

Stereotactic Breast Biopsy Accreditation Program Requirements



Overview

The American College of Radiology's Stereotactic Breast Biopsy Accreditation Program provides facilities performing stereotactic breast biopsy procedures with peer review and constructive feedback on their staff's qualifications, equipment, quality control (QC), quality assurance, accuracy of needle placement, image quality and dose. Applicants must accredit each x-ray unit used for stereotactic breast biopsies. This document outlines the requirements a facility must meet in order to apply for stereotactic breast biopsy accreditation. Although stereotactic breast biopsy is currently exempt from the Food and Drug Administration's (FDA) Mammography Quality Standards Act (MQSA) regulations, the program's quality standards are consistent with those of MQSA in order to prepare for possible future regulatory inclusion.

Mandatory Accreditation Time Requirements

Submission of all accreditation material is subject to mandatory timelines. Detailed information about specific time requirements is located in the [Overview for the Diagnostic Modality Accreditation Program](#). Please read and be familiar with these requirements.

Withdrawn, Added, or Replacement Units

The Stereotactic Breast Biopsy Accreditation Program is unit based. Consequently, facilities **must contact the ACR** if they have permanently **withdrawn** (i.e., removed) a unit from biopsy service, if they have **replaced** that unit with a new one or have **added** another unit for biopsies. The type of accreditation options available for a new unit will depend on the amount of **time the facility has left on its current accreditation certificate**:

- **Over 13 months** – The facility needs to submit only unit information and additional testing materials. Once accreditation is approved, the new unit's expiration date will be the same as the previous expiration date.
- **Less than 13 months** – The facility must renew accreditation for all units at the facility including the new one. Once approved, all of the units at the facility will have an expiration date that is three years from the old expiration date.

Personnel Qualifications

All physicians, radiologic technologists and medical physicists working in stereotactic breast biopsy (including part-time and locum tenens staff) **must meet and document** specific requirements **at the time of application** in order for their facility to be accredited by the ACR. The specific qualifications required for the interpreting physician depend on the setting in which the physician practices (i.e., “collaborative” or “independent”). Radiologists, radiologic technologists and medical physicists must be **currently qualified** for mammography under MQSA. Although continuing education specific to stereotactic breast biopsy is required for accreditation, the FDA allows these credits to count towards the continuing education requirements for MQSA. Further information is available on the FDA website at www.fda.gov/cdrh/mammography.

The continuing education and continuing experience requirements are based on **previous full calendar years**. For example, if a site applies for accreditation in July 2009, the physicians and medical physicists at that site must have met the full requirement for continuing education from January 1, 2006 to December 31, 2008. Likewise, they must have met the full continuing experience requirements from January 1, 2008 to December 31, 2008. If they did not meet these requirements in the given timeframes, the ACR will accept continuing education credits or continuing experience obtained in 2009.

Interpreting Physician Qualifications – Collaborative Setting

A collaborative setting is one where both radiologists and surgeons (or other physicians) conduct stereotactic breast biopsy procedures using the accredited unit. Both radiologists and surgeons (or other physicians) have joint responsibility for:

- Patient selection
- Quality assurance including the medical audit (tracking of the number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications)

The radiologist is responsible for:

- Mammographic interpretation
- Oversight of all quality control and quality assurance
- Supervision of the radiologic technologist and the medical physicist

All physicians supervising and conducting stereotactic breast biopsies in a collaborative setting **must** meet the following minimum criteria:

Interpreting Physician - Collaborative Setting		
Qualifications	Radiologist*	Other Physician
Initial	Performed 12 stereotactic breast biopsy procedures or 3 hands-on stereotactic breast biopsy procedures under a qualified physician ¹	
	<p style="text-align: center;">AND</p> 3 hours of Category 1 CME in stereotactic breast biopsy <p style="text-align: center;">AND</p> Experienced in recommendations for biopsy and lesion identification at time of biopsy <p style="text-align: center;">AND</p> Qualified as an interpreting physician under MQSA	<p style="text-align: center;">AND</p> 3 hours of Category 1 CME in stereotactic breast biopsy (that includes image triangulation for lesion location) <p style="text-align: center;">AND</p> Experienced in post-biopsy patient management
Continuing Experience	12 stereotactic breast biopsies per year (or requalify according to above initial requirements)	
Continuing Education	3 hours of Category 1 CME in stereotactic breast biopsy every 3 years	

*radiologists **must be currently** qualified as an interpreting physician under MQSA

Interpreting Physician Qualifications - Independent Setting

An independent setting is one where either radiologists or other physicians (typically surgeons) conduct stereotactic breast biopsies using the accredited unit. In an independent setting, the physician's responsibilities include:

- Patient selection (including documentation of correlative clinical breast exams)
- Quality assurance including the medical audit (tracking of the number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications)
- Oversight of all quality control
- Supervision of the radiologic technologist and the medical physicist
- Post-biopsy management of the patient

¹ For training purposes, a qualified physician is one who is qualified to interpret mammography under MQSA and has performed at least 24 stereotactic breast biopsies. A surgeon (or other physician) who is not qualified to interpret mammograms under MQSA may be qualified as instructor/trainer for stereotactic breast biopsy if he/she meets the following criteria:

1. At least 50% of his or her professional time should be devoted to breast practice; consulting/advising patients with breast disease and to performing diagnostic and therapeutic procedures, including reviewing 480 mammograms a year either independently or in consultation with an MQSA-qualified radiologist.
2. Should have taken formal stereotactic training course(s) for at least 24 hours in Category 1 CME, including 4 hours of Category 1 instruction in radiation physics.
3. Should have 2 years experience in stereotactic biopsy, having performed an average of 50 procedures a year.
4. Should maintain records of stereotactic breast biopsy procedures, including complications, pathologic results, and follow-up of patients with either mammography or open biopsy to establish false negative and positive predictive values in his or her practice.
5. Should publish and make related presentations at scientific meetings and be recognized by his or her peers as a teacher.
6. Should continue to meet all other continuing requirements, including:
 - Being responsible for oversight of all quality control and quality assurance, if practicing independently.
 - Being responsible for supervision of the radiologic technologist and medical physicist staff, if practicing independently.
 - Being responsible for post-biopsy management of patient.
 - Performing at least 12 stereotactic breast biopsies per year and obtaining 3 hours of Category I CME every 3 years.

A radiologist practicing in an independent setting is also responsible for:

- Mammographic interpretation
- Documentation of correlative breast examinations
- Referring patients to a surgeon for follow-up on certain lesions

All physicians supervising and conducting stereotactic breast biopsies in an independent setting **must** meet the following minimum criteria:

Interpreting Physician - Independent Setting		
Qualifications	Radiologist*	Other Physician
Initial	Performed 12 stereotactic breast biopsy procedures or 3 hands-on stereotactic breast biopsy procedures under a qualified physician ¹	
	<p style="text-align: center;">AND</p> 3 hours of Category 1 CME in stereotactic breast biopsy <p style="text-align: center;">AND</p> 15 hours of Category 1 CME in breast imaging including pathophysiology of benign and malignant breast disease as well as clinical breast examinations <p style="text-align: center;">AND</p> Qualified as an interpreting physician under MQSA	<p style="text-align: center;">AND</p> 15 hours of Category 1 CME in stereotactic breast biopsy or 3 years experience having performed 36 stereotactic breast biopsies <p style="text-align: center;">AND</p> 4 hours of Category 1 CME in medical radiation physics <p style="text-align: center;">AND</p> Evaluated ² 480 mammograms every 2 years in consultation with MQSA-qualified physician
Continuing Experience	12 stereotactic breast biopsies per year (or requalify according to above initial requirements)	12 stereotactic breast biopsies per year (or requalify according to above initial requirements) <p style="text-align: center;">AND</p> Evaluate 480 mammograms every 2 years in consultation with MQSA-qualified physician
Continuing Education	3 hours of Category 1 CME in stereotactic breast biopsy every 3 years (that includes post-biopsy management of the patient)	3 hours of Category 1 CME in stereotactic breast biopsy every 3 years

*radiologists **must be currently** qualified as an interpreting physician under MQSA

Radiologic Technologist Qualifications

Radiologic technologists working in any setting must be **currently qualified under MQSA** and meet the following minimum criteria:

Qualifications	Radiological Technologist
Initial	Qualified to perform mammography under MQSA <p style="text-align: center;">AND</p> 3 Category A CEUs in stereotactic breast biopsy <p style="text-align: center;">AND</p> Performed 5 stereotactic breast biopsy procedures under supervision of a qualified physician or technologist
Continuing Experience	12 stereotactic breast biopsy exams per year
Continuing Education	3 Category A CEUs in stereotactic breast biopsy every 3 years

² Evaluation means review of the mammographic films in direct consultation with an MQSA-qualified interpreting physician and/or independent review of mammograms with the authenticated mammographic report.

Medical Physicist Qualifications

A medical physicist performing surveys of stereotactic breast biopsy units in any setting must be *currently qualified under MQSA* and meet the following minimum criteria:

Qualifications	Medical Physicist
Initial	Qualified to perform mammography surveys under MQSA AND Performed 1 hands-on stereotactic breast biopsy survey under a qualified medical physicist or at least 3 independent surveys prior to 6/1/97
Continuing Experience	1 stereotactic breast biopsy unit physics survey per year
Continuing Education	3 CEUs in stereotactic breast biopsy every 3 years

Equipment

The ACR only accredits the following types of equipment:

- Specially designed, dedicated stereotactic breast biopsy units
- Mammographic units using a specially designed add-on device for breast biopsy
- Mammographic units exclusively using lateral arm devices, but only if the needle can be seen in relation to the target lesion in two views

Quality Control

Documentation of quality control is required as part of the application process. All facilities applying for accreditation *must comply* with the minimum frequencies listed below. Detailed instructions for each of the tests listed below are contained in the *1999 ACR Stereotactic Breast Biopsy Quality Control Manual*. Upon acceptance of a facility's initial application, the ACR will send a QC manual to the modality's supervising physician at the practice site address.

Annual Medical Physicist Survey

The medical physicist must perform the following QC tests when the equipment is installed and at least annually thereafter:

Annual Medical Physicist's QC	
Test	Description
1. Stereotactic Breast Biopsy Unit Assembly	Ensures that the mechanical components of the system are reliable and safe for patient use
2. Collimation Assessment	Ensures that the x-ray collimation does not allow significant radiation to extend beyond the edges of the image receptor and that the biopsy window aligns with the x-ray field
3. Focal Spot Performance and System Limiting Resolution	Ensures that the focal spot performance is adequate to minimize geometric blur in the image, and that the system-limiting resolution is adequate for the imaging requirements of the procedure
4. kVp Accuracy and Reproducibility	Ensures that the indicated peak x-ray energy is accurate and reproducible, so that consistent contrast may be maintained
5. Beam Quality Assessment (<i>Half-Value Layer Measurement</i>)	Ensures that the x-ray beam is sufficiently penetrating to minimize patient dose, but not so penetrating that contrast is reduced

Annual Medical Physicist's QC	
Test	Description
6. Automatic Exposure Control (AEC) System or Manual Exposure Performance Assessment	Assesses the performance of the system's AEC or manual techniques regarding appropriate film optical density or detector signal levels over a range of breast thicknesses
7. Receptor Speed Uniformity	Ensures that intensifying screens are adequately uniform in speed or that the digital detector is adequately uniform across its entire useful area
8. Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility	Ensures that breast radiation doses are adequately low to protect the patient and sufficient to maintain adequate image quality
9. Image Quality Evaluation	Ensures that image quality is consistently high enough to meet the demands of the procedure
10. Artifact Evaluation	Detects the presence of artifacts, isolates their sources and ensures that they are eliminated or minimized
11. Localization Accuracy Test	Ensures the accuracy of the localization system, including needle position, stereo position calculations and the user interface

Radiologic Technologist Quality Control Tests

The technologist must perform the following QC tests at the specified frequencies:

Radiologic Technologist's QC		
Test	Description	Frequency
1. Localization Accuracy Test	Verifies system alignment and performance (procedure varies by manufacturer and system type)	Daily before patient exams
2. Darkroom Cleanliness <i>(NA if digital used)</i>	Minimizes artifacts on film images by maintaining the cleanest possible conditions in the darkroom	Daily
3. Processor QC <i>(NA if digital used)</i>	Ensures consistent performance of the film processor	Daily
4. Phantom Images	Ensures that film density, contrast, uniformity, and image quality of the x-ray imaging system are optimal	Weekly
5. Screen Cleanliness <i>(NA if digital used)</i>	Ensures that cassettes and screens are free of dust and dirt particles that may degrade image quality or mimic calcifications	Weekly
6. Viewboxes and Viewing Conditions <i>(if film used)</i>	Ensures that the viewboxes and viewing conditions are optimized and maintained at optimal levels	Weekly
7. Hardcopy Output Quality <i>(if hardcopy produced from digital data)</i>	Ensures that the quality of hardcopy output is consistent over time and matches the gray scales presented on the CRT monitor	Monthly
8. Visual Checklist	Ensures that the mammography x-ray system and, if applicable, the digital imaging system are working properly and that the mechanical rigidity and stability of the system are optimal	Monthly
9. Analysis of Fixer Retention in Film <i>(NA if digital used)</i>	Determines the quantity of residual fixer (hypo) in processed film as an indicator of keeping quality	Quarterly

Radiologic Technologist's QC		
Test	Description	Frequency
10. Compression	Ensures that the x-ray imaging system can provide adequate compression in the manual and automatic powered mode	Semiannually
11. Repeat Analysis	Determines the number and causes of repeated patient exposures and identifies ways to improve efficiency, reduce patient breast dose, and cut costs	Semiannually
12. Screen-Film Contact (NA if digital used)	Ensures that optimum contact is maintained between the screen and the film in each cassette	Semiannually
13. Darkroom Fog (NA if digital used)	Ensures that darkroom safelights and other light sources inside and outside of the darkroom do not fog film	Semiannually
14. Zero Alignment Test (if required by manufacturer)	Verifies that zero coordinate is accurate	Before each patient
15. Any additional tests required by manufacturer		As required by manufacturer

Quality Assurance

Outcome Data

Facilities **must** conduct ongoing medical audits of stereotactically guided breast biopsy procedures to evaluate and improve performance. 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 requiring treatment. The ACR will request the following audit data as part of the application process.

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of stereotactic biopsies needing repeat biopsy (open excisional or stereotactic biopsy)
 1. Insufficient sample
 2. Non-concordance with imaging
 3. Ductal atypia, radial scar
 4. Other
- Total number of complications
 1. Hematomas requiring surgical attention
 2. Infections requiring treatment
 3. Other

Exam Identification and Labeling

Images are an important part of the medical record. Each image should be clearly and permanently labeled with the information below. If the required items are absent, the case will fail accreditation.

Examination Identification
<ul style="list-style-type: none"> • Patient's first and last names (<i>required</i>) • Identification number and/or date of birth (<i>required</i>) • Examination date (<i>required</i>) • Facility name and location • Designation of right or left breast • Technologist's identification number or initials

Accreditation Testing

Procedure performance and image quality assessments are the cornerstones of the ACR accreditation program. All clinical and phantom images should be submitted on film or high-quality photographic paper.

Clinical Images

As part of accreditation testing for each stereotactic breast biopsy unit, facilities must submit:

- One calcification biopsy case that demonstrates accurate needle placement
- The case's corresponding mammograms (high quality copies are acceptable)

The calcification(s) must be easily appreciated on *both* the mammograms and on all biopsy images. At least 2 ACR-trained radiologist clinical image reviewers will evaluate the images for accuracy of needle positioning (with respect to the target) and image quality. The ACR Committee on Stereotactic Breast Biopsy Accreditation understands that *all* images obtained during *all* stereotactic breast biopsy procedures may not meet these criteria. However, submitted images should demonstrate that physicians possess the skills necessary for appropriate needle positioning during these procedures. The reviewers *will assume that the cases are examples of the facility's best work*.

Phantom and Dose

Image quality and dose will be evaluated using the same breast phantom used for routine stereotactic breast biopsy QC. The phantom simulates a 4.2 cm compressed breast of average density and has a wax insert containing decreasing sizes of fibers, specks and masses. At least two ACR-trained medical physicist phantom image reviewers will score the image. The ACR evaluation criteria are outlined in the *1999 ACR Stereotactic Breast Biopsy Quality Control Manual*. The minimum scores required to pass accreditation will depend on the type of phantom and image recording system:

Passing Stereotactic Breast Biopsy Phantom Image Scores						
Recording System	ACR Mammography Phantom			Mini Digital Stereotactic Phantom		
	Fibers	Speck Groups	Masses	Fibers	Speck Groups	Masses
Screen-film	4.0	3.0	3.0	2.0	2.0	2.0
Digital	5.0	4.0	3.5	3.0	3.0	2.5

The facility must purchase the phantom directly from the manufacturer. At this time, the ACR has approved the following phantoms for use in the Stereotactic Breast Biopsy Accreditation Program:

Gammex RMI (800) GAMMEX-1 www.gammex.com RMI Model 156	Fluke Biomedical, RMS (800) 850-4608 www.flukebiomedical.com/rms Nuclear Associates Model 18-220 Nuclear Associates Model 18-250	Computerized Imaging Reference Systems, Inc. (800) 617-1177 or (757) 855-2765 www.cirsinc.com CIRS Model 015
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Facility personnel must expose the ACR-supplied dosimeter on the phantom at the same time the accreditation image is produced. The average glandular dose **may not exceed 300 mrad** (3 mGy).

Accreditation Fees

The accreditation fees are as follows:

Cycle	Fees*
Accreditation (<i>Initial cycle and renewal</i>)	\$1400 for the first unit \$1200 for each additional unit at the same geographic location
Repeat	\$625 for one or more categories
Reinstate/Corrective Action Plan	\$1400 for the first unit \$1200 for each additional unit
Additional units (<i>mid-cycle</i>)	\$775 for each unit
Replacement Certificate	\$65 per certificate
Replacement Dosimeter	\$70 per dosimeter

* Fees subject to change without notice

For Additional Information

For further information log on to the ACR Web site at www.acr.org, click on "[Accreditation](#)" and click on "[Stereotactic Breast Biopsy](#)". A link to "[Frequently Asked Questions](#)" is available in the stereotactic breast biopsy menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR Stereotactic Breast Biopsy Accreditation Program office by phone, dial (800) 770-0145.