quality evaluation. Phantom image shall meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures shall be corrected before further procedures are performed.

(10) Artifact evaluation. Any significant black or white artifacts seen in the image detector field shall be corrected within 30 days of the survey.

(11) Localization simulation (gelatin phantom) test. Localization accuracy shall be within 1 mm of target, and the test shall include a portion of the test “lesion” in the sample chamber. Failures shall be corrected before further procedures are performed.

b. Analyzing the performance monitoring results to determine if there are any problems requiring correction.

c. Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

41.19(3) Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired.

41.19(4) The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

a. Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate shall be within manufacturer specifications for the intended target value. Failures shall be corrected before further procedures are performed.

b. Visual checklist (monthly). Any failed items shall be corrected within 30 days.

c. Phantom image (weekly). Phantom image shall meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures shall be corrected before further procedures are performed.

d. Compression (semiannually). The maximum auto drive compression force cannot exceed 45 pounds. Failures shall be corrected within 30 days.

e. Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer shall be completed as outlined in the quality control manual applicable to the unit.

41.19(5) Medical audit program. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include all of the following:

a. An imaging-pathology correlation for each biopsy performed;

b. An ongoing analysis of biopsy results and periodic review of the utilization of the procedure;

c. The number of biopsies performed;

d. The number of cancers found;

e. The number of benign lesions found;

f. The number of biopsies repeated.

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