

Stereotactic Breast Biopsy Accreditation Program Requirements



OVERVIEW	1
MANDATORY ACCREDITATION TIME REQUIREMENTS.....	2
WITHDRAWN, ADDED, OR REPLACEMENT UNITS	2
LOANER UNITS.....	2
PERSONNEL QUALIFICATIONS	2
INTERPRETING PHYSICIAN – COLLABORATIVE SETTING.....	3
INTERPRETING PHYSICIAN – INDEPENDENT SETTING	4
RADIOLOGIC TECHNOLOGIST	5
MEDICAL PHYSICIST	6
EQUIPMENT	6
QUALITY CONTROL	6
ACCEPTANCE TESTING	6
ANNUAL MEDICAL PHYSICIST SURVEY	7
RADIOLOGIC TECHNOLOGIST QUALITY CONTROL TESTS.....	7
PREVENTIVE MAINTENANCE	8
QUALITY ASSURANCE.....	8
OUTCOME DATA	8
ACCREDITATION TESTING.....	9
CLINICAL IMAGES	9
EXAM IDENTIFICATION AND LABELING	9
PHANTOM IMAGES AND DOSE	10
ACCREDITATION FEES.....	10
FOR ADDITIONAL INFORMATION	11
ACR PRACTICE GUIDELINES AND TECHNICAL STANDARDS.....	11
REFERENCES.....	11

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. Facilities must submit clinical images and phantom images with

corresponding data for each x-ray unit used for stereotactic breast biopsies at their site. Although stereotactic breast biopsy is currently exempt from the Food and Drug Administration's (FDA) Mammography Quality Standards Act (MQSA) regulations¹, the program's quality standards are consistent with those of MQSA in order to prepare for possible future regulatory inclusion. This document outlines the requirements a facility must meet in order to apply for stereotactic breast biopsy accreditation.

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Withdrawn, Added, or Replacement Units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 Consequently, facilities must notify the ACR if they have permanently withdrawn (i.e., removed) a unit from biopsy service, if they have replaced that unit with a new one or have added another unit for biopsies.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.

Loaner Units

Accredited facilities may use a “loaner” stereotactic breast biopsy unit to temporarily replace an accredited unit that is out of service for repairs, etc., for up to 6 months without submitting images for evaluation. The accredited facility must immediately notify the ACR of the installation date, manufacturer, and model of the loaner. Any loaner unit that is in use for more than 1 month will be required to submit evidence of testing by a qualified medical physicist within 90 days of installation. If the loaner is in place for longer than 6 months, the facility must submit an application to accredit the unit.

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 physician depend on the setting in which he or she 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 from the FDA Policy Guidance Help System².

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, 2007 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 – Collaborative Setting

A collaborative setting is one where both radiologists and surgeons (or other physicians) conduct stereotactic breast biopsy procedures using the accredited unit. The physicians should be present at the appropriate time during the procedure. 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

Radiologists must be currently qualified as interpreting physicians under MQSA. 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	24 stereotactic breast biopsies in the prior 24 months	
Continuing Education	3 hours of Category 1 CME in stereotactic breast biopsy (includes related topics such as lesion targeting, imaging-pathology correlation, general needle biopsy information and techniques, or lesion-target assessment) in the prior 36 months	3 hours of Category 1 CME in stereotactic breast biopsy

Interpreting Physician – 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

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

- Mammographic interpretation
- Documentation of correlative breast examinations

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 physician who is not qualified to interpret mammograms under MQSA may be qualified as instructor/trainer for stereotactic breast biopsy by meeting 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, performing diagnostic and therapeutic procedures (including reviewing 480 mammograms a year either independently or in consultation with an MQSA-qualified radiologist).
2. 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. Have 2 years experience in stereotactic biopsy, having performed an average of 50 procedures a year.
4. Maintains 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. Publishes and makes related presentations at scientific meetings; recognized by his or her peers as a teacher.
6. Continues 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.

- Referring patients to a surgeon for follow-up on certain lesions

Radiologists must be currently qualified as interpreting physicians under MQSA. 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 AND 3 hours of Category 1 CME in stereotactic breast biopsy AND 15 hours of Category 1 CME in breast imaging including pathophysiology of benign and malignant disease as well as clinical breast examinations AND Qualified as an interpreting physician under MQSA	AND 15 hours of Category 1 CME in stereotactic breast imaging and biopsy or 3 years experience having performed at least 36 stereotactic breast biopsies AND 4 hours of Category 1 CME in medical radiation physics AND Evaluated ² 480 mammograms every 2 years in consultation with MQSA-qualified physician
Continuing Experience	24 stereotactic breast biopsies in the prior 24 months	24 stereotactic breast biopsies in the prior 24 months AND Evaluate 480 mammograms in the prior 24 months in consultation with MQSA-qualified physician
Continuing Education	3 hours of Category 1 CME in stereotactic breast biopsy (includes related topics such as post-biopsy management of the patient, lesion targeting, imaging-pathology correlation, general needle biopsy information and techniques, or lesion-target assessment) in the prior 36 months	3 hours of Category 1 CME in stereotactic breast biopsy in the prior 36 months

Radiologic Technologist

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 AND 3 Category A CEUs in stereotactic breast biopsy AND Performed 5 stereotactic breast biopsy procedures under supervision of a qualified physician or technologist
Continuing Experience	24 stereotactic breast biopsy exams in the prior 24 months

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.

Qualifications	Radiological Technologist
Continuing Education	<ul style="list-style-type: none"> • Registered technologists <ul style="list-style-type: none"> - In compliance with the CE requirements of their certifying organization for the imaging modality in which they perform services - CE includes credits pertinent to the technologist's ACR accredited clinical practice • State licensed technologists <ul style="list-style-type: none"> - 24 hours of CE every 2 years - CE is relevant to imaging and the radiologic sciences, patient care - CE includes credits pertinent to the technologist's ACR accredited clinical practice • All others <ul style="list-style-type: none"> - 24 hours of CE every 2 years - CE is relevant to imaging and the radiologic sciences, patient care - CE includes credits pertinent to the technologist's ACR accredited clinical practice

Medical Physicist

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 physics survey under a qualified medical physicist or at least 3 independent surveys prior to 6/1/97
Continuing Experience	2 stereotactic breast biopsy physics surveys over a 24-month period
Continuing Education	3 CEUs in stereotactic breast biopsy every 3 years

Equipment

The ACR accredits only 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.

Acceptance Testing

Initial performance testing should be performed upon installation of new stereotactic breast biopsy equipment. This testing should be more comprehensive than periodic performance and compliance testing and should be consistent with current acceptance testing practices.

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 System Performance Evaluation	
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 Spatial 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
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		
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

Radiologic Technologist's QC		
5. Screen Cleanliness (NA if digital used)	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 (if film used)	Ensures that the viewboxes and viewing conditions are optimized and maintained at optimal levels	Weekly
7. Hardcopy Output Quality (if hardcopy produced from digital data)	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 (NA if digital used)	Determines the quantity of residual fixer (hypo) in processed film as an indicator of keeping quality	Quarterly
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

Preventive Maintenance

Preventive maintenance should be scheduled, performed, and documented by a qualified service engineer on a regular basis. Service performed to correct system deficiencies should also be documented and service records maintained by the facility.

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)
 - Insufficient sample
 - Non-concordance with imaging
 - Ductal atypia, radial scar
 - Other
- Total number of complications
 - Hematomas requiring surgical attention
 - Infections requiring treatment
 - Other

Accreditation Testing

Procedure performance and image quality assessments are the cornerstones of the ACR accreditation program. At this time, all clinical and phantom images must 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. The submitted images should demonstrate that physicians possess the skills necessary for appropriate needle positioning during these procedures.

Facilities should select cases that represent their best work. The ACR Committee on Stereotactic Breast Biopsy Accreditation understands that all images obtained during all procedures may not meet these criteria. Consequently, the ACR allows sufficient time to select cases that are examples of "best work." ACR reviewers will evaluate them accordingly. The cases must meet the following criteria:

- Select stereotactic breast biopsy cases no older than 2 months from the date you return the testing materials.
- All images of a case must be from the same patient.
- The lead interpreting physician must review and approve the clinical 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.

Exam Identification and Labeling

Images are an important part of the medical record. One of the requirements for clinical images is correct labeling to include patient identification. The ACR understands that as providers, facilities are subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and that is why the ACR executes a HIPAA business associate agreement (BAA) with facilities. This agreement allows the collection of patient information in the performance of ACR accreditation activities which are specifically mentioned in the HIPAA regulations. If the facility has a BAA with ACR, they are covered under HIPAA. If not, contact the ACR to obtain an agreement for signature.

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 (required) • Identification number and/or date of birth (required) • Examination date (required) • Facility name and location • Designation of right or left breast • Technologist's identification number or initials

Phantom Images and Dose

Image quality and dose will be evaluated using the same breast phantom used for routine stereotactic breast biopsy QC. Facilities may use either an ACR-approved Mammography Phantom or a Mini Digital Stereotactic Phantom that simulates a 4.2 cm compressed breast of average density and has a wax insert containing decreasing sizes of fibers, specks and masses. The facility must purchase a phantom directly from the manufacturer. The following phantoms have been approved by the ACR for use in the Stereotactic Breast Biopsy Accreditation Program:

	Computerized Imaging Reference Systems, Inc.	Gammex, Inc.	Fluke Biomedical, RMS
Model #	CIRS Model 015	Gammex Model 156 Gammex Model 156D	Nuclear Associates Model 18-220 Nuclear Associates Model 18-250
Phone #	(800) 617-1177 or (757) 855-2765	(800) GAMMEX-1	(800) 850-4608
Website	www.cirsinc.com	www.gammex.com	www.flukebiomedical.com/rms

At least 2 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 Manual³. The minimum scores required to pass accreditation will depend on the type of phantom and image recording system:

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

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

Facilities must submit the appropriate fee with their application. All fees are non-refundable and subject to change without notice.

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

For Additional Information

For further information about the [ACR Stereotactic Breast Biopsy Accreditation Program](#), downloadable [accreditation program forms](#) and [Frequently Asked Questions](#), log on to the ACR web site at www.acr.org, click on “Accreditation” then click on “Stereotactic Breast Biopsy”. Also, check out the ACR's [Breast Imaging Resources](#) page at www.acr.org/Breast-Imaging for the latest information about the ACR's breast imaging accreditation programs (including the [Breast Imaging Centers of Excellence](#) initiative) as well as breast imaging information in general. To contact the ACR Stereotactic Breast Biopsy Accreditation Program office by phone, dial (800) 770-0145.

ACR Practice Guidelines and Technical Standards

The following ACR Practice Guidelines and Technical Standards are pertinent to achieving and maintaining Stereotactic Breast Biopsy Accreditation. These guidelines and standards form the basis of the accreditation program.

1. [ACR Practice Guideline for the Performance of Stereotactically Guided Breast Interventional Procedures](#)
2. [ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#)
3. [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#)
4. [ACR Position Statement: Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns](#)

References

1. Food and Drug Administration. Mammography Quality Standards; Final Rule. Available at: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110906.htm>
2. Food and Drug Administration. Mammography Policy Guidance Help System. Available at: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm>

3. Hendrick RE, Dershaw DD, Kimme-Smith C, et al. Stereotactic Breast Biopsy Quality Control Manual. Reston, Va: American College of Radiology; 1999.
4. D'Orsi CJ, Bassett LW, Berg WA, et al: Breast Imaging Reporting and Data System: ACR BI-RADS-Mammography (ed 4), Reston, VA, American College of Radiology, 2003.