

New York State Department of Health  
Bureau of Environmental Radiation Protection

Guide for a Quality Assurance Program for Facilities Performing  
Stereotactic Breast Biopsy

**Introduction**

Each facility utilizing stereotactic equipment or dedicated mammography equipment solely for needle biopsy purposes, must incorporate that equipment into the facility's Radiation Safety-Quality Assurance Program. These Quality Assurance requirements include periodic testing to ensure that equipment performance is within the manufacturer's specifications and that other test parameters are within limits. Facilities are required to develop a manual component which would include, but not necessarily be limited to: sample test forms, test procedures, acceptability limits, and the frequency under which each test must be performed.

**Medical Physicist's Quality Control Tests**

Test Frequency-Annually

1. Stereotactic Unit Assembly

Performed to ensure that all locks, detents, angulation indicators, and mechanical support devices for the x-ray tube, compression plate and image receptor holder assembly are operating properly.

2. Focal Spot Performance and System Limiting Spatial Resolution

Performed to evaluate focal spot size by measuring limiting spatial resolution using a high-contrast resolution pattern both parallel and perpendicular to the anode-cathode axis using film. System limiting spatial resolution of the digital image receptor, if present, must also be evaluated.

3. kVp Accuracy/Reproducibility

Performed to ensure that the actual kVp is accurate (within +/- 5% of the indicated kVp) and that the kVp is reproducible, having a coefficient of variation equal to or less than 0.02.

4. Beam Quality Assessment (Half-Value Layer Measurement)

Performed to ensure that the half-value layer of the x-ray beam is adequate to minimize patient breast dose, while not so excessive that contrast is lost in the resultant image.

5. Automatic Exposure Control (AEC) or Manual Exposure Performance Assessment

Performed to assess the stereotactic breast biopsy unit's AEC system or manual techniques with regard to appropriate film optical density or detector signal levels over the range of breast thicknesses.

6. Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility

Performed to measure the typical entrance exposure for a standardized breast thickness and composition (approximately 4.2-cm compressed breast thickness-50% adipose, 50% glandular composition), to calculate the associated average glandular dose, and to assess short-term exposure reproducibility.

7. Image Quality Evaluation

Performed to ensure that image quality for stereotactic biopsy procedures meets, or exceeds, that of mammography, and to detect any temporal changes in image quality.

8. Artifact Evaluation

Performed to assess the degree and source of artifacts visualized in screen/film or digital stereotactic images. This procedure allows the source of artifacts to be isolated to x-ray equipment, image receptor, or film processor (for film-screen images) so that appropriate measures for elimination of artifacts can be taken.

9. Digital Receptor Uniformity

Performed to identify geometrical distortion, misalignment of the lens system, poor fiber optic contact and Charge Coupled Device (CCD) element drop out. CCD drop out can cause non-uniformities in the image.

10. Localization Accuracy (Gelatin phantom) test

Performed to ensure the accuracy of the localization system, including needle position, stereo position calculations and the user interface.

**Radiologic Technologist's Quality Control Tests**

Test Frequency Semi-Annually

1. Compression force adjustment

Performed semi-annually to assure that the x-ray imaging system can provide adequate compression in the manual and automatic powered mode.

## 2. Repeat Analysis

Performed to determine the number and cause of repeated patient exposures. Analysis of this data will help identify ways to improve efficiency, reduce costs and reduce patient breast dose.

### Test Frequency Monthly

#### 1. Hardcopy Output Quality

Performed to ensure that the quality of hardcopy output is consistent over time and that it matches the grayscale presented on the CRT monitor.

### Test Frequency Weekly

#### 1. Phantom Image

Performed to assure that film density, contrast, field uniformity and image quality of the x-ray imaging system is optimal. The image quality must equal or exceed that of screening or diagnostic mammography equipment.

#### 2. Visual Checklist

Performed to assure that the mammography x-ray system and the digital imaging system are working properly and that the mechanical rigidity and stability of the system is optimal.

### Test Frequency Daily

#### 1. Localization System Accuracy (In Air)

Performed daily prior to system use on a patient to verify system alignment and performance. Each manufacturer's recommendation for system alignment and performance measurements should be followed.

#### 2. Film Processor Quality Control

Performed daily, if film is used to ensure consistent performance of the film processor.

## Infection Control Procedures

Each facility must establish infection control procedures and a manual item detailing infection control methods, in accordance with the equipment manufacturer's recommendations. The procedures should be established in conjunction with the facility's overall infection control program.

## Medical Quality Assurance

Ongoing medical audits of stereotactically guided pre-operative localization, Fine Needle Aspiration (FNA), Core Needle Biopsy (CNB), programs should be performed. At a minimum, the physician should be able to provide the number of procedures done by type, the number of cancers diagnosed and the number of complications that required treatment. The audit should be done for each physician who performs stereotactic breast biopsy procedures.

The following items should be tracked:

- The number of, and the indication for, repeat biopsies and excisional biopsies recommended following stereotactically guided FNA or CNB. (i.e. inconclusive result, inadequate sample, ductal hyperplasia with atypia, complex sclerosing lesions/radial scar, lesions requiring more tissue for accurate diagnosis or technical failure, etc.)
- The rate of compliance with recommended follow-up in women with benign results following stereotactically guided FNA or CNB.
- Follow-up of all biopsies should be pursued to detect and record false-negative or false-positive results.