

# Breast Magnetic Resonance Imaging (MRI) Accreditation Program Requirements



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## Overview

The American College of Radiology’s Breast Magnetic Resonance Imaging (MRI) Accreditation Program provides facilities performing breast MRI procedures with peer review and constructive feedback on their staff’s qualifications, equipment, quality control (QC), quality assurance, MR safety

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policies and image quality. Facilities must submit clinical images and corresponding data for each magnet performing breast MRI examinations at their site. Every unit used to produce diagnostic clinical images for patients must successfully pass accreditation testing for the facility to be accredited. Facilities that use units that have been withdrawn, expired, or failed accreditation testing or facilities that never submit a unit for accreditation testing are subject to revocation of their accreditation. Such revocation could adversely affect reimbursement. Although facilities applying for accreditation are not required to submit phantom images for accreditation review at this time, the ACR may require phantom image submission as this accreditation program matures. ***In addition, facilities performing breast MRI must have the capacity to perform mammographic correlation, directed breast ultrasound, and MRI-guided intervention, or create a referral arrangement with a cooperating facility that could provide these services. The ACR strongly recommends that the cooperating facility be accredited by the ACR in breast MRI.*** This document outlines the requirements a facility must meet in order to apply for breast MRI accreditation.

### **Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)**

It is important to note that under the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), all facilities that bill for advanced diagnostic imaging services, such as breast MRI, under technical component of part B of the Medicare Physician Fee Schedule must be accredited by a CMS designated accrediting organization by January 1, 2012 to qualify for Medicare reimbursement. This rule affects providers of MRI, CT, PET and nuclear medicine imaging services for Medicare beneficiaries on an outpatient basis.

For accredited facilities that receive reimbursement from Medicare for the technical component of imaging examinations under the Fee Schedule there are additional mandatory requirements. As with all accreditation requirements verification of compliance with these requirements will take place during any on site survey by the ACR or CMS.

1. Each facility must have a process in place for all patients to obtain copies of their records and images that is HIPAA compliant. Patients should be made aware of this process at the time of examination or if requested by the patient at a later date.
2. Each facility must have a procedure for documenting the qualifications of the facility's personnel from the primary source when appropriate for licenses and certifications. Facilities must also verify that personnel are not included on the Office of Inspector General's (OIG) exclusion list at <http://oig.hhs.gov/fraud/exclusions.asp>.
3. All facilities must make publically available a notification for patients, family members or consumers that they may file a written complaint with the ACR.

While these procedures are mandatory only for facilities that receive reimbursement from Medicare for the technical component of imaging examinations under the Fee Schedule, the ACR encourages all facilities to implement such procedures.

## Mandatory Accreditation Time Requirements

Submission of all accreditation materials 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.

<b>Materials Required</b>	<b>Due</b>
Renewal application	60 calendar days from date sent
Testing materials	45 calendar days from date sent
Repeat Option forms (after deficiency)	15 calendar days from date sent

## Withdrawn, Added, or Replacement Units

The Breast MRI Accreditation Program is unit based. Consequently, facilities must notify the ACR if they have permanently withdrawn (i.e., removed) a breast MRI unit from service, if they have replaced that unit with a new one or have added another unit for breast MRI. 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 3 years from the old expiration date.

## Loaner Units

Accredited facilities may use a “loaner” MRI 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 magnet that is in use for more than 1 month will be required to submit evidence of testing by a qualified medical physicist/MR scientist 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** interpreting physicians, medical physicists (or MR scientists) and technologists working in breast MRI (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 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**

The physician interpreting breast MRI examinations must have knowledge and expertise in breast disease and breast imaging diagnosis. In addition, the physician has the responsibility for all aspects of the study including:

- Reviewing all indications for the examination
- Specifying the pulse sequences to be performed
- Specifying the use and dosage of contrast agents
- Ensuring that a physician is present and immediately available when contrast is administered to patients
- Interpreting images
- Generating official interpretations (final reports)
- Assuring the quality of both the images and interpretations

All physicians supervising and/or interpreting breast MRI examinations ***must*** meet the following ***minimum*** criteria:

Qualifications	Radiologist	Other Physician
Initial	<p style="text-align: center;"><b><u>Board Certified</u></b></p> <ul style="list-style-type: none"> <li>• <b>Certification</b> in Radiology or Diagnostic Radiology by the <ul style="list-style-type: none"> <li>- American Board of Radiology, <b>or</b></li> <li>- American Osteopathic Board of Radiology, <b>or</b></li> <li>- Royal College of Physicians and Surgeons of Canada, <b>or</b></li> <li>- Le College des Medecins du Quebec, <b>or</b></li> <li>- Radiologist graduating from residency after June 30, 2014, must be board eligible as defined by the American Board of Radiology</li> </ul> </li> </ul> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>• If board certified <b>before 2008</b>, must also meet 1 of the following: <ul style="list-style-type: none"> <li>- Oversight, interpretation and reporting of <b>150 breast MRI examinations in the last 36 months, or</b></li> <li>- Interpretation and reporting of <b>100 breast MRI examinations in the last 36 months</b> in a supervised situation*</li> </ul> </li> </ul> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>- <b>15 hours</b> of Category 1 Continuing Medical Education (CME) in MRI (including clinical applications of MRI in breast imaging, MRI artifacts, safety, and instrumentation)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p style="text-align: center;"><b><u>Not Board Certified</u></b></p> <ul style="list-style-type: none"> <li>• Completion of an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) approved diagnostic radiology residency program, <b>and</b></li> <li>• Interpretation and reporting of <b>100 breast MRI examinations</b> in the last 36 months <b>in a supervised situation</b>*, <b>and</b></li> <li>• <b>15 hours</b> of Category 1 CME in MRI (including clinical applications of MRI in breast imaging, MRI artifacts, safety, and instrumentation)</li> </ul>	<ul style="list-style-type: none"> <li>• Completion of an ACGME approved residency program in the specialty practiced, <b>and</b></li> <li>• Interpretation and reporting of <b>300 breast MRI</b> examinations in the last 36 months <b>in a supervised situation</b>*, <b>and</b></li> <li>• <b>200 hours</b> of Category 1 CME in MRI (including clinical applications of MRI in breast imaging, MRI artifacts, safety, and instrumentation)</li> </ul>
Continuing Experience	Upon renewal, <b>75 breast MRI examinations</b> in the prior <b>36 months</b> <sup>†</sup>	

\* The supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised. The supervising interpreting physician does not have to be present at the time of initial interpretation. However, the supervising physician must review and, if necessary, correct the final interpretation. Supervision may also be accomplished through a formal course that includes a lecture format in addition to all of the following: 1) a database of previously performed and interpreted cases, 2) an assessment system traceable to the individual participant, and 3) direct feedback regarding the responses. Examples of suitable assessment systems are an audience response system, a viewbox or monitor based program or an individual CD-ROM or web-based instruction system.

† Double-reading (2 or more physicians interpreting the same examination) is acceptable. Interpreting physicians may also re-interpret a previously interpreted examination and count it towards meeting the continuing experience requirement, as long as he/she did not do the initial interpretation.

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Qualifications	Radiologist	Other Physician
<b>Continuing Education</b>	Upon renewal, must meet one of the following: 1. Currently meets the Maintenance of Certification (MOC) requirements for the ABR (See <a href="#">ABR MOC</a> ) <p style="text-align: center;"><b>OR</b></p> 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 <a href="#">ACR Guideline</a> ) <p style="text-align: center;"><b>OR</b></p> 3. Completes 15 hours CME (half of which must be in category 1) in the prior 36 months specific to the imaging modality or organ system	

In addition to being in compliance with the interpreting physician qualifications stated above, the **supervising physician** also has the following responsibilities:

- Develop, implement and enforce policies and procedures in compliance with the ACR White Paper on Magnetic Resonance (MR) Safety.
- Develop, implement and enforce policies and procedures to address safety issues, including contrast use and sedation.
- Ensure that a physician is present and immediately available when contrast is administered to patients.
- Develop, implement and enforce policies and procedures to identify pregnant or potentially pregnant patients.
- Develop, implement and enforce policies and procedures consistent with ACR's Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns.
- Be responsible for assuring compliance with the recommendations of the medical physicist.
- Be responsible for the oversight and submission of all materials, including clinical images, quality control data and such other information as required by the Breast MRI Accreditation Program.
- Be responsible for notifying the ACR within 15 days of any changes in imaging equipment (units) or changes in the use of equipment that could affect clinical images.
- Ensure that all accreditation criteria are met and that the same standard of performance is maintained during the 3-year accreditation period.
- Provide immediate written notice to the ACR upon the termination of any accredited services provided by the Practice Site or a change in ownership of the operating location.
- Ensure that all physicians providing services at this facility are actively participating in a formal peer review program that meets the stated accreditation requirements. (For breast MRI, the facility must participate in a medical outcomes audit program in order to meet the requirement.)

## Technologist

All technologists performing breast MRI 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. In addition, the ACR **recommends** that technologists performing breast MRI hold the Current Basic Life Support certification and be capable of using an automatic external defibrillator.

Qualifications	Technologist
Initial	<ul style="list-style-type: none"> <li>• Registered in MRI by the <ul style="list-style-type: none"> <li>- American Registry of Radiologic Technologists (ARRT), <b>or</b></li> <li>- American Registry of MRI Technologists (ARMRIT), <b>or</b></li> <li>- Canadian Association of Medical Radiation Technologists (CAMRT)</li> </ul> </li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>• Registered in radiography by the ARRT and/or unlimited state license, <b>and</b></li> <li>• 6 months supervised clinical MRI scanning experience</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>• Associate's or bachelor's degree in an allied health field, <b>and</b></li> <li>• Certification in another clinical imaging field (e.g., ARDMS or NMTCB), <b>and</b></li> <li>• 6 months supervised clinical MRI scanning experience</li> </ul>
	<p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>• Licensure in the state in which he/she practices (if required for MRI technologists)</li> </ul>
	<p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>• Supervised experience in breast MRI, <b>and</b></li> <li>• Supervised experience in the intravenous administration of MR contrast (if contrast administration is performed by the technologist)</li> </ul>
Continuing Experience	Upon renewal, <b>50</b> breast MRI examinations in the prior <b>24 months</b>
Continuing Education	<ul style="list-style-type: none"> <li>• Registered technologists <ul style="list-style-type: none"> <li>- In compliance with the CE requirements of their certifying organization for the imaging modality in which they perform services</li> <li>- CE includes credits pertinent to the technologist's ACR accredited clinical practice</li> </ul> </li> <li>• State licensed technologists <ul style="list-style-type: none"> <li>- 24 hours of CE every 2 years</li> <li>- CE is relevant to imaging and the radiologic sciences, patient care</li> <li>- CE includes credits pertinent to the technologist's ACR accredited clinical practice</li> </ul> </li> <li>• All others <ul style="list-style-type: none"> <li>- 24 hours of CE every 2 years</li> <li>- CE is relevant to imaging and the radiologic sciences, patient care</li> <li>- CE includes credits pertinent to the technologist's ACR accredited clinical practice</li> </ul> </li> </ul>

## Medical Physicist or MR Scientist

The medical physicist/MR scientist must:

- Be familiar with the principles of MRI safety for patients, personnel, and the public; the Food and Drug Administration's guidance for MR diagnostic devices; and other regulations pertaining to the performance of the equipment being monitored.
- Be knowledgeable in the field of MR physics and familiar with MRI technology, including function, clinical uses, and performance specifications of MRI equipment, as well as calibration processes and limitations of the performance testing hardware, procedures, and algorithms.
- Have a working understanding of clinical imaging protocols and methods of their optimization. This proficiency should be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

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The qualified medical physicist/MR scientist is responsible for the conduct of all surveys of the breast MRI equipment. The medical physicist/MR scientist may be *assisted* by properly trained individuals in obtaining data. These individuals must be approved by the medical physicist/MR scientist in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The medical physicist/MR scientist *must be present* during the surveys; review, interpret, and approve all data; and provide a report of the conclusions *with his/her signature*. Medical physicists/MR scientists providing these services *must* meet the following minimum criteria:

Qualifications	Medical Physicist	MR Scientist
<b>Initial</b>	<p style="text-align: center;"><b><u>Board Certified</u></b></p> <ul style="list-style-type: none"> <li>• Certified in Diagnostic Radiological Physics, Diagnostic Medical Physics, or Radiological Physics by the American Board of Radiology; in Diagnostic Imaging Physics or Magnetic Resonance Imaging Physics by the American Board of Medical Physics; or in Diagnostic Radiology Physics or Magnetic Resonance Imaging Physics by the Canadian College of Physicists in Medicine</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p style="text-align: center;"><b><u>Not Board Certified in Required Subspecialty</u></b></p> <ul style="list-style-type: none"> <li>• Graduate degree in medical physics, radiologic physics, physics, or other relevant physical science or engineering discipline from an accredited institution, <b>and</b></li> <li>• Formal coursework in the biological sciences with at least <ul style="list-style-type: none"> <li>– 1 course in biology or radiation biology, and</li> <li>– 1 course in anatomy, physiology, or similar topics related to the practice of medical physics</li> </ul> </li> <li>• 3 years of documented experience in a clinical MRI environment</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p style="text-align: center;"><b><u>Grandfathered</u></b></p> <p>Conducted surveys of at least 3 MRI units between January 1, 2007 and January 1, 2010</p>	<ul style="list-style-type: none"> <li>• Graduate degree in a physical science involving nuclear MR (NMR) or MRI</li> <li>• 3 years of documented experience in a clinical MRI environment</li> </ul>
<b>Continuing Experience</b>	Upon renewal, <b>2 MRI unit</b> surveys in prior <b>24 months</b>	
<b>Continuing Education</b>	Upon renewal, <b>15 CEU/CME</b> (1/2 Cat 1) in prior <b>36 months</b> (must include credits pertinent to the accredited modality)	

## Equipment

There is no requirement for minimum field strength. However, the MR equipment must:

- Have a dedicated, bilateral breast coil
- Be capable of simultaneous, bilateral, imaging
- Meet all state and federal performance requirements, including those for:
  - Maximum static magnetic field strength
  - Maximum rate of change of magnetic field strength (dB/dt)
  - Maximum radiofrequency power deposition (specific absorption rate)
  - Maximum auditory noise levels

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For clarification of terms, consult the ACR's MRI Terminology Glossary<sup>1</sup>.

In addition, facilities performing breast MRI **must** have the equipment to perform mammographic correlation, directed breast ultrasound, and MRI-guided intervention, or create a referral arrangement with a cooperating facility that could provide these services. The ACR strongly recommends that the cooperating facility be accredited by the ACR in breast MRI.

## 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 are contained in the *2004 ACR Magnetic Resonance Imaging (MRI) Quality Control Manual*<sup>2</sup>. The ACR will send a QC manual to the modality's supervising physicians of facilities not previously accredited in MRI.

As part of the accreditation application, facilities must demonstrate compliance with the ACR requirements for QC by providing:

- The most recent Annual MRI System Performance Evaluation report, including indication that the performance of the site's bilateral breast coil(s) has been checked and was acceptable
- Documentation of corrective action (if the Annual MRI System Performance Evaluation and/or QC data identify performance problems)

Although many of the procedures and action criteria outlined in the *2004 ACR Magnetic Resonance Imaging (MRI) Quality Control Manual*<sup>2</sup> were written specifically for the ACR MRI Accreditation Phantom, the **ACR understands that the use of this phantom may not be possible for all QC in breast imaging. Some facilities use the ACR Small MRI Phantom for this purpose**<sup>3</sup>. **The ACR leaves the choice of the QC phantom and the resultant action criteria to the facility.** This decision must be made by the qualified medical physicist/MR scientist in cooperation with the system vendor.

## Acceptance Testing

Acceptance testing is intended to measure quantifiable system parameters, which may then be compared to the manufacturer's specifications and used to develop baseline performance. The medical physicist/MR scientist should perform a complete evaluation of the MRI system performance after installation and prior to patient imaging. This testing should be more comprehensive than periodic performance testing and should be consistent with current acceptance testing practices. It should include all of the **technologist's QC tests** as well as the annual tests in the *2004 ACR Magnetic Resonance Imaging (MRI) Quality Control Manual*<sup>2</sup> and an evaluation of all coils, including all breast imaging and biopsy coils. Useful guidance is also available in *Acceptance Testing and Quality Assurance Procedures for Magnetic Resonance Imaging Facilities: Report of MR Subcommittee Task group I*<sup>4</sup>.

## Annual Medical Physicist/MR Scientist Survey

The medical physicist/MR scientist **must** perform the QC tests listed in the table below when the equipment is installed and **at least annually thereafter**<sup>2</sup>. 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/MR scientist 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 MRI equipment. If appropriate, the medical

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physicist/MR scientist 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/MR scientist must take immediate action to preclude use of the equipment.

Annual Medical Physicist/MR Scientist's MR System Performance Evaluation	
QC Test	Description
1. Magnetic Field Homogeneity	Checks the uniformity of the main magnetic field strength ( $B_0$ ) over a designated volume. Inhomogeneities can contribute to geometrical distortion of images, adversely influence image quality, and compromise the signal-to-noise ratio (SNR) in some fast imaging sequences.
2. Slice Position Accuracy	Checks the accuracy with which axial slices are positioned at specific locations utilizing a sagittal localizing image. The test determines whether the actual locations of acquired slices differ from their prescribed locations by substantially more than is normal for a well-functioning scanner.
3. Slice Thickness Accuracy	Checks the prescribed slice thickness against that of the measured slice thickness. Poor slice thickness accuracy may not only suggest that slices are too thick or thin, but can extend to factors such as incorrect image contrast or SNR.
4. Radiofrequency Coil Checks	Checks the trade-off between maximizing image uniformity and enhancing SNR that is inherent to various types of radiofrequency coils. Tests should be performed on <b>all coils used clinically (including breast coils)</b> and include 1) frequency and gain/attenuator verification (prescan values), 2) image signal-to-noise ratio (SNR), 3) intensity uniformity for volume coils, and 4) phase stability and image artifact assessment.
5. Soft-Copy Displays (Monitors)	Checks that display devices meet manufacturer's published specifications for 1) maximum and minimum luminance, 2) luminance uniformity, 3) resolution, and 4) spatial accuracy.
6. Evaluation of QC Program	Provides an external assessment of QC, checks that appropriate actions are taken to correct problems, identifies areas where quality and QC testing may be improved, and enables a comparison of QC practices with those of other MRI sites.

## Technologist Quality Control Tests

A QC program must be implemented for all MRI units and should be established with the assistance of a medical physicist/MR scientist. The technologist must perform the QC tests listed in the table below at the specified **minimum** frequencies<sup>2</sup>. The medical physicist/MR scientist should identify the person responsible for performing the tests and may choose to increase the frequency of testing based on the facility and MRI usage. If any QC parameter being monitored falls outside of the control limits, corrective action should be taken. A medical physicist/MR scientist should be available to assist in prescribing corrective actions for unresolved problems.

Technologist's QC		
QC Test	Description	Minimum Frequency
1. Table Positioning	To determine that the MRI scanner is functioning properly with regards to performing patient set up.	Weekly
2. Setup and Scanning	To determine that the MRI scanner is functioning properly with regards to performing data entry and prescan tasks.	Weekly
3. Center (Central) Frequency	To determine if the MRI system is set on-resonance. The effects of off-resonance relate primarily to system sensitivity and appear as a reduction in image SNR.	Weekly
4. Transmitter Gain or Attenuation	To determine if there are problems with the radiofrequency chain (coil RF calibration).	Weekly
5. Geometric Accuracy	To determine if the geometric relationships of the MR image are not in error (gradient calibration).	Weekly
6. High-Contrast (Spatial) Resolution	To assess the scanner's ability to resolve small objects.	Weekly
7. Low-Contrast Resolution (Detectability)	To assess the extent to which objects of low-contrast are discernible in the images.	Weekly
8. Artifact Analysis	To assess the presence of artifacts that may be early indicators of declining MRI system performance.	Weekly
9. Film (Hardcopy Image) QC	To ensure artifact-free laser films are produced with consistent gray levels that match the image appearance on the filming console.	Weekly
10. Visual Checklist	To ensure the MRI system patient bed transport, alignment and system indicator lights, RF room integrity, emergency cart, safety lights, signage and monitors are present and working properly and are electrically and mechanically stable.	Weekly

## MRI Safety

Safety guidelines, practices, and policies must be written, enforced, reviewed, and documented at least annually by the MR supervising physician. See *ACR Recommendations for Safe MR Practices; 2007*<sup>5</sup> and the *ACR Manual on Contrast Media*<sup>6</sup>. The annual medical physicist/MR scientist performance evaluation must also include an assessment of the MRI safety program (signage, access control, screening procedures and cryogen safety) as well as an inspection of the physical and mechanical integrity of the system.

## Preventive Maintenance

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

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## Quality Assurance

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.

Each facility must establish and maintain a medical outcomes audit program to follow up positive assessments and to correlate pathology results with the interpreting physician's findings. (If the facility does not perform MRI-guided intervention, it must be able to obtain the correlative pathology results from the accredited facility with whom they have a referral arrangement.) The audit must include evaluation of the accuracy of interpretation as well as appropriate clinical indications for the examination. Facilities must use the Breast Imaging Reporting and Data System (BI-RADS®)<sup>7</sup> final assessment codes and terminology for reporting and tracking outcomes. The BI-RADS® Atlas contains guidance on monitoring outcomes and conducting the audit. Summary statistics and comparisons generated for each physician and for each facility should be reviewed annually by the lead interpreting physician.

## Reporting

The interpreting physician must prepare a written report containing the results of each examination in addition to the following information:

- Name of the patient and an additional patient identifier
- Date of the examination
- Name of the interpreting physician
- An overall final assessment

Further guidance is available in the *ACR Practice Guideline for Communication of Diagnostic Imaging Findings*. The final assessment **must** be categorized into one of the BI-RADS®<sup>7</sup> breast MRI final assessment categories:

BI-RADS® Category	Breast MRI 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 BI-RADS® Category 0 (Assessment is Incomplete: Need Additional Imaging Evaluation) should be used and reasons why a final assessment cannot be made provided. (The ACR believes that a meaningful audit of examinations requires that the recommendations for recall imaging (BI-RADS® Category 0) also be considered “positive” and thus recommends that the facility collect and review outcome data on Category 0 exams.)

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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

Image quality and procedure performance assessments are the cornerstones of ACR accreditation programs. All images must be in DICOM format. Facilities can choose to submit images uploaded electronically, or on CD or DVD with an embedded viewer.

## Clinical Images

The facility must submit 1 case with a **known, enhancing, biopsy-proven carcinoma** clearly visible in the breast parenchyma. The case must be a bilateral exam of native breasts (i.e., no TRAM or autologous tissue reconstructions). The MRI must be performed prior to any surgery on the breast with cancer (e.g., excisional biopsy or lumpectomy).

Facilities should select a case that represents their **best work**. The ACR Committee on Breast MRI Accreditation understands that images obtained during all breast MRI examinations may not meet these criteria. Consequently, sufficient time (45 days) is allowed to select a case that is an example of "best work." ACR reviewers will evaluate them accordingly. The cases must meet the following criteria:

- The **lead interpreting physician must review and approve** the clinical images and forms. (Incorrect clinical images or incorrect information listed on the Test Image Data form may result in accreditation failure.)
- The case should **not be older than 6 months** from the date on the Testing Memorandum.
- The case must be from an actual patient (not a model or volunteer) and must have been formally interpreted.
- All images of a case must be from the **same patient**.
- The case should not be from a mastectomy patient.
- Each case **must** include **localizer or scout sequences**.
- Each case **must** include the following **4 sequences**. (Aurora systems acquire a pre-contrast T1-weighted series that is also a T2-weighted/bright fluid series. For those cases, only 3 sequences need be submitted.) If possible, only submit the required sequences.

Sequence	Criteria
<b>T2-Weighted/Bright Fluid Series</b>	<ul style="list-style-type: none"> <li>• Adequate SNR/not too grainy</li> <li>• Sufficient bright fluid contrast</li> </ul>
<b>Multi-Phase T1-Weighted Series:</b>	
Pre-Contrast T1	<ul style="list-style-type: none"> <li>• Adequate SNR/not too grainy</li> </ul>
Early Phase (first) Post-Contrast T1	<ul style="list-style-type: none"> <li>• Adequate SNR/not too grainy</li> <li>• Completed within 4 minutes of completion of injection</li> <li>• Technical factors match pre-contrast T1</li> </ul>
Delayed Phase (last) Post-Contrast T1	<ul style="list-style-type: none"> <li>• Adequate SNR/not too grainy</li> <li>• Technical factors match pre-contrast T1</li> </ul>

- The **T2-weighted/bright fluid series** may be run as a single series on both breasts or as 2 separate series, 1 on each breast.
- The **multi-phase T1-weighted series** - The intent of early phase and delayed phase post-contrast imaging is to capture information on lesion enhancement in the early and late phases of post-contrast enhancement.
  - Must be run bilaterally, with both the left and right breasts in the same series.
  - May be in 3 separate series, in 2 series (i.e., 1 for pre-contrast, the rest for post-contrast), or in a single series (i.e., pre-contrast and post-contrast).
  - If chemical-shift (i.e., frequency-selective) fat suppression is not used or is not evident, then subtraction of pre-contrast from post-contrast series may be used to eliminate the bright signal from fat. If this is done, then both the unsubtracted (source) series and the subtracted series (i.e., pre-contrast subtracted from post-contrast, slice by slice) must be included for both the early and delayed phases.
  - IV contrast must be evident in the 2 post-contrast T1-weighted series.
- If possible, each sequence should be presented separately and not as “stacked” or “interleaved” sequences. (Contact your MRI manufacturer representative for assistance).
- All sequences must demonstrate adequate breast positioning and include the entire breast, including the axillary tail.
- All sequences must demonstrate sufficient signal-to-noise ratio (SNR) and not appear too grainy.
- If artifacts are present, they must not compromise the diagnostic value of the images.

For the pre-contrast and post-contrast T1-weighted series, the following parameters **must** be met:

Sequence Acquisition Plane	Slice Thickness	Gap	Maximum In Plane Pixel Dimension for Phase and Frequency
Sagittal, axial, coronal, and/or slightly oblique	≤3.0 mm	0 mm	≤1.0 mm

At least 2 ACR radiologist reviewers will score the 5 categories listed in the table below. See the [ACR Breast MRI Accreditation Clinical Image Quality Guide](#) for more information.

<b>Clinical Image Review Categories</b>
1. Pulse sequences and image contrast
2. Positioning and anatomic coverage
3. Artifacts
4. Spatial and temporal resolution
5. Exam identification

**Exam Identification and Labeling**

Images are an important part of the medical record. All of the parameters below should be displayed on the image or easily accessed through the DICOM header. These parameters will be evaluated by the ACR reviewer. The ACR will maintain confidentiality of all patient information. *If laterality is absent or is incorrect, the case will fail accreditation.*

<b>Exam Identification</b>
<ul style="list-style-type: none"> <li>• Patient’s first and last names</li> <li>• Patient age or date of birth</li> <li>• Patient Identification number</li> <li>• Facility name</li> <li>• Examination date</li> <li>• Laterality, left or right of midline section</li> </ul>

**Phantom Images**

Facilities applying for accreditation are not required to submit phantom images for accreditation review at this time. However, the ACR may require phantom image submission as this accreditation program matures.

**Accreditation Fees**

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

<b>Cycle</b>	<b>Fees</b>
<b>Accreditation</b> <i>(Initial cycle and renewal)</i>	<b>\$2,900</b> for the first unit used for breast MRI <b>\$2,800</b> for each additional unit used for breast MRI at the same geographic location <b>\$2,100</b> for each unit used for breast MRI <i>if it is already accredited in the ACR’s MRI Accreditation Program (or has applied)</i>
<b>Repeat</b>	<b>\$1200</b> for each unit
<b>Reinstate/Corrective Action Plan</b>	<b>\$2,900</b> for the first unit <b>\$2,800</b> each additional unit at the same geographic location
<b>Add units</b> <i>(mid cycle)</i>	<b>\$2,100</b> for each unit
<b>Replacement Certificate</b>	<b>\$50</b> per certificate

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## For Additional Information

For further information about the ACR Breast MRI Accreditation Program, downloadable accreditation program forms and Frequently Asked Questions, log on to the ACR web site at [www.acr.org](http://www.acr.org), click on “Accreditation” then click on “Breast Magnetic Resonance Imaging (MRI)”. Also, check out the ACR's [Breast Imaging Resources](http://www.acr.org/Breast-Imaging) page at [www.acr.org/Breast-Imaging](http://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 Breast MRI Accreditation Program office by phone, dial (800) 227-6440 or email [breastmri-accred@acr.org](mailto:breastmri-accred@acr.org).

## ACR Practice Guidelines and Technical Standards

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

1. [ACR Practice Guideline for the Performance of Contrast-Enhanced Magnetic Resonance Imaging \(MRI\) of the Breast](#)
2. [ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#)
3. [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging \(MRI\) Equipment](#)
4. [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#)
5. [ACR Practice Guideline for the Use of Intravascular Contrast Media](#)
6. [ACR Position Statement: Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns](#)

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3. American College of Radiology. Phantom Test Guidance for Use of the Small MRI Phantom. Reston (VA): American College of Radiology 2008. Available at: [http://www.acr.org/accreditation/mri/mri\\_qc\\_forms/PhantomTestGuidanceSmallPhantom.aspx](http://www.acr.org/accreditation/mri/mri_qc_forms/PhantomTestGuidanceSmallPhantom.aspx).
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[http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/BIRADSAtlas.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/BIRADSAtlas.aspx).

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