

Breast Ultrasound Accreditation Program Requirements



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Overview

The American College of Radiology’s Breast Ultrasound Accreditation Program provides facilities performing breast ultrasound and ultrasound-guided breast biopsies peer review and constructive feedback on their staff’s qualifications, equipment, quality control (QC), quality assurance (QA), accuracy of needle placement and image quality. The Breast Ultrasound Accreditation Program can accommodate a variety of practice settings. A facility that performs only breast ultrasound should apply for [breast ultrasound accreditation](#); a facility that performs both breast ultrasound and ultrasound-guided breast biopsies must also apply for the [Ultrasound-Guided Breast Biopsy Module](#). This document outlines the requirements a facility must meet in order to apply for breast ultrasound accreditation.

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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.

Personnel Qualifications

All interpreting physicians and technologists working in breast ultrasound (including part-time and locum tenens staff) must **meet and document** specific requirements in order for their facility to be accredited by the ACR. If the interpreting physicians and technologists are working in mammography they must also meet the Mammography Quality Standards Act (MQSA) qualifications.

The continuing education and continuing experience requirements are based on previous full calendar years. For example, if a site applies for 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

The physician performing or interpreting breast ultrasound exams or biopsies must:

- Be licensed medical practitioners
- Have a thorough understanding of the indications for breast ultrasound examinations
- Be familiar with the basic physical principles and limitations of the technology of ultrasound imaging
- Be familiar with alternative and complementary imaging and diagnostic procedures
- Be capable of correlating the results of mammographic and other procedures with the sonographic findings
- Have a thorough understanding of ultrasound technology and instrumentation, ultrasound power output, equipment calibration, and safety
- Be able to demonstrate familiarity with breast anatomy, physiology, and pathology
- Be familiar with interpretation and documentation in accordance with the *ACR Practice Guideline for Communication of Diagnostic Imaging Findings*

In addition, all physicians supervising, performing, and/or interpreting breast ultrasound examinations at facilities accredited by the ACR in breast ultrasound **must** meet the following **minimum** criteria:

Interpreting Physician - Breast Ultrasound		
Qualifications	Radiologist	Other Physician
Initial	<p align="center"><u>Board Certified</u></p> <ul style="list-style-type: none"> • Certification in Radiology or Diagnostic Radiology by the <ul style="list-style-type: none"> – American Board of Radiology, or – American Osteopathic Board of Radiology, or – Royal College of Physicians and Surgeons of Canada, or – Le College des Medecins du Quebec <p align="center"><u>Not Board Certified</u></p> <ul style="list-style-type: none"> • Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved diagnostic radiology residency program, and • Oversight and/or performance, interpretation, and reporting of 300 breast ultrasound examinations in the last 36 months¹ 	<ul style="list-style-type: none"> • Completion of an ACGME approved residency program in specialty practice, and • 200 hours of Category I CME in breast ultrasound, and • Performance, interpretation, and reporting of 500 breast ultrasound examinations in the last 36 months in a supervised situation
Continuing Experience	<p>Upon renewal, 200 breast ultrasound examinations in the prior 36 months (recommended)</p> <p align="center">OR</p> <p>Monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation and appropriateness of evaluation</p>	
Continuing Education	<p>Upon renewal, must meet one of the following:</p> <ol style="list-style-type: none"> 1. Currently meets the Maintenance of Certification (MOC) requirements for the ABR (See ABR MOC) <p align="center">OR</p> <ol style="list-style-type: none"> 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) <p align="center">OR</p> <ol style="list-style-type: none"> 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 	

All physicians performing and supervising *ultrasound-guided biopsies* must *also* meet the ultrasound-guided breast biopsy *minimum* criteria:

Interpreting Physician - Ultrasound-Guided Breast Biopsy		
Qualifications	Radiologist	Other Physician
Initial	<ul style="list-style-type: none"> • Qualified to interpret mammograms under MQSA 	<ul style="list-style-type: none"> • Review the mammographic findings with a MQSA-qualified physician AND • Perform 3 ultrasound-guided breast biopsy procedures under the supervision of a qualified physician, or • Complete a residency or fellowship that includes instruction in ultrasound-guided breast needle procedures AND • Have 3 hours of Category 1 CME didactic instruction in ultrasound-guided breast biopsy
Continuing Experience	<p>Upon renewal, 36 image-guided breast biopsies in the prior 36 months</p>	

Sonographer/Technologist

All sonographers or technologists performing breast ultrasound examinations **must** meet the minimum criteria in the table below. The ACR **recommends** that technologists be certified and actively registered in the modality they perform.

Qualifications	Sonographer or Technologist - Breast Ultrasound
Initial	<ul style="list-style-type: none"> • Registered by the <ul style="list-style-type: none"> – American Registry of Diagnostic Medical Sonographers as a Registered Diagnostic Medical Sonographer (RDMS), or – American Registry of Radiologic Technologists (ARRT) with post-primary certification and current registration in breast sonography, or – ARRT (or unrestricted state license) and meets MQSA requirements for mammography technologists <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • 5 CEUs specific to breast ultrasound
Continuing Experience	<ul style="list-style-type: none"> • Regular performance of breast ultrasound exams
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

The physician is not required to be present during breast ultrasound examinations performed by RDMS sonographers or ARRT technologists with certification in breast sonography. However, the **physician must be in the department during breast ultrasound examinations performed by ARRT technologists without an advanced registry in breast sonography**. In all situations, the physician is ultimately responsible to see that the appropriate images are obtained.

Equipment

Breast ultrasound procedures must be performed with:

- High-resolution, real-time, linear array scanners
- Transducers operating at a center frequency of at least 10 MHz (and preferably higher)
- Equipment capable of electronic focal zone(s) adjustment

In general, the highest frequency capable of adequate penetration to the depth of interest should be used. A stand-off device may be helpful for the evaluation of superficial lesions. Other transducers may be utilized in special circumstances.

Quality Control

The following routine QC should be performed on all ultrasound units used for breast imaging as recommended in the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment:

Recommended Quality Control for Breast Ultrasound		
Test	Frequency	Performed By
Maximum depth of visualization and hardcopy recording with a tissue-mimicking phantom	Semiannually	Service engineer/medical physicist
Vertical and horizontal distance accuracy	Semiannually	Service engineer/medical physicist
Uniformity	Semiannually	Service engineer/medical physicist
Electrical-mechanical cleanliness condition	Semiannually	Service engineer/medical physicist
Anechoic void perception	Semiannually	Service engineer/medical physicist
Ring down	Semiannually	Service engineer/medical physicist
Lateral resolution	Semiannually	Service engineer/medical physicist
Quality control checklist	Semiannually	Service engineer/medical physicist
Adherence to universal infection control procedures	After each biopsy	Technologist
Clean transducers	After each patient	Technologist
Vertical and horizontal distance accuracy	Quarterly	Technologist
Grey-scale photography	Quarterly	Technologist

As part of accreditation, facilities must submit a copy of the service engineer's most recent preventive maintenance report or the medical physicist's most recent equipment survey. Although the ACR will not initially use this information to determine whether a facility passes or fails accreditation, it may be used in the future to set criteria.

Quality Assurance

Physician Peer-Review Requirements

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Complications and adverse events or other activities that have the potential to become sentinel events must be monitored, analyzed and reported as required, and periodically reviewed in order to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.

All sites initially applying for ACR accreditation and all sites renewing their accreditation must actively participate in a physician peer review program that performs the following functions:

- Includes a double reading (2 MDs interpreting the same study) assessment
- Allows for random selection of studies to be reviewed on a regularly scheduled basis
- Exams and procedures representative of the actual clinical practice of each physician

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- Reviewer assessment of the agreement of the original report with subsequent review (or with surgical or pathological findings)
- A classification of peer-review findings with regard to level of quality concerns (one example is a 4-point scoring scale)
- Policies and procedures for action to be taken on significant discrepant peer-review findings for the purpose of achieving quality outcomes improvement
- Summary statistics and comparisons generated for each physician by imaging modality
- Summary data for each facility/practice by modality

There are several options available to meet this requirement. Sites may develop their own peer-review program, use a vendor product or use [RADPEER™](#) (a peer-review process developed by the ACR). For information about [RADPEER™](#) or [eRADPEER™](#), visit the ACR web site at www.acr.org/SecondaryMainMenuCategories/quality_safety/radpeer.aspx.

The ***Ultrasound-Guided Breast Biopsy Module is exempt*** from this requirement because outcomes are monitored as part of accreditation and physician peer review applies only to review of image interpretation.

Outcome Data – Ultrasound-Guided Breast Biopsy Accreditation Module Only

Each facility applying for the Ultrasound-Guided Breast Biopsy Module must submit outcome data. Although the ACR does not currently use this information as pass/fail criteria, it may be used in the future to help set criteria. The minimum data elements to be collected are:

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of ultrasound-guided biopsies needing repeat biopsy, categorized by reason and type of biopsy (i.e., CNB, FNAC):

Reason for Repeat Biopsy	Data
Insufficient sample	<ul style="list-style-type: none"> • total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision
Discordance with imaging	<ul style="list-style-type: none"> • total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision
Cellular atypia, radial scar	<ul style="list-style-type: none"> • total # cellular atypia cases • total # radial scar cases (CNB only) • # with repeat biopsy performed by core • # with repeat biopsy performed by excision
Other	<ul style="list-style-type: none"> • total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision

- Complications categorized by type of biopsy (i.e., CNB, FNAC)
 1. Total number
 2. Number with hematoma (requiring intervention)
 3. Number with infection
 4. Number with pneumothorax (CNB only)

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The ACR strongly recommends that the biopsy report include a statement referring to the pathology results, imaging/pathologic concordance, and follow-up recommendations based on pathology results. The ACR will review a facility’s biopsy reports as part of a validation site visit.

Reporting

The interpreting physician must prepare a concise written report that includes the name of the patient, an additional patient identifier, the date of the examination and the name of the interpreting physician organized according to the following structure¹:

- Clinical history
- Comparison with previous studies, if available and pertinent
- Statement of scope of examination (targeted or survey) and technique used
- Analysis of the significant lesion(s) or finding(s)
- Correlation with physical, mammographic or MRI finding(s)
- Overall assessment
- Management recommendations

The ACR strongly recommends that the final assessment be categorized into one of the *Breast Imaging Reporting and Data System (BI-RADS®)*¹ breast ultrasound final assessment categories:

BI-RADS® Category	Overall Final Assessment
1	Negative
2	Benign Finding(s)
3	Probably Benign Finding – Short-Interval Follow-Up Suggested
4	Suspicious Abnormality – Biopsy Should Be Considered
5	Highly Suggestive of Malignancy – Appropriate Action Should Be Taken
6	Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken

In cases where no final assessment can be assigned due to incomplete work-up, the ACR recommends that BI-RADS® Category 0 (Assessment is Incomplete: Need Additional Imaging Evaluation) be used and reasons why no assessments can be made provided.

This written report, signed by the interpreting physician, must be provided to the patient’s health care provider within 30 days of the examination date. If the assessment is “suspicious abnormality” or “highly suggestive of malignancy” reasonable attempts must be made to communicate this to the health care provider (or designee) as soon as possible. The ACR recommends that this communication be no more than 3 business days.

Accreditation Testing

Procedure performance and image quality assessments are the cornerstones of the ACR accreditation program. At this time, all clinical images *must* be submitted on film or high-quality photographic paper. Mammograms must be printed either “true size” (i.e., without magnification or minification) or with a scale.

Clinical Images

Image quality and procedure performance assessments are the cornerstones of ACR accreditation programs. Facilities must apply for accreditation for all services provided. For example, if no biopsies are conducted, the facility should only apply for accreditation in breast ultrasound. If both core-needle biopsies (CNB) and fine needle aspiration cytology (FNAC) of solid masses are performed, the facility must also apply for the Ultrasound-Guided Breast Biopsy Module and submit both types of cases. (For accreditation purposes, FNAC is the sampling for cytology of a **solid breast** mass. **Do not submit needle aspirations of cysts or axillary lymph nodes for FNAC.**)

Required Examinations	
Breast Ultrasound Module	Ultrasound-Guided Biopsy Module
<ul style="list-style-type: none"> • Simple cyst, and • Solid mass 	<ul style="list-style-type: none"> • Core needle biopsy, and/or • Fine needle aspiration cytology

Facilities should select cases that are examples of their best work. The ACR Committee on Breast Ultrasound Accreditation understands that all images obtained during all ultrasound examinations or ultrasound-guided breast biopsy procedures may not meet these criteria. Consequently, sufficient time is allowed to select cases that are examples of “best work.” ACR reviewers will evaluate them accordingly.

For all submissions, the cyst or mass being evaluated **must be well visualized and clearly circled on both mammographic views.** (Do not use a radiopaque marker.) If the cyst or mass is not circled, the facility will fail accreditation because the ACR reviewers will not be able to determine if the intended cyst or mass was imaged. Circling more than one will also result in accreditation failure because the ACR reviewers may be uncertain which cyst or mass is being evaluated or biopsied. Evaluation of the quality of the mammogram is not part of the assessment.

Clinical Images - Breast Ultrasound Accreditation

As part of accreditation testing for breast ultrasound, facilities **must** submit the following images:

Breast Ultrasound Accreditation (both cases required)	
Simple Cyst	Solid Mass
1. 2 orthogonal mammographic views with a single cyst circled and visible on both	1. 2 orthogonal mammographic views with a single mass circled and visible on both
2. 2 orthogonal views (e.g., 1 transverse, 1 sagittal) with no calipers visible on the cyst	2. 2 orthogonal views (e.g., 1 transverse, 1 sagittal) with no calipers visible on the mass
3. 1 image with appropriate caliper measurements	3. 1 image with appropriate caliper measurements

The cyst must meet the BI-RADS® criteria for a simple cyst: a) anechoic, b) circumscribed margin, and c) posterior enhancement. Do not submit images using methods such as compound imaging which may diminish posterior enhancement.

Clinical Images - Ultrasound-Guided Breast Biopsy Accreditation Module

Images submitted for the ultrasound-guided breast biopsy module should demonstrate that physicians performing these procedures possess the skill necessary for appropriate needle positioning. Facilities **must** include the following images for each type of case submitted for accreditation review:

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Core Needle Biopsy <i>(one of either case)</i>	
Devices Used in Fire Mode	Devices Used in Non-Fire Mode <i>(i.e., manually advanced)</i>
1. 2 orthogonal mammographic views with a single solid mass circled and visible on both views	1. 2 orthogonal mammographic views with a single solid mass circled and visible on both views
2. Pre-biopsy sonogram showing solid mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)	2. Pre-biopsy sonogram showing solid mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)
3. Pre-fire sonogram showing needle in the long axis	3. Post-biopsy sonogram showing the long axis of the needle in tissue acquiring position, either under or through the mass
4. Post-biopsy (post-fire) sonogram showing needle in the long axis	

and/or

Fine Needle Aspiration Cytology <i>(only submit solid masses; do NOT submit axillary lymph nodes or cyst aspirations)</i>
1. 2 orthogonal mammographic views with a single solid mass (marked and visible on both views)
2. Pre-biopsy sonogram showing solid mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)
3. Post-biopsy sonogram showing the needle clearly within the solid mass in the long axis

For **all biopsies**, only select BI-RADS® Category 4 or 5 cases to submit for accreditation review.

For **all biopsies**, the position of the needle relative to the solid mass must be easily appreciated on the pre-biopsy sonogram and on the images obtained during the biopsy.

For **devices used in fire mode** (i.e., fired into tissue sampling position) for core needle biopsies, the pre-fire sonogram must demonstrate the needle aiming towards the mass just prior to insertion. The position of the needle should be in the long axis and approximately parallel to the chest wall.

For **devices used in non-fire mode** (i.e., manually advanced into biopsy position) for core needle biopsies, the post-biopsy sonogram must demonstrate the long axis of the needle in tissue acquiring position, either under or through the mass.

For **fine needle aspiration cytology**, the biopsy sonogram must demonstrate the needle position clearly within the mass in the long axis.

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 sonogram 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 (required) • Facility location • Designation of right or left breast (required) • Anatomic location using clock face notation or labeled diagram of the breast (required) • Transducer orientation • Distance from the nipple to the abnormality (required) • Sonographer's and/or physician's identification number, initials, or other symbol

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)	\$1,000 for breast ultrasound \$1,200 for breast ultrasound with biopsy
Repeat	\$500 for one or both modules
Reinstate/Corrective Action Plan	\$1,000 for breast ultrasound \$1,200 for breast ultrasound with biopsy
Replacement Certificate	\$50 per certificate

For Additional Information

For further information about the ACR Breast Ultrasound 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 "Breast Ultrasound". Also, check out the ACR's [Breast Imaging Resources](http://www.acr.org/Breast-Imaging) 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](http://www.acr.org/Breast-Imaging-Centers-of-Excellence)) as well as breast imaging information in general. To contact the ACR Breast Ultrasound Accreditation Program office by phone, dial (800) 227-6440 or email breastultrasound-accred@acr.org.

ACR Practice Guidelines and Technical Standards

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

1. [ACR Practice Guideline for the Performance of a Breast Ultrasound Examination](#)
2. [ACR Practice Guidelines for the Performance of Ultrasound Guided Percutaneous Breast Interventional Procedures](#)
3. [ACR Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations](#)

4. [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#)
5. [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#)
6. [ACR Practice Guideline for Continuing Medical Education](#)
7. [ACR Technical Standard for Electronic Practice of Medical Imaging](#)
8. [ACR Position Statement: Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns](#)

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