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. 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) regulations[1], 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Withdrawn, Added, or Replacement Units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 Consequently, facilities must notify the ACR if they have permanently withdrawn (i.e., removed) a unit from biopsy service, if they have replaced that unit with a new one or have added another unit for biopsies.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 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 System[2].

The continuing education and continuing experience requirements are based on previous full calendar years. For example, if a site renews their accreditation in July 2011, the physicians at that site must have met the full requirement for continuing education from January 1, 2008 to December 31, 2010. Likewise, they must have met the full continuing experience requirements from January 1, 2008 to December 31, 2010. If they did not meet these requirements in the given timeframes, the ACR will accept continuing education credits or continuing experience obtained in 2011.

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 or immediately available through PACS to review images 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]	
	AND 3 hours of Category 1 CME in stereotactic breast biopsy **AND** Experienced in recommendations for biopsy and lesion identification at time of biopsy **AND** Qualified as an interpreting physician under MQSA	**AND** 3 hours of Category 1 CME in stereotactic breast biopsy (that includes image triangulation for lesion location) **AND** Experienced in post-biopsy patient management
Continuing Experience	Upon renewal, ***36 image-guided breast biopsies*** in the prior ***36 months***; at least ***9*** of these must be ***stereotactic breast biopsies***	
Continuing Education	Upon renewal, must meet one of the following: 1. Currently meets the Maintenance of Certification (MOC) requirements for the ABR (See ABR MOC) **OR** 2. Completes 150 hours (that includes 75 hours of Category 1 CME) in the prior 36 months pertinent to the physician's practice patterns (See ACR Guideline) **OR** 3. Completes 15 hours CME (half of which must be Category 1) in the prior 36 months specific to the imaging modality or organ system	

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

[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.
   - Meet the above continuing experience and continuing education requirements.

- Post-biopsy management of the patient

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

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	Upon renewal, ***36 image-guided breast biopsies*** in the prior ***36 months***; at least ***9*** of these must be ***stereotactic breast biopsies***	Upon renewal, ***36 image-guided breast biopsies*** in the prior ***36 months***; at least ***9*** of these must be ***stereotactic breast biopsies*** **AND** Evaluate 720 mammograms in the prior 36 months in consultation with MQSA-qualified physician
Continuing Education	Upon renewal, must meet one of the following: 1. Currently meets the Maintenance of Certification (MOC) requirements for the ABR (See ABR MOC) **OR** 2. Completes 150 hours (that includes 75 hours of Category 1 CME) in the prior 36 months pertinent to the physician's practice patterns (See ACR Guideline) **OR** 3. Completes 15 hours CME (half of which must be Category 1) in the prior 36 months specific to the imaging modality or organ system	

Radiologic Technologist

All technologists working in any setting performing stereotactic breast biopsy ***must*** be currently qualified under MQSA and meet the minimum criteria in the table below. The ACR ***recommends*** that technologists be certified and actively registered in the modality they perform.

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
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	Upon renewal, ***24 stereotactic breast biopsy exams*** in the prior ***24 months***
Continuing Education	• Registered technologists – 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 – 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 – 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	Upon renewal, ***2 stereotactic breast biopsy unit surveys*** in the prior ***24 months***
Continuing Education	Upon renewal, ***3 CEUs*** in stereotactic breast biopsy in the prior ***36 months***

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 lateral arm device is the only option for biopsy and the needle can be seen in relation to the target calcification 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 QC tests listed in the table below when the equipment is installed and at least annually thereafter. The ACR realizes that surveys cannot usually be scheduled exactly on the anniversary date of the previous survey. Therefore a period of up to 14 months between surveys is acceptable. The medical physicist must provide a written report of findings of acceptance testing and performance evaluations to the responsible physician(s) and to the professional(s) responsible for service of the equipment. If appropriate, the medical physicist should inform the site supervisor of the required service. Written reports must be provided in a timely manner consistent with the importance of any adverse findings. If use of the equipment poses imminent danger to patients or staff, the medical physicist must take immediate action to preclude use of the equipment.

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 *(Half-Value Layer Measurement)*	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

A QC program must be implemented for all units and should be established with the assistance of a medical physicist. The radiologic technologist must perform the QC tests listed in the table below at the specified minimum frequencies. The medical physicist should identify the person responsible for performing the tests and may choose to increase the frequency of testing based on the facility and usage. If any QC parameter being monitored falls outside of the control limits, corrective action should be taken. A medical physicist should be available to assist in prescribing corrective actions for unresolved problems.

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 *(NA if digital used)*	Minimizes artifacts on film images by maintaining the cleanest possible conditions in the darkroom	Daily
3. Processor QC *(NA if digital used)*	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 *(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. Additional tests (if 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, categorized by reason and type of biopsy:

Reason for Repeat Biopsy	Data
Insufficient sample	• total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision • final pathology results
Discordance	• total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision • final pathology results
Cellular atypia, radial scar	• total # cellular atypia cases • total # radial scar cases (CNB only) • # with repeat biopsy performed by core • # with repeat biopsy performed by excision • final pathology results
Other	• total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision • final pathology results

- Complications requiring treatment categorized by type of biopsy (i.e., CNB, FNAC)
  1. Total number
  2. Number with hematoma (requiring intervention)
  3. Number with infections requiring treatment
  4. Number of other complications

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 BI-RADS® Category 4 or 5 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 6 months from the date on the Testing Memorandum.
- 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
• Patient's first and last names ***(required)***
• Identification number and/or date of birth ***(required)***
• Examination date ***(required)***
• Facility name ***(required)***
• Facility location (city, state and zip)
• Designation of left or right breast ***(required)***
• Annotation of mammographic view (e.g., CC, MLO/ML/LM)
• 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 Manual[3]. 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
Digital	5.0	4.0	3.5	3.0	3.0	2.5
Screen-Film	4.0	3.0	3.0	2.0	2.0	2.0

Facility personnel must expose the ACR-supplied dosimeter at the same time the phantom 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 *(Initial cycle and renewal)*	**$1,700** for the first unit **$1,500** for each additional unit at the same geographic location
Repeat	**$925** for one or more categories
Reinstate/Corrective Action Plan	**$1,700** for the first unit **$1,500** for each additional unit
Additional units *(mid-cycle)*	**$1,300** for each unit
Replacement Certificate	**$50** 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) 227-6440 or email stereo-accred@acr.org.

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.