Although the Mammography Quality Standards Act (MQSA) passed when analog mammography and film processors were used across the United States, now most health care facilities have full-field digital mammography. This article reviews MQSA requirements including qualifications for personnel, the clinical image evaluation process, and components of a quality control program. In light of technological advances, the U.S. Food and Drug Administration’s extension certificate for digital breast tomosynthesis is discussed, along with the American College of Radiology’s Breast Imaging Center of Excellence designation and laws regarding density notification.

When Congress passed the Mammography Quality and Standards Act (MQSA) in 1992, analog mammography was the standard in breast imaging in the United States. Today, most health care facilities use full-field digital mammography (FFDM), and the use of digital breast tomosynthesis (DBT) is on the rise. Breast cancer death rates have been on the decline since the enactment of MQSA. Before its implementation, mammography equipment, image quality, and radiation dose to patients varied among imaging facilities. Under the law, the U.S. Food and Drug Administration (FDA) established quality regulations for mammography. Several aspects of mammography were taken into account to develop these guidelines such as equipment standards, personnel qualifications, and facility practices. These components must be evaluated and approved by an accreditation body for the facility to perform mammography legally.

Certification vs Accreditation

Certification is a separate process from accreditation. Accreditation is the first step; only after a facility becomes accredited can it receive certification. The American College of Radiology (ACR) is an accrediting organization, and 3 states also have been approved by the FDA as accrediting bodies: Arkansas, Iowa, and Texas. Facilities in these states also must comply with any additional state laws that exist independently of MQSA.

Certification is administered by a certifying agency, either the FDA or an FDA-approved state certifying agency. Certifying states can certify only mammography facilities located within state borders. Currently, the only FDA-approved state certifying agencies are Illinois, Iowa, South Carolina, and Texas. Only the FDA can certify facilities located outside those states.

For purposes of accreditation, a mammography facility can be classified as a new applicant, a reaccrediting applicant,
or a reinstating applicant. New facilities must apply for accreditation and receive a provisional MQSA certificate from the FDA or the state certifying agency before performing examinations. The provisional MQSA certificate is valid for 6 months. During this time, the facility must collect high-quality clinical images and comply with all the requirements of the accrediting body. If the facility does not meet the accrediting body’s requirements within the 6-month period, it must stop performing mammography and request a reinstatement of its provisional MQSA certificate. If the facility meets specific criteria, the FDA can issue a one-time 90-day extension of the provisional certificate.

A facility that is reaccrediting has held accreditation and has been certified for 3 years. During the last few months of the accreditation period, the facility must repeat the accreditation process. Reinstating applicants have either let their certification lapse or have had their accreditation denied. This scenario necessitates submission of a corrective action plan by the facility to the accrediting body to demonstrate improvement in areas of prior deficiency.

**ACR Accreditation Personnel Qualifications**

The ACR evaluates several aspects of mammography programs before granting accreditation (see Figure 1). Physicians, radiologic technologists, and medical physicists must comply with both initial and continuing education requirements. Radiologic technologists must be certified by the American Registry of Radiologic Technologists (ARRT), the American Registry of Clinical Radiologic Technologists, or be licensed to perform radiographic examinations in a state. In addition, technologists must complete 40 hours of initial mammography training and an additional 8 hours of training in digital mammography before they can use that modality.

**Figure 1.** American College of Radiology (ACR) accreditation process. Reprinted with permission of the ACR. No other representation of this material is authorized without expressed, written permission from the ACR. The most current and complete document is online at: [http://www.acr.org/~/media/ACR/Documents/Accreditation/Mammography/Requirements.pdf](http://www.acr.org/~/media/ACR/Documents/Accreditation/Mammography/Requirements.pdf). Accessed March 24, 2015.
independently. For technologists who qualified after April 28, 1999, further training in breast anatomy and physiology, positioning and compression, quality assurance and quality control procedures, and breast implant imaging techniques is needed along with a minimum of 25 mammographic examinations performed with supervision by a suitable MQSA-qualified individual. In addition, a mammographer must obtain at least 15 continuing education credits in a 36-month period. Physician and medical physicist requirements are listed in Tables 1 and 2.

Clinical Image Review
Clinical image quality is paramount in breast imaging. The ACR requires submission of clinical images from 2 mammographic studies performed at the facility. One study must be of a predominantly fatty breast and one of a predominantly dense breast. The studies must have a “negative” or Breast Imaging-Reporting and Data System (BI-RADS) category 1 interpretation and should represent the facility’s best work. In certain circumstances, the ACR might permit submission of studies with an assessment category of BI-RADS 2, or “benign” with prior approval. FFDM images must have:

- Standard image identification including the patient’s name.
- An identifying number such as a medical record number.
- The date of the examination.
- Laterality and projection marker placed near the axilla.

Table 1

| Mammography Quality Standards Act (MQSA)-Required Qualifications for Interpreting Physicians |
|-----------------------------------------------|--------------------------------------------------|
| Qualifications | Board Certified in Radiology | Not Board Certified in Radiology |
| Initial | Licensed to practice medicine and | Licensed to practice medicine and |
| | Certified in diagnostic radiology by: | Documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection: |
| | ❦ American Board of Radiology, or | ❦ 2 months (if initially qualified before April 28, 1999), or |
| | ❦ American Osteopathic Board of Radiology, or | ❦ 3 months (if initially qualified after April 28, 1999) |
| | ❦ Royal College of Physicians and Surgeons of Canada and | and |
| | Initial experience: | Initial experience: interpreted 240 examinations within the 6 months immediately prior to the physician’s qualification date |
| | ❦ Interpreted 240 examinations in any 6 months within the last 2 years of residency (if board certified at 1st possible opportunity), or | and |
| | ❦ Interpreted 240 examinations within the 6 months immediately prior to the physician’s qualification date (if not board certified at 1st possible opportunity) | 8 hours of training in a mammographic modality (eg, digital) before beginning to use that modality |
| and | and | |
| | Category 1 continuing medical education (CME) in mammography (at least 15 of which must have been acquired in the 3 years immediately prior to the physician’s qualification date): | |
| | ❦ 40 hours (if initially qualified before April 28, 1999), or | ❦ 40 hours (if initially qualified before April 28, 1999), or |
| | ❦ 60 hours (if initially qualified after April 28, 1999) | ❦ 60 hours (if initially qualified after April 28, 1999) |
| and | and | |
| | 8 hours of training in a mammographic modality (eg, digital) before beginning to use that modality | |

Continuing experience | Interpret 960 mammographic examinations over a 24-month period |
Continuing education | 15 Category 1 CME units in mammography in a 36-month period |

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mediolateral oblique (MLO) projection (see Figure 2). Inadequate pectoralis muscle, sagging breast tissue, poor visualization of posterior tissue, and overlying skin folds are problematic positioning issues. Ideally, the pectoralis muscle should be visible to the nipple line and should appear convex. The breast tissue should be lifted out, the inframammary fold should be open, and all posterior tissue should be included. If possible, dense fibroglandular tissue should not extend to the edge of the image, as this indicates that tissue was excluded.\textsuperscript{8, 9}

Some common deficiencies seen on the craniocaudal (CC) projection are inadequate inclusion of posterior tissue, excessive exaggeration, and skin folds (see Figure 3). The CC projection should demonstrate posterior medial tissue because this is the area of the breast most likely to be excluded on the MLO projection. The nipple should be positioned in the midline of the CC projection, indicating no rotation medially or laterally. Ideally, the pectoralis muscle should be seen

Table 2

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Master’s Degree or Higher</th>
<th>Bachelor’s Degree (must be qualified before April 28, 1999)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>□ Master’s degree or higher in a physical science, and</td>
<td>□ Bachelor’s degree in a physical science, and</td>
</tr>
<tr>
<td></td>
<td>□ 20 semester hours of physics, and</td>
<td>□ Qualified under the Interim Regulations, and</td>
</tr>
<tr>
<td></td>
<td>□ 20 contact hours of training in conducting surveys of mammography facilities, and</td>
<td>□ 10 semester hours of physics, and</td>
</tr>
<tr>
<td></td>
<td>□ Experience in conducting surveys of 10 units and 1 facility</td>
<td>□ 40 contact hours of training in conducting surveys of mammography facilities, and</td>
</tr>
<tr>
<td></td>
<td>□ Experience in conducting surveys of 20 units and 1 facility</td>
<td>□ Experience in conducting surveys of 20 units and 1 facility</td>
</tr>
<tr>
<td>and</td>
<td>□ Certified in Diagnostic Radiological Physics, Diagnostic Medical Physics, Imaging Physics, or Radiological Physics by:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ American Board of Radiology, or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ American Board of Medical Physics, or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Licensed or approved by a state</td>
<td></td>
</tr>
<tr>
<td>and</td>
<td>□ 8 hours of training in a mammographic modality (eg, digital) before surveying units of that modality</td>
<td></td>
</tr>
</tbody>
</table>

Continuing experience: Survey 2 mammography facilities and 6 mammography units over a 24-month period

Continuing education: 15 CME/continuing education units (CEUs) in mammography in a 36-month period

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Table 3

**Potential Deficiencies in Image Quality Used in the Clinical Image Evaluation Process**

<table>
<thead>
<tr>
<th>Category</th>
<th>Deficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning</td>
<td>Poor visualization of posterior tissues</td>
</tr>
<tr>
<td></td>
<td>Sagging breast</td>
</tr>
<tr>
<td></td>
<td>Inadequate amount of pectoralis major muscle on image</td>
</tr>
<tr>
<td></td>
<td>Excessive exaggeration on the craniocaudal projection</td>
</tr>
<tr>
<td></td>
<td>Portion of breast cut off</td>
</tr>
<tr>
<td></td>
<td>Skin folds</td>
</tr>
<tr>
<td></td>
<td>Other body parts projected over breast</td>
</tr>
<tr>
<td></td>
<td>Nonstandard angulation</td>
</tr>
<tr>
<td></td>
<td>Posterior nipple line on craniocaudal projection not within 1 cm of that on mediolateral oblique projection</td>
</tr>
<tr>
<td></td>
<td>Breast positioned too high on image receptor</td>
</tr>
<tr>
<td>Compression</td>
<td>Poor separation of parenchymal densities</td>
</tr>
<tr>
<td></td>
<td>Nonuniform exposure levels</td>
</tr>
<tr>
<td>Contrast</td>
<td>Inadequate contrast</td>
</tr>
<tr>
<td></td>
<td>Excessive contrast</td>
</tr>
<tr>
<td>Noise</td>
<td>Visually striking mottle pattern</td>
</tr>
<tr>
<td></td>
<td>Noise-limited visualization of detail</td>
</tr>
<tr>
<td>Artifacts</td>
<td>Punctate or lint*</td>
</tr>
<tr>
<td></td>
<td>Scratches or pickoff*</td>
</tr>
<tr>
<td></td>
<td>Roller marks*</td>
</tr>
<tr>
<td></td>
<td>Grid-related artifacts*</td>
</tr>
<tr>
<td></td>
<td>Hair, deodorant, etc</td>
</tr>
<tr>
<td></td>
<td>Image handling*</td>
</tr>
<tr>
<td></td>
<td>Image fogging*</td>
</tr>
<tr>
<td></td>
<td>Poor film-screen alignment*</td>
</tr>
<tr>
<td>Exposure</td>
<td>Generalized underexposure</td>
</tr>
<tr>
<td></td>
<td>Generalized overexposure</td>
</tr>
<tr>
<td></td>
<td>Inadequate penetration of dense areas</td>
</tr>
<tr>
<td></td>
<td>Excessive penetration of radiolucent areas</td>
</tr>
<tr>
<td>Sharpness</td>
<td>Poor delineation of linear structures</td>
</tr>
<tr>
<td></td>
<td>Poor delineation of feature margins</td>
</tr>
<tr>
<td></td>
<td>Poor delineation of microcalcifications</td>
</tr>
<tr>
<td>Examination identification</td>
<td>Failure to identify patient, facility, date, projection, axillary side, or technologist or to use a number to identify intensifying screen in the cassette</td>
</tr>
</tbody>
</table>

*Denotes film-screen.


**Figure 2.** Deficiencies in positioning for the mediolateral oblique (MLO) projection. A. The pectoralis muscle extends below the posterior nipple line but is not wide enough and has a slightly concave anterior margin (arrow) resulting in exclusion of the posterior tissues. B. The fibro glandular tissue extends to the edge of the film (arrow), which could result in nonvisualization of a posterior abnormality. Note the absence of the inframammary fold. C. Skin folds could obscure a lesion. On this MLO image, skin folds are seen at the inframammary fold and the axilla (arrows). D. Sagging breast. The radiologic technologist did not hold the breast up and out as compression was applied. Note the low position of the nipple and prominent skin fold at the inframammary area (arrow). Reprinted with permission from Bassett L, Hoyt A, Oshiro T. Digital mammography: clinical image evaluation. Radiol Clin North Am. 2010;48(5):903-915. doi:10.1016/j.rcl.2010.06.006.
Compression reduces the radiation dose to the breast. Other critical factors, including sharpness, exposure, and contrast, have been shown to correlate directly with compression. Inadequate compression can result in motion unsharpness and usually is demonstrated by poor visualization of fine linear structures or calcifications (see Figure 4).

A final report on the image review is sent to the facility approximately 60 days after the ACR receives the submission. This report states detailed findings and recommendations. If a mammography unit passes accreditation, a 3-year accreditation certificate is provided. The ACR also notifies the FDA, and the facility subsequently receives a 3-year MQSA certificate.

A facility that does not pass the accreditation process receives corrective action recommendations as part of the final report. If it is the first deficiency for a mammography unit, the facility may resubmit the unacceptable items if more than 60 days remain on its MQSA certificate. If 60 days or fewer remain on the certificate, reinstatement by testing in all areas is necessary. The facility also can appeal the decision or withdraw its application. The facility can continue to perform mammography for the remaining time on its MQSA certificate.

If clinical image quality is deemed unacceptable, the facility must resubmit both sets of clinical images, regardless of whether only one or both of the studies failed to meet the ACR’s minimum criteria. Moreover, the images must be obtained after the facility was notified of the deficiency. This is to ensure that the facility considered the ACR’s comments and took corrective action.

If the facility receives a second deficiency, it is considered its first failure. In this case, the FDA is notified of the results and the facility must submit documentation of its corrective action plan. The facility’s options include reinstating, appealing, or withdrawing its request for accreditation. A third deficiency is considered a second failure. After a second failure, the facility may withdraw, appeal, or reinstate. If the facility chooses to reinstate, it must participate in an on-site inspection.

The ACR accreditation process also includes a dosimeter reading on a phantom image. A mammography phantom mimics a 4.2-cm compressed breast of average density. The phantom houses varying sizes.
of fibers, masses, and specks that are scored from the image produced. Any artifacts seen on the image also affect the score. A dosimeter is included in the ACR’s testing packet and is exposed along with the phantom. The recorded dose must be below 3 mGy.⁶

**Quality Control Program**

Mammography equipment, both film-screen and FFDM equipment, must meet all FDA standards. If a facility uses FFDM, the FDA requires that facility to adhere to the quality control guidelines of the unit’s manufacturer. This includes the FFDM units as well as the review workstations and laser printers. The FDA recommends that review workstations and laser printers be approved by its Office of Device Evaluation; however, this is not mandatory.⁶ The FDA recently modified its regulations regarding laser printers. It is no longer required that facilities maintain a laser printer; however, they must be able to provide a digital copy of images to a requester. The FDA’s MQSA inspection has omitted printer quality control questions from its inspection protocol. If a facility chooses to use a laser printer, the medical physicist must include the printer quality control testing as part of the mammography equipment evaluation upon installation, following a significant repair, and annually, if these are required by the printer’s or image receptor’s manufacturer quality control program.¹¹

A qualified medical physicist must perform a mammography equipment evaluation when equipment is installed. This includes new units, previously owned units, and accredited units moved from one site to another. The mammography equipment evaluation must meet all FDA guidelines for a facility to use that equipment or apply for accreditation.⁶ Each FFDM unit also must undergo annual testing by a medical physicist. Guidelines vary, depending on the manufacturer.

To see a list of the required tests for an annual physics survey, visit asrt.org/asrt?la8Dk2.

A standard practice for mammography facilities is to designate a quality control technologist. This technologist is responsible for carrying out the duties of the quality assurance program that are not designated to the medical physicist or lead interpreting physician. The quality control technologist must be a qualified mammography technologist. Delegating QC testing to other technologists is permitted by the FDA; however,
the QC technologist is responsible for ensuring that all testing is performed and documented accurately.\textsuperscript{12}

Quality Control Tests for Full-Field Digital Mammography

Some manufacturer-recommended quality control tests that should be performed by a radiologic technologist include:

- Modulator transfer function – measures detector performance in terms of resolution. It is reviewed to identify an issue with the processes surrounding digital image production and display.\textsuperscript{13}
- Automatic optimization parameters – evaluates the proper selection of kilovoltage peak, anode, filter, and milliampere seconds given varying phantom thicknesses and the correct level of signal-to-noise ratio (SNR).\textsuperscript{13}
- Flat field uniformity – an analysis of the homogeneity of the detector field. This test typically is performed weekly or as recommended by the manufacturer. The flat field test involves placing an acrylic plate directly on the detector field, with exposures taken at set parameters. A visual inspection for artifacts is performed, and if artifacts are identified, the medical physicist and field engineer should be notified to take corrective action.\textsuperscript{14}
- Contrast-to-noise ratio (CNR) – a measure of the detector’s ability to differentiate between an object in an image and image noise. To establish normal operating levels, a 5-day average CNR test must be performed. This test is performed with a dedicated phantom and usually is conducted weekly.\textsuperscript{14}
- SNR – a comparison of the level of the desired signal to the level of the background noise. In general, a higher SNR produces an improved image.\textsuperscript{14}
- Visual check – ensures that there are no irregularities or malfunctions of the mammography unit or acquisition workstation.\textsuperscript{15}
- Society of Motion Picture and Television Engineers test pattern – useful for determining acceptable contrast and brightness levels of the workstation monitor. The pattern also can be used to evaluate laser printer quality.\textsuperscript{15}
- Repeat and reject analysis – at least 250 patients should be included in the quarterly analysis. Images that are repeated or rejected are classified by reason for the repeat or reject such as patient motion, incorrect positioning, or artifacts. This analysis is useful for identifying areas for improving patient care and efficiency.\textsuperscript{14}
- Compression force test – should be performed on a semiannual basis. MQSA requires the compression force to be a minimum of 25 lb (111 N) and a maximum of 45 lb (200 N). The test is performed with an analog-type scale and measures both initial force and maximum force.\textsuperscript{16}
- Phantom image quality – the mammographic phantom represents a breast composed of 50% adipose tissue and 50% glandular tissue with a thickness of approximately 4.2 cm. An exposure is taken at optimal established technique. To score the phantom image, each type of object visible on the image is scored separately. Each fiber is counted if the full length of the fiber is visible and properly located and oriented. Speck groups should be counted as one point if 4 or more of the specks in that group are visualized. If 2 or 3 of the specks are visualized, it should be scored as 0.5. Masses are counted as one point if a minus-density object is seen as a generally circular shape against the background in its correct location. A mass that is visualized in its correct location without a circular appearance is counted as 0.5. The background should be evaluated for artifacts, and deductions should be recorded if artifacts are seen. The current criteria for ACR accreditation are visualization of the 4 largest fibers, the 3 largest masses, and the 3 largest speck groups on the phantom image.\textsuperscript{17} The appearance of phantom images should remain consistent from week to week. Differences should not decrease by more than one-half, assuming the same evaluator is scoring under identical viewing conditions.\textsuperscript{17}

In addition, monitor cleaning and viewing conditions must be consistent. Ideal image review conditions require a monitor screen that is free from dust, fingerprints, and other marks. Typically, the acquisition workstation monitor and the interpretation monitor should be wiped daily with a soft, dry, lint-free cloth to ensure optimal conditions. Ambient light in the reading room should be low (ie, within the 20–45 lux range).\textsuperscript{18}
Additional MQSA Requirements

The FDA requires all facilities performing mammography to complete medical outcomes audits that compare mammography results with outcomes data. Any mammogram that is deemed “suspicious” or “highly suggestive of malignancy” must be followed up. The facility may implement a system that suits it, but basic components must be considered. First, a definition of a positive mammogram and required follow-up must be established. Next, a process to follow up those findings must be implemented. Tracking of pathology, including a correlation with mammographic findings, also is necessary. The audit must include any malignant cases that were imaged at that facility that later became known to the facility. Finally, a review of the data by the interpreting physician or physicians must be performed.19

A consumer complaint policy is another necessity under MQSA.20 ACR-accredited facilities must have a written, documented procedure for collecting and addressing consumer complaints. Any complaint that is deemed serious must remain on record for 3 years from the time of complaint. A serious complaint is defined as an event that compromises a clinical outcome or failure to comply with a corrective action within an appropriate time frame. If the facility cannot resolve the issue, the consumer may file a complaint with the facility’s accreditation body. The facility is obligated to provide the consumer with information needed to do so. The FDA permits each accreditation body to handle complaints as it sees fit; however, the FDA might conduct its own investigation of the event.20

The FDA has defined serious adverse events in cases where the mammography facility demonstrated poor image quality, employed unqualified personnel, or failed to notify the referring physician or patient of results within 30 days of an examination. If the FDA believes a facility poses a risk to human health, an additional mammography review might be warranted. This review is conducted by an FDA-approved accrediting body. In the event that the FDA determines that the quality of mammography was compromised, the facility is responsible for notifying patients and referring physicians within a time frame set by the FDA.21

A facility that is planning to close should notify its accrediting body as well as its state radiation protection office to determine what measures might be necessary. The facility should attempt to contact its patients with instructions on how to obtain their mammography records. The FDA has established protocol to ensure that patients have access to their mammography records in the event that a facility closes. If a facility has closed, and the FDA is notified, the FDA will notify the responsible party at the facility of the obligation under MQSA to provide patients access to their records.22

Annual Inspections

MQSA certification for mammography facilities requires accreditation in conjunction with an annual inspection conducted by an official FDA representative. A thorough inspection of the mammography facility, including equipment performance tests and quality assurance records, is performed. A review of the medical outcomes audit also is part of the inspection process. To ensure a smooth inspection, facilities should have all documentation prepared for review.21 Personnel records for technologists, physicians, and physicists must be provided to ensure compliance with initial and continuing education mandates. A policy and procedure manual documenting the facility’s consumer complaint policy, infection control policy, and other protocols also is examined as part of the inspection. In addition, the facility’s current MQSA certificate should be prominently displayed within the facility.21

The FDA implemented a rating system for noncompliances found during inspections. Level 1 is the most serious violation and indicates that the quality of mammography is greatly compromised. A level 2 violation generally is acceptable; however, it indicates that one or more deviations from MQSA guidelines were noted during an inspection. Level 3 findings typically are minor. All violations must be addressed with corrective action. If no observations were made, a grade of “all items in compliance” is given.24

Systematic annual inspections ensure that facilities maintain high standards. Consistent and accurate documentation of all quality control tests throughout the year is crucial to a successful inspection.
BI-RADS

BI-RADS was implemented in the late 1980s to standardize mammography findings reporting. Advantages of the system include the use of standardized language, a uniform reporting structure along with recommendations, and a means to aid future data collection. The system also introduced a mammography lexicon of descriptors of radiographic findings.26

The BI-RADS committee suggested that mammography reports should be “decision oriented” to resolve the American Medical Association’s past dissatisfaction with previous reporting methods. As a result, the impression of the report must include a final assessment category in conjunction with the standard recommendations for that category (see Table 4).25

Since its introduction, BI-RADS has been through several revisions based on the need for clarification or for quality assurance. For example, at one time the term density was used to describe the overall density of breast tissue, as well as specific findings on a mammogram. Under revised BI-RADS terminology, a finding on a mammogram is now termed a focal asymmetry, rather than a focal asymmetric density, to avoid misinterpretation.25

A facility must provide its patients with written results of their examinations in lay terms within 30 days of the examination. In addition, the interpreting physician must send a signed written report to the patient’s referring physician. Self-referred patients must receive both documents. For patients with BI-RADS assessment categories of “suspicious” or “highly suggestive of malignancy,” the results must be communicated to the patient as soon as possible. A facility that accepts patients who are self-referred must have a system in place for referring a patient to a health care provider if it is clinically indicated.26

Breast Density Reporting Laws

Research has shown that having dense breast tissue could increase breast cancer risk. Moreover, the presence of dense breast tissue can make it more difficult to detect a cancer on a mammogram.27 In 2009, Connecticut became the first state to pass legislation mandating that breast density be communicated to patients in their mammography reports. Since then, 24 other states have followed suit.28 The Breast Density and Mammography Reporting Act of 2015 was introduced in the U.S. Senate in February 2015 but is not yet a federal law.29 Notifying patients of their dense breast tissue facilitates discussion between patients and their health care providers about alternative screening methods including breast ultrasonography, DBT, and magnetic resonance (MR) imaging of the breasts.

Digital Breast Tomosynthesis

DBT technology has been approved by the FDA as a new imaging modality. DBT involves the same positioning and compression as traditional mammography, but the x-ray tube moves in an arc around the breast. The result of the tube motion is a series of exposures that can be reconstructed to demonstrate thin slices of breast tissue. This allows for more detailed visualization of a lesion without overlapping breast tissue.30

Standards have not yet been developed for DBT; therefore, accreditation bodies cannot accredit DBT units at this time. However, the FDA has developed an

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Table 4

Breast Imaging-Reporting and Data System (BI-RADS) Categories and Associated Final Assessments

<table>
<thead>
<tr>
<th>Category</th>
<th>Overall Final Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative</td>
</tr>
<tr>
<td>2</td>
<td>Benign finding(s)</td>
</tr>
<tr>
<td>3</td>
<td>Probably benign finding – initial short-term follow-up suggested</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious abnormality – biopsy should be considered</td>
</tr>
<tr>
<td>5</td>
<td>Highly suggestive of malignancy – appropriate action should be taken</td>
</tr>
<tr>
<td>6</td>
<td>Known biopsy-proven malignancy – appropriate action should be taken</td>
</tr>
</tbody>
</table>

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extension certificate program for DBT. Before using DBT, a facility must apply for an extension certificate from the FDA. Standard 2-D clinical images may be submitted for accreditation. Physicians, technologists, and medical physicists using DBT technology must comply with all the usual MQSA guidelines and complete 8 hours of initial training.

The FDA has determined that each manufacturer's DBT is its own separate modality. Although commonalities can exist between systems, technologists, physicians, and medical physicists must be trained on the unique features of each system. Under MQSA, this training can be provided by either the manufacturer or another qualified instructor, defined as “an individual whose training and experience adequately prepare him or her to carry out specified training assignments.”

To qualify for the DBT extension certificate, facilities must submit several documents to the FDA for approval (see Box).33

**Breast Imaging Centers of Excellence**

In addition to offering the mandatory Mammography Accreditation Program, the ACR also can designate a facility a Breast Imaging Center of Excellence. These facilities comply with standards in additional breast imaging modalities. To earn this status, facilities must first obtain mammography accreditation either from the ACR or an FDA-approved state accrediting body. In addition, the facility must comply with high quality standards in stereotactic breast biopsy and breast ultrasonography including ultrasound-guided breast biopsy. Effective January 1, 2016, meeting breast MR imaging standards also is required to earn this designation.34

Once a facility earns the prestigious Breast Imaging Center of Excellence designation, it is enrolled in a national mammography database that offers an opportunity for collaboration among breast centers. Collaboration enables facilities to benchmark their performance, compare processes and outcomes, and identify quality improvement opportunities.35

**Stereotactic Breast Biopsy**

MQSA does not require that units used solely for stereotactic breast biopsy be certified. However, these units must not be used for conventional mammography. All interpreting physicians, radiologic technologists, and medical physicists must meet the requirements stated by the ACR to obtain stereotactic breast biopsy accreditation. Technologists and physicists must be qualified for mammography under MQSA, comply with initial training requirements, and earn continuing education credits specific to stereotactic breast biopsy. Table 5 identifies specific qualifications for mammography technologists who perform this procedure.36,37

Interpreting physicians may work in a collaborative setting for stereotactic breast biopsy. The radiologist and the surgeon (or other physician) share responsibility for patient selection as well as quality assurance indicated by the medical outcome audit. The radiologist and the collaborating physician must meet initial training requirements and specific experience and continuing education requirements.36,37

A radiologist or other physician, typically a surgeon, may also perform stereotactic breast biopsies in an independent setting. In this case, the physician is responsible for patient selection, and quality assurance including the medical audit, oversight of quality control, and supervision of technologists and physicists. If the independent physician is a radiologist, he or she is responsible for the mammographic interpretation, the documentation of correlative breast examinations, and referring patients to a surgeon for follow-up on certain findings.36,37

A quality control program for the stereotactic breast biopsy unit is another requirement for accreditation. Acceptance testing and an annual medical physicist survey must be performed. A designated technologist or technologists must perform specific quality control testing at set intervals (see Table 6).

Outcome data is another significant component of stereotactic breast biopsy quality control. Facilities must maintain statistics regarding the outcomes of biopsies to evaluate and improve performance. Data should include the number of procedures performed by type, the number of cancers diagnosed, and the number of complications requiring treatment. The ACR also requires statistics regarding repeat biopsies (see Table 7).37

As with mammography, facilities must submit clinical images to the ACR for review by ACR-trained clinical image reviewers to obtain stereotactic breast biopsy accreditation. Stereotactic breast biopsy images
submitted for review must demonstrate proper needle positioning. The corresponding mammogram that prompted the biopsy (BI-RADS category 4 or 5) also must be submitted. Proper examination identification and labeling are necessary, and the study should represent the facility’s best work.36,37

Breast Ultrasonography
Facilities also must meet certain standards for breast ultrasonography to be designated a Breast Imaging Center of Excellence. Similar to the process for mammography accreditation, facilities must submit documentation for interpreting physicians as well as for technologists. Sonographers must be registered by the American Registry for Diagnostic Medical Sonography or by the ARRT with postprimary certification and current registration in breast sonography or have an unrestricted state license and meet MQSA requirements for mammography technologists. Documentation of a quality control program in breast ultrasonography must

<table>
<thead>
<tr>
<th>MQSA Facility Certification Extension Requirements or Digital Breast Tomosynthesis (DBT) Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOTE 1:</strong> For MQSA purposes, DBT is a new mammographic modality separate from full-field digital mammography.</td>
</tr>
<tr>
<td><strong>NOTE 2:</strong> To use the tomosynthesis portion of the unit, the facility must apply to the U.S. Food and Drug Administration (FDA) to have its certificate extended to include that portion of the unit. The certification extension only applies to the DBT portion of the unit. The facility must have the 2-D portion of the unit accredited by one of the accreditation bodies approved to accredit the 2-D portion.</td>
</tr>
</tbody>
</table>

**Requirements**

1. **Facility status information**
   a. Facility name and FDA facility ID number
   b. FDA certificate expiration date
   c. Current accreditation body for the 2-D unit
   d. Accreditation expiration date
   e. Facility contact person for DBT unit
   f. Contact person’s title
   g. Contact person’s telephone, fax, e-mail
   h. Facility address
   i. Facility owner

2. **DBT unit identification**
   a. Machine manufacturer
   b. Machine model
   c. Year of manufacture
   d. Serial number
   e. Accreditation body unit number

3. **DBT digital image receptor identification** (if interchangeable)
   a. Receptor manufacturer
   b. Receptor model
   c. Year of manufacture
   d. Serial number (if applicable)

4. **Identification of printer for hard-copy interpretation** (mandatory even for facilities performing only soft-copy interpretation)
   a. Printer manufacturer
   b. Printer model
   c. Year of manufacture
   d. Serial number

5. **Final interpretation review monitor identification** (if soft-copy display is available)
   a. Monitor manufacturer
   b. Monitor model
   c. Year of manufacture
   d. Serial number

6. **Phantom identification**
   a. Phantom manufacturer
   b. Phantom model

7. **Hard-copy phantom image (3-D mode) must be included when submitting application**

8. **Personnel qualifications**
   a. Interpreting physicians who are qualified to interpret DBT mammograms
   b. Radiologic technologists who are qualified to perform DBT mammography examinations and the manufacturer-recommended quality assurance tests
   c. Medical physicists who are qualified to perform equipment evaluations and/or surveys of DBT mammography units
9. Detailed report of mammography equipment evaluation (MEE) (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to the request for use approval).
   a. Statement that equipment performance, as required under the following sections of the MQSA final regulation 21 CFR 900.12(b), is met:
      (1) Prohibited equipment
      (2) Specifically designed for mammography
      (3) Motion of tube-image receptor assembly
      (4)(iii) Removable grid (if applicable to the DBT system used)
      (5) Beam limitation and light fields
      (6) Magnification
      (7) Focal spot selection
      (8) Compression
      (9) Technique factor selection and display
      (10) Automatic exposure control
   b. The results of quality control tests as required under the following sections of the MQSA final regulations 21 CFR 900.12(e):
      (4)(iii) Compression device performance
      (5)(i) Automatic exposure control performance (if applicable to the DBT system used)
      (5)(ii) Kilovoltage peak accuracy and reproducibility
      (5)(iii) Focal spot condition (resolution)
      (5)(iv) Beam quality and half-value layer
      (5)(v) Breast entrance air kerma and automatic exposure control reproducibility (if applicable to the DBT system used)
      (5)(vi) Dosimetry
      (5)(vii) X-ray field/light field/image receptor/compression paddle alignment
      (5)(ix) System artifacts
      (5)(x) Radiation output
      (5)(x) Decompression (or alternative standards allowed for these requirements)
   c. The results of the phantom image quality tests, including a sample image
   d. If any of the requirements in 8 a, b, or c are not met, submit documentation of successful corrective action
   e. If any of the requirements in 8 a or b are not performed, explain why the requirement is not applicable
   f. Date of the MEE
   g. Name and address of the physicist(s) who performed the MEE

10. DBT manufacturer’s quality control program
   a. Name of the quality control manual
   b. Year published
   c. Revision number, if not the original
   d. Printing number, if not the original

11. Signature of facility contact person for the DBT unit

Comply with minimum frequencies established by the ACR including the report for the most recent annual physicist’s survey and documentation of corrective actions taken. The ACR recommends that a medical physicist performs the testing; however, it is acceptable for another qualified individual with appropriate ultrasound equipment training to perform the tests. If a survey cannot be performed on the exact anniversary date of the previous survey, the ACR has deemed a period of 14 months within acceptable limits.38

Clinical images must be submitted for all services provided by the center. If a facility performs breast ultrasonography but does not perform ultrasound-guided biopsies, the facility would apply for only breast ultrasound accreditation. Images demonstrating a simple cyst and a solid mass are required. If interventional procedures are performed, facilities also must request the ultrasound-guided breast biopsy module. To meet the clinical image requirements for this module, facilities must submit an example of a core needle biopsy or a fine-needle aspiration biopsy.39

**Breast Magnetic Resonance Imaging**

The ACR also has established minimum requirements for personnel, equipment, training, and quality assurance in breast MR imaging. Equipment standards include a dedicated bilateral breast coil, the ability to image both breasts simultaneously, and compliance with all state and federal requirements. In addition, the MR supervising physician is responsible for enforcement, documentation, and annual review of written MR guidelines, practices, and policies.39
For clinical image evaluation, facilities must submit a study with a clearly visible, enhancing, biopsy-proven carcinoma. The images must be bilateral and may not be from a reconstructed breast. In addition, the imaging must be performed before any surgical intervention on the breast. Proper examination identification and labeling are required as well as specific imaging sequences. Reports must be provided to patients’ health care practitioners within 30 days of the examination and must include a BI-RADS category assessment. Just as in mammography, findings suggestive of malignancy should be communicated as soon as possible, with an acceptable limit of 3 business days."

The Technologist’s Role
Mammographers combine scientific knowledge, technical skill, and patient interaction to provide safe and effective examinations. Practice standards set forth by the American Society of Radiologic Technologists (ASRT) include expectations such as participation in quality improvement processes and professional performance assessments. Furthermore, technologists must remain familiar with various state and federal regulations regarding quality control and stay abreast of emerging technology. Hands-on workshops, seminars, and other continuing education activities can be valuable tools for mammographers to comply with MQSA standards. These tools can provide technologists with an opportunity to improve their skills. In addition, the ASRT implemented the ASRT Communities, a social network that provides technologists with a convenient way to share best practices and an opportunity for colleagues to disseminate helpful information or seek advice.

Conclusion
Breast cancer screening has undergone a revolution since MQSA became law more than 2 decades ago. At that time, most mammography facilities relied on film-screen technology; today, more than 95% have converted to FFDM. In addition, many facilities now offer DBT, stereotactic breast biopsy, breast ultrasound, and breast MR imaging. New programs and standards are evolving for these modalities to help

---

Table 5

<table>
<thead>
<tr>
<th>MQSA-Required Qualifications for Technologists Who Perform Stereotactic Breast Biopsies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualifications</td>
</tr>
<tr>
<td>Initial</td>
</tr>
<tr>
<td>Continuing experience</td>
</tr>
</tbody>
</table>
| Continuing education (CE)      | ☐ 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 |

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Table 6

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Localization accuracy test</td>
<td>Verifies system alignment and performance (procedure varies by manufacturer and system type)</td>
<td>Daily before patient exams</td>
</tr>
<tr>
<td>2. Darkroom cleanliness*</td>
<td>Minimizes artifacts on film images by maintaining the cleanest possible conditions in the darkroom</td>
<td>Daily</td>
</tr>
<tr>
<td>3. Processor quality control*</td>
<td>Ensures consistent performance of the film processor</td>
<td>Daily</td>
</tr>
<tr>
<td>4. Phantom images</td>
<td>Ensures that film density, contrast, uniformity, and image quality of the x-ray imaging system are optimal</td>
<td>Weekly</td>
</tr>
<tr>
<td>5. Screen cleanliness*</td>
<td>Ensures that cassettes and screens are free of dust and dirt particles that might degrade image quality or mimic calcifications</td>
<td>Daily</td>
</tr>
<tr>
<td>6. Viewboxes and viewing conditions (if film is used)</td>
<td>Ensures that the viewboxes and viewing conditions are optimized and maintained at optimal levels</td>
<td>Weekly</td>
</tr>
<tr>
<td>7. Hardcopy output quality (if hardcopy is produced from digital data)</td>
<td>Ensures that the quality of hardcopy output is consistent over time and matches the gray scales presented on the cathode ray tube monitor</td>
<td>Monthly</td>
</tr>
<tr>
<td>8. Visual checklist</td>
<td>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</td>
<td>Monthly</td>
</tr>
<tr>
<td>9. Analysis of fixer retention in film*</td>
<td>Determines the quantity of residual fixer (hypo) in processed film as an indicator of keeping quality</td>
<td>Quarterly</td>
</tr>
<tr>
<td>10. Compression</td>
<td>Ensures that the x-ray imaging system can provide adequate compression in the manual and automatic powered mode</td>
<td>Semiannually</td>
</tr>
<tr>
<td>11. Repeat analysis</td>
<td>Determines the number and causes of repeated patient exposures and identifies ways to improve efficiency, reduce patient breast dose, and cut costs</td>
<td>Semiannually</td>
</tr>
<tr>
<td>12. Film-screen contact*</td>
<td>Ensures that optimum contact is maintained between the screen and the film in each cassette</td>
<td>Semiannually</td>
</tr>
<tr>
<td>13. Darkroom fog*</td>
<td>Ensures that darkroom safelights and other light sources inside and outside of the darkroom do not fog film</td>
<td>Semiannually</td>
</tr>
<tr>
<td>14. Zero alignment test (if required by manufacturer)</td>
<td>Verifies that zero coordinate is accurate</td>
<td>Before each patient</td>
</tr>
<tr>
<td>15. Additional tests (if required by manufacturer)</td>
<td></td>
<td>As required by manufacturer</td>
</tr>
</tbody>
</table>

*Not applicable if digital imaging is used.

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ensure that women continue to have access to optimal breast cancer screening and diagnosis, and mammographers play a crucial role in upholding these standards.

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References

Table 7
Required Data for Repeated Stereotactic Breast Biopsy

<table>
<thead>
<tr>
<th>Reason for Repeat Biopsy</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient sample</td>
<td>Total No. of cases</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by core</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by excision</td>
</tr>
<tr>
<td></td>
<td>Final pathology results</td>
</tr>
<tr>
<td>Discordance</td>
<td>Total No. of cases</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by core</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by excision</td>
</tr>
<tr>
<td></td>
<td>Final pathology results</td>
</tr>
<tr>
<td>Cellular atypia, Radial scar</td>
<td>Total No. of cellular atypia cases</td>
</tr>
<tr>
<td></td>
<td>Total No. of radial scar cases (core-needle biopsy only)</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by core</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by excision</td>
</tr>
<tr>
<td></td>
<td>Final pathology results</td>
</tr>
<tr>
<td>Other</td>
<td>Total No. of cases</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by core</td>
</tr>
<tr>
<td></td>
<td>No. with repeat biopsy performed by excision</td>
</tr>
<tr>
<td></td>
<td>Final pathology results</td>
</tr>
</tbody>
</table>

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Excellence requirements. http://www.acr.org/~/media/ACR
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tion extension requirements for digital breast tomosynthesis
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program/facilitycertificationandinspection/ucm413482.pdf.

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tation.org/~/media/Documents/Stereotactic/Requirements

38. American College of Radiology. Breast ultrasound accredita-
tion program requirements. http://www.acr.org/~/media
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39. American College of Radiology. Breast magnetic resonance
imaging (MRI) accreditation program requirements. http://
www.acr.org/~/media/ACR/Documents/Accreditation

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Regulatory Compliance in Mammography

To earn continuing education credit:
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New and rejoining members are ineligible to take DRs from journal issues published prior to their most recent join date unless they have purchased access to the quiz from the ASRT. To purchase access to other quizzes, go to www.asrt.org/store.

*Your answer sheet for this Directed Reading must be received in the ASRT office on or before this date.

Read the preceding Directed Reading and choose the answer that is most correct based on the article.

1. How long is a provisional Mammography Quality Standards Act (MQSA) certificate valid?
   a. 45 days
   b. 90 days
   c. 6 months
   d. 3 years

2. Technologists must complete _______ hours of additional training in digital mammography before they can use that modality independently.
   a. 0
   b. 3
   c. 6
   d. 8

3. The most common deficiency found during clinical image evaluation is:
   a. inadequate compression.
   b. patient motion.
   c. incorrect positioning.
   d. improper labeling.

4. Which of the following is false regarding the appearance of the pectoralis muscle on a properly positioned mediolateral oblique projection?
   a. It should be visible to the nipple line.
   b. The inframammary fold should be open.
   c. It should appear concave.
   d. All posterior tissue should be included.

5. _______ have been show to correlate directly with compression.
   a. Sharpness and noise
   b. Exposure and contrast
   c. Noise and exposure
   d. Sharpness, exposure, and contrast

continued on next page
6. Which of the following is true regarding the accreditation process?
   a. The U.S. Food and Drug Administration will be notified of a facility’s first deficiency.
   b. An on-site survey is conducted at a facility after its first failure.
   c. After a second failure, a facility may withdraw, appeal, or reinstate.
   d. A facility must cease performing mammography after its first deficiency.

7. The American College of Radiology (ACR) testing packet includes a dosimeter that must be exposed on a phantom image, and the recorded dose must be below ______ mGy.
   a. 1
   b. 2
   c. 3
   d. 4

8. The quality control test that measures the detector’s ability to distinguish between an object in an image and image noise is called:
   a. signal-to-noise ratio.
   b. contrast-to-noise ratio.
   c. modulator transfer function.
   d. automatic optimization parameters.

9. A repeat and reject analysis must be performed ______ with a minimum of ______ patients.
   a. monthly; 250
   b. monthly; 350
   c. quarterly; 250
   d. quarterly; 350

10. Which of the following is true when evaluating a phantom image?
    a. A minimum of 4 fibers, 4 speck groups, and 3 masses must be visualized.
    b. If 3 specks are visualized, they should be counted as one point.
    c. Artifacts must be recorded but not deducted from the overall score.
    d. A mass that is visualized in its correct location without a circular appearance is counted as 0.5 point.

11. A level 3 violation is the most serious finding on an annual inspection.
    a. true
    b. false

12. The FDA has determined that each manufacturer’s digital breast tomosynthesis system is considered a(n) ______ mammographic modality.
    a. existing
    b. separate
    c. combined new
    d. unexamined

13. Before January 1, 2016, ______ standards were not required to earn ACR Breast Imaging Center of Excellence designation.
    a. mammography
    b. breast ultrasonography
    c. stereotactic breast biopsies
    d. breast magnetic resonance imaging

14. Repeat analysis for repeated patient exposures during stereotactic breast biopsy should be performed:
    a. monthly.
    b. quarterly.
    c. semiannually.
    d. annually.

Your post-test is now complete.
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