

# Breast Ultrasound Accreditation Program Requirements



## Overview

The 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, quality assurance, 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.

## 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 **at the time of application** 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 2009, the physicians 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

All physicians who supervise, perform, and/or interpret **breast ultrasound** examinations at facilities accredited by the ACR in breast ultrasound must:

- Be licensed medical practitioners
- Have a thorough understanding of the indications for breast ultrasound examinations

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- 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, they *must* meet the following *minimum* criteria:

| Qualifications               | Interpreting Physician - Breast Ultrasound   |
|------------------------------|--|
| <b>Initial</b>               | <p><b>Certification</b> in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada or Le College des Medecins du Quebec, <b>and</b><br/>           Involvement with the supervision and/or performance, interpretation, and reporting of <b>300 breast ultrasound examinations</b> within the last 36 months<sup>1</sup></p> <p style="text-align: center;"><b>OR</b></p> <p>Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved diagnostic radiology residency program <b>and</b><br/>           Involvement with the supervision and/or performance, interpretation, and reporting of <b>300 breast ultrasound examinations</b> in the past 36 months<sup>1</sup></p> <p style="text-align: center;"><b>OR</b></p> <p>Completion of an ACGME approved residency program in specialty practice plus <b>200 hours of Category I CME in breast ultrasound, and</b><br/>           Supervision and/or performance, interpretation, and reporting of <b>500 breast ultrasound examinations</b> during the past 36 months in a supervised situation</p> |
| <b>Continuing Experience</b> | <p><b>100 breast ultrasound examinations</b> per year (<b>recommended</b>)</p> <p style="text-align: center;"><b>OR</b></p> <p>Monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation and appropriateness of evaluation</p>   |
| <b>Continuing Education</b>  | <p>Should be in accordance with the <a href="#">ACR Practice Guideline for Continuing Medical Education</a> (CME) and should include CME in ultrasonography, as appropriate to the physician's practice needs (<b>recommended</b>)</p>   |

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

<sup>1</sup> Completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience or the performance, reporting, and interpreting requirement.

| Qualifications        | Interpreting Physician – Ultrasound-Guided Breast Biopsy   |
|-----------------------|--|
| Initial               | Be qualified to interpret mammograms under MQSA, <b>or</b><br>Review the mammographic findings with a MQSA-qualified physician<br><b>AND</b><br>Perform <b>3 ultrasound-guided breast biopsy procedures</b> under the supervision of a qualified physician, <b>or</b><br>Complete a residency or fellowship that includes instruction in ultrasound-guided breast needle procedures<br><b>AND</b><br>Have <b>3 hours of Category 1 CME</b> didactic instruction in ultrasound-guided breast biopsy |
| Continuing Experience | 12 ultrasound-guided breast biopsies per year  |
| Continuing Education  | 3 hours of Category 1 CME in ultrasound-guided breast biopsy every 3 years   |

### Sonographer/Mammography Technologist Qualifications

All sonographers or mammography technologists performing breast ultrasound examinations are required to meet the following minimum criteria. This includes technologists assisting physicians with ultrasound-guided breast biopsy procedures:

| Qualifications        | Sonographer or Mammography Technologist - Breast Ultrasound   |
|-----------------------|---|
| Initial               | ARDMS certification and current registration, <b>or</b><br>ARRT post-primary certification and current registration in breast sonography, <b>or</b><br>ARRT certification and current registration (or unrestricted state license) <b>and</b> MQSA qualified<br><b>AND</b><br><b>5 CEUs</b> specific to breast ultrasound |
| Continuing Experience | Regular performance of breast ultrasound exams  |

The physician is not required to be present during breast ultrasound examinations performed by ARDMS 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 on appropriately equipped ultrasound units:

- High-resolution, real-time, linear arrays
- Operating at a center frequency of at least 10 MHz and preferably higher
- 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 is recommended for all ultrasound units used for breast imaging<sup>1,2</sup>:

| 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 activities that may have the potential for 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.<sup>3</sup>

<sup>1</sup> Goodsitt MM, Carson PL, Witt S, et al. Real-time B-mode ultrasound quality control test procedures. Report of AAPM Ultrasound Task Group no. 1. Med Phys 1998;25:1385-1406.

<sup>2</sup> 2006 ACR Guidelines and Technical Standards. [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#). 1093-1095.

<sup>3</sup> 2006 ACR Guidelines and Technical Standards. [ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns](#). Page vi.

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.
- 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 [RADPEER™](#), a peer-review process developed by the ACR. For information about [RADPEER™](#) or [eRADPEER™](#) please visit the ACR web site at ([www.acr.org/SecondaryMainMenuCategories/quality\\_safety/radpeer.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/radpeer.aspx)).

Biopsy programs/modules are 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"> <li>• total # cases</li> <li>• # with repeat biopsy performed by core</li> <li>• # with repeat biopsy performed by excision</li> </ul>   |
| Discordance with imaging     | <ul style="list-style-type: none"> <li>• total # cases</li> <li>• # with repeat biopsy performed by core</li> <li>• # with repeat biopsy performed by excision</li> </ul>   |
| Cellular atypia, radial scar | <ul style="list-style-type: none"> <li>• total # cellular atypia cases</li> <li>• total # radial scar cases (CNB only)</li> <li>• # with repeat biopsy performed by core</li> <li>• # with repeat biopsy performed by excision</li> </ul> |
| Other                        | <ul style="list-style-type: none"> <li>• total # cases</li> <li>• # with repeat biopsy performed by core</li> <li>• # with repeat biopsy performed by excision</li> </ul>   |

- 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)

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.

## Exam Identification and Labeling

Images are an important part of the medical record. 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"> <li>• Patient’s first and last names (<b>required</b>)</li> <li>• Identification number and/or date of birth (<b>required</b>)</li> <li>• Examination date (<b>required</b>)</li> <li>• Facility name and location</li> <li>• Designation of right or left breast (<b>required</b>)</li> <li>• Anatomic location using clock face notation or labeled diagram of the breast (<b>required</b>)</li> <li>• Transducer orientation and distance from the nipple to the abnormality or the area being scanned. (<b>required</b>)</li> <li>• Sonographer’s identification number, initials, or other symbol</li> </ul> |

## Accreditation Testing

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) 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** mass. **Do not submit needle aspirations of cysts for FNAC.**)

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

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. All images should be submitted on film or high-quality photographic paper.

## Clinical Images - Breast Ultrasound Accreditation

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

| Breast Ultrasound Accreditation<br>(both cases required)                                    |   |
|---|---|
| Simple Cyst   | Solid Mass  |
| 1. 2-view mammogram with a single cyst (marked and visible on both views)                   | 1. 2-view mammogram with a single mass (marked and visible on both views)                   |
| 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  |

If the cyst or mass is not marked, the facility will *fail* accreditation because the ACR reviewers will not be able to determine if the intended cyst or mass was imaged. Marking more than one will also result in accreditation failure because the ACR reviewers may be uncertain which cyst or mass is being evaluated. Evaluation of the quality of the mammogram is not part of the assessment.

## Clinical Images - Ultrasound-Guided Breast Biopsy Accreditation Module

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

| Core Needle Biopsy<br>(either case)  |  |
|--|--|
| Non-Vacuum Device  | Vacuum Suction Device  |
| 1. 2-view mammogram with a single solid mass (marked and visible on both views)                  | 1. 2-view mammogram 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) | 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. Sonogram showing the needle adjacent to the solid mass in the long axis                       |
| 4. Post-fire sonogram showing needle in the long axis  |  |

And/Or

| Fine Needle Aspiration Cytology<br>(do not submit needle aspirations of cysts)                   |
|--|
| 1. 2-view mammogram 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. Sonogram showing the needle clearly within the solid mass in the long axis                    |

If the mass is not marked, the facility will *fail* accreditation because the ACR reviewers will not be able to determine if the intended mass was biopsied. Marking more than one will also result in accreditation failure because the ACR reviewers may be uncertain which mass is being evaluated. Evaluation of the quality of the mammogram is not part of the assessment.

## Accreditation Fees

The fees for accreditation are listed below:

| Cycle  | Fees*  |
|--|--|
| <b>Accreditation</b> (Initial cycle and renewal) | \$1000 for breast ultrasound<br>\$1200 for breast ultrasound with biopsy |
| <b>Repeat</b>                                    | \$500 for one or both modules  |
| <b>Reinstate/Corrective Action Plan</b>          | \$1000 for breast ultrasound<br>\$1200 for breast ultrasound with biopsy |
| <b>Replacement Certificate</b>                   | \$65 per certificate   |

\* Fees subject to change without notice.

## For Additional Information

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