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## **ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF SCREENING AND DIAGNOSTIC MAMMOGRAPHY**

### **PREAMBLE**

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

### **I. INTRODUCTION**

Periodic mammography screening of age-appropriate asymptomatic women is currently the only imaging modality that has been shown by the preponderance of data to reduce breast cancer mortality [1-3]. Unlike screening mammography, diagnostic mammography is intended to provide specific analytic evaluation of patients with clinical or screen-detected abnormalities. A screening mammogram is an X-ray examination of the breast of an asymptomatic woman performed in order to detect breast cancer before it becomes clinically evident. A diagnostic mammogram is an X-ray examination of the breast of a patient who has signs or symptoms of breast disease or who has a possible abnormality detected on screening mammography or by other imaging technique [4].

It is essential that all mammography be performed and interpreted with the highest quality possible [5]. Key points to be considered are the criteria for credentialing professionals (radiologists, radiologic technologists, and medical physicists), equipment specifications, monitoring and maintenance schedules, standards for image quality, standardized image evaluation procedures, meticulous record keeping, and periodic review of data for outcomes of the mammography services. All mammography must

be performed in concordance with the Mammography Quality Standards Act (MQSA) final rule as published by the Food and Drug Administration (FDA) [6]. Nothing in this document should be construed to contradict those regulations.

## II. DEFINITIONS

### A. Screening Mammography

Screening mammography is a radiological examination performed to detect unsuspected breast cancer in asymptomatic women. Standard views are obtained, and thus the interpreting physician does not need to be present at the facility to monitor the examination when the patient is imaged.

### B. Diagnostic Mammography

Diagnostic mammography is a radiographic examination performed to evaluate patients who have signs and/or symptoms of breast disease, imaging findings of concern, or prior imaging findings requiring specific follow-up. Diagnostic mammography requires direct supervision.<sup>1</sup>

## III. GOALS

The goal of all mammography is the detection and evaluation of breast cancer and other breast diseases. The goal of diagnostic mammography is to obtain information that leads to specific interpretive conclusions and/or further diagnostic and management recommendations or courses of action. The patient's history, symptoms, and signs, the reported findings on physical examination, and results of any prior mammography will focus the diagnostic breast evaluation. A diagnostic mammogram should be performed under the direct supervision of a physician qualified in mammography under MQSA.

## IV. PATIENT SELECTION

### A. Screening Mammography

#### 1. Indications

Screening mammography is indicated for asymptomatic women 40 years of age or older. It is reasonable to institute screening mammography at an earlier age for high risk women. Symptomatic women, and women with a previously detected abnormality for whom short interval follow-up or further evaluation has

been recommended, are not candidates for screening mammography.

#### 2. Frequency

Asymptomatic women 40 years of age or older should have an annual screening mammogram. It is unclear at what age, if any, women cease to benefit from screening mammography. Because this age is likely to vary depending on the individual's overall health, the decision as to when to stop routine mammography screening should be made on an individual basis by each woman and her physician.

#### 3. Self-referred woman

For screening mammography, a "self-referred" woman is one who refers herself for medical services and who does not have an identified referring physician or other health care provider. To maximize utilization of screening, direct access by individuals is permissible without requiring physician referral in advance. However, screening facilities that elect to accept self-referred patients must have procedures for referring them to a qualified health care provider if abnormal clinical or mammographic findings are present.

#### 4. Self-requesting woman

A self-requesting woman comes for mammography on her own initiative but is able to provide the name of her personal physician or health care provider. In cases where the provider declines to accept the mammography report from the mammography facility, the facility should treat the woman as if she were self-referred [7].

#### 5. Breast implants

Asymptomatic women with breast implants may undergo screening mammography. At the discretion of the facility, asymptomatic women with breast implants may receive a diagnostic mammogram.

### B. Diagnostic Mammography

Diagnostic mammography may be appropriate for patients:

1. With a specific focus of clinical concern including, but not limited to, mass, induration, axillary lymphadenopathy, some types of nipple discharge, skin changes, or persistent focal areas of pain or tenderness.

<sup>1</sup>Direct supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision may also be accomplished via telemammography as long as the interpreting physician is immediately available.

2. With a possible radiographic abnormality detected on screening mammography.
3. Recommended for short-interval follow-up (e.g., less than 1 year) for probably benign radiographic findings as defined by the ACR Breast Imaging Reporting and Data System (BI-RADS®) [8].
4. Whose examination requires direct involvement of the radiologist for special views, physical breast examination, or consultation.
5. Who have been treated for breast cancer. At the discretion of the facility, asymptomatic women may undergo screening or diagnostic mammography [9].

If a woman arriving for a screening examination indicates she has a clinical problem (with the exception of bilateral breast pain), the facility should have a process by which she is converted into a diagnostic case, or there should be some means to have her mammogram brought to the attention of the reading radiologist to avoid a delay in reporting.

#### C. The Augmented Breast

Facilities must have procedures in place to inquire whether patients have breast implants prior to the actual mammographic examination. The facility and/or interpreting physician can then determine whether the woman with breast implants will be imaged at that facility. For asymptomatic women, mammography may be performed as a screening or, at the discretion of the facility, a diagnostic examination. However, if the facility does not provide implant imaging services, it should refer the patient to other facilities that provide such services.

#### D. Pregnancy

For the pregnant or potentially pregnant patient, see the [ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#).

However, the potential radiation risk of mammography to the fetus is minimal [10,11]. Shielding should be used, as appropriate.

### V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiological technologists who work in mammography must meet the requirements in the MQSA final rule as published by the FDA [6].

### VI. SPECIFICATIONS OF THE EXAMINATION

#### A. Screening Mammography

The screening examination should ordinarily be limited to craniocaudal (CC) and mediolateral oblique (MLO) views of each breast. On occasion, supplemental views may be required to visualize breast tissue completely or optimally, but such views are not ordinarily part of the routine screening examination except for women with implants [12]. Views may be modified to accommodate patient positioning limitations.

#### B. Diagnostic Mammography

A diagnostic mammogram may include MLO, CC, and/or additional views to evaluate an area of clinical or radiographic concern. Additional mammographic views might include spot compression, spot compression with magnification, tangential views, or other special views [12-14]. When selecting a view, the proximity of the area of concern to the image receptor should be considered [12].

#### C. Digital Mammography

Digital mammography has been shown to be at least equivalent in accuracy to screen-film mammography [15]. In some patient subgroups, digital mammography may have improved accuracy compared to screen-film mammography. Digital mammography systems must produce images of diagnostic quality at least equivalent to screen-film mammography at the same or lower radiation dose [6].

#### D. Request for Mammography

The written or electronic request for a diagnostic mammography examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason(s) for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for a diagnostic examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with

the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006)

#### E. Image Labeling

Adequate documentation of pertinent patient and technical information is essential for high-quality patient care. All radiographic images should be labeled in accordance with the current ACR Mammography Quality Control Manual [12]. Both hardcopy and softcopy labeling must include the following information in a permanent, legible, and unambiguous manner, placed so as not to obscure anatomic structures [6]:

<b>Mammographic Image Identification</b>
<ol style="list-style-type: none"><li>1. Facility name and location, including city, state, and zip code.</li><li>2. Patient's first and last names.</li><li>3. Unique identification number and/or date of birth.</li><li>4. Examination date.</li><li>5. Technologist's initials (or identification number).</li><li>6. Cassette (screen) number for nondigital and computed radiography images.</li><li>7. Mammographic unit identification, if there is more than one unit in the facility.</li><li>8. View and laterality (placed on the image in a position near the axilla).</li></ol>

#### F. Markers

Appropriate markers may be used to identify areas of clinical concern, areas of prior intervention, skin abnormalities, etc. and to help correlate them with ultrasound findings. Radiographic demonstration of surface markers may provide positioning guidance for routine views, spot compression, tangential, and other views. The markers and type of lesion marked should be identified on the image itself or, in the case of digital images, in the report or printed at the bottom of all reports. This is especially important when reports and mammograms are sent to other facilities.

#### G. The Augmented Breast

Evaluation of the augmented breast should include, when possible, standard CC and MLO views as well as implant displaced views in both projections [12]. Lateral views may be helpful in cases where the implant cannot be displaced.

#### H. Viewing Issues

##### 1. General

- a. Viewboxes and electronic viewing stations should be positioned to avoid light from

windows, other viewboxes, and other sources of bright light, either direct or reflected. General lighting should be diffuse and at a low level.

- b. All viewboxes should be checked periodically to ensure that they are in optimal condition.

##### 2. Screen-film

- a. Screen-film images should be viewed in accordance with the ACR Mammography Quality Control Manual [12].
- b. Variable-intensity viewboxes that can provide high intensity light (greater than  $3,000 \text{ cd/m}^2$ ) are recommended for viewing conventional mammograms [12].
- c. It is essential to mask the area around the mammograms to exclude extraneous light.
- d. Bright lights must also be available for viewing screen-film mammograms [6].

##### 3. Digital mammography

- a. Hardcopy images obtained from digital mammographic systems should be viewed in accordance with the [ACR-AAPM-SIIM Practice Guideline for Determinants of Image Quality in Digital Mammography](#).
- b. Electronic displays (image monitors) should be operated at the luminance specified by the manufacturer and must be evaluated according to the image quality control specified by the manufacturer [16].
- c. High intensity viewboxes (a minimum of  $3,000 \text{ cd/m}^2$ ) may also be useful for reading hardcopy output of digital mammography (depending on the optical density of the film being evaluated).
- d. Digital images should be reviewed at full resolution to obtain maximum possible diagnostic information. The use of electronic magnification or zoom does not replace the use of geometrically obtained magnification views.
- e. As digital mammography becomes more widely used, radiologists will compare digital images with previous conventional screen-film mammograms. These comparison films should be viewed under the same conditions described for screen-film.

#### I. Double Reading and Computer-Aided Detection

Double reading and computer-aided detection (CAD) may slightly increase the sensitivity of mammographic interpretation, and may be used. However, this sensitivity

is at the expense of decreased specificity with increased recall and, at this time, they are not considered standards of care.

#### J. Image Retention

Original mammograms must be retained by a facility for not less than 5 years and, in some cases, at least 10 years if no additional mammograms of the patient are performed at the facility. Longer retention periods may be mandated by state or local laws. For digital mammography, the facility must maintain, in retrievable form, either the original or lossless-compressed full-field digital data or hardcopy films of final interpretation quality for these time periods. If screen-film images have been digitized, the analog images must be retained [16].

### VII. COMPARISON WITH PRIOR BREAST IMAGING STUDIES

Comparison with available prior breast imaging studies is an important part of mammography [17]. Digitized images of previously obtained screen-film mammograms may be used for comparison purposes if the interpreting physician deems that acceptable [16]. If previous breast imaging studies are needed for assessing mammographic findings, an attempt should be made to obtain them.

Facilities must be able to provide images to new mammography facilities or referring physicians with the original high diagnostic quality. Upon the written request of the patient, original films and copies of the report must be transferred to a health care provider or to the patient directly. For digital examinations, the facility must be able to provide the medical institution, physician, health care provider, patient, or patient's representative with hardcopy films of final interpretation quality or, when it is acceptable to the recipient, with original or lossless electronic compressed images. Digital mammograms provided on computer discs may not be optimal for diagnostic purposes when viewed on non-high resolution monitors. Laser hardcopy printers for digital mammographic images should support the Integrating the Healthcare Enterprise (IHE) Mammography Image Profile and the IHE Consistent Presentation of Images Profile [18]. In addition it is helpful to have the Secure Node or Secure Application actor: IHE Audit Trail and Node Authentication [19].

### VIII. DOCUMENTATION AND COMMUNICATION OF RESULTS

#### A. The Mammographic Report

If a diagnostic mammogram is performed, the clinical or radiographic concern(s) that prompted the examination should be acknowledged.

The location of any mammographic abnormality can be indicated by using clock face notation and/or quadrant of the breast; and/or location within the anterior, middle, or posterior third of the breast; and/or distance from the nipple. The mammogram report should describe detected abnormalities and pertinent observations, establish levels of suspicion of malignancy based on the imaging findings, and provide recommendations for diagnosis, patient management, and follow-up. If additional, separate breast imaging studies or procedures are performed or are available, they may be correlated in the diagnostic mammography report. The ACR BI-RADS® is available to provide a framework for reporting, lesion assessment, imaging-pathologic correlation, and quality improvement. Reporting should be in accordance with the [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#) and consistent with the MQSA final rule published by the FDA [6].

A description of detected abnormalities and recommendations for subsequent follow-up studies should be included in the report. Overall final assessment of findings may be based on all imaging studies performed that day. In addition, they must be classified according to the FDA-approved final assessment categories [6] and should follow the categories defined in the ACR BI-RADS® 4th edition, 2003 [8] (or any subsequent revisions).

Mammographic Assessment	BI-RADS® Assessment Category	Description
Incomplete	0	Need additional imaging evaluation and/or prior mammograms for comparison.
Complete	1 2 3 4 5 6	Negative. Benign finding(s). Probably benign finding – initial short-interval follow-up suggested. Suspicious abnormality – biopsy should be considered. Highly suggestive of malignancy – appropriate action should be taken. Known biopsy – proven malignancy – appropriate action should be taken.

BI-RADS® Category 0 assessments are assigned to incomplete evaluations. Additional mammography views, ultrasound, or previous studies are necessary to assign a

final assessment category. If additional imaging is recommended, the facility should have the capacity to perform the recommended examinations, or it must make an arrangement with a cooperating facility where it can refer the patient for the performance of these examinations.

A category 3, 4, or 5 assessment is not recommended for a screening mammogram, although in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. Patients with screening abnormalities will be given a BI-RADS® category 0 and recalled for further diagnostic studies. Reporting should be in accordance with the [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#) and be consistent with the MQSA final rule published by the FDA [6].

B. Communication of Mammography Results to Health care Providers (when the patient has a referring health care provider or has named a health care provider)

1. Under MQSA, a facility must provide a written report of the mammography examination, including the name of the patient and an additional patient identifier, to the patient's health care provider as soon as possible, but no later than 30 days from the date of the mammography examination.
2. However, in cases where the assessment is a BI-RADS® category 4 or 5, the facility should make a reasonable attempt to communicate directly with the health care provider as soon as possible. This should occur within 3 working days from the date of interpretation, using either documented verbal communication or a written report. If the health care provider is unavailable, a report should be given to the responsible designee of the health care provider. The actual or attempted direct communication should be documented in the mammogram report.

C. Written Communication to Patients

1. Under MQSA, a facility must send or give directly to all patients a written summary, in lay terms, of the results of the study no later than 30 days from the date of the mammographic examination.
2. However, in cases where the assessment is a BI-RADS® category 4 or 5, the facility should make a reasonable attempt to communicate the results to the patient as soon as possible. This should occur within 5 working days from the date of interpretation. The actual or attempted communication should be documented.

3. For self-referred patients (patients who do not name a health care provider), the facility must send or directly give the patient the actual mammographic report and a summary in lay terms no later than 30 days from the date of the mammographic examination. Facilities must also have a system to refer such patients to a health care provider when clinically indicated. Reports with an assessment of BI-RADS® category 0, 3, 4, or 5 should be communicated as soon as possible to the self-referred patient. This should occur within 5 working days from the date of interpretation. The actual or attempted communication should be documented.

## IX. EQUIPMENT SPECIFICATIONS

A. Mammography equipment must meet the MQSA final rule published by the FDA [6]. Equipment used for diagnostic mammography must have magnification and spot-compression capability.

B. Digital mammography systems differ in anode material, detector technology, grids, image processing, and display workstations, and have large data storage requirements. (See the [ACR–AAPM–SIIM Practice Guideline for Determinants of Image Quality in Digital Mammography](#).)

1. The X-ray tube target and beam filtration should be capable of producing an X-ray spectrum matched to the breast thickness and composition and to the response characteristics of the X-ray detector so as to provide an acceptable signal-to-noise ratio at an acceptable dose to the breast. The inherent high contrast of digital systems may allow the use of a slightly higher kVp, which may decrease radiation dose while maintaining image contrast.
2. Most digital detectors also serve as sensors for automatic exposure control (AEC). Multiple AEC modes may be useful, including automatic spectral selection. A display of the target, filter, actual kilovoltage, mAs, or radiation level used during the exposure should be provided and retained or be retrievable.
3. The digital mammography system should include a display system so that the technologist can view the digital image at the time of the examination to ensure that the positioning and image quality are acceptable, as well as a high-quality high resolution display system to allow image interpretation by the radiologist. Any electronic display system should allow control of image display settings to enable the interpreting

physician to assess all of the relevant information in the digital image.

## X. FREE STANDING, MOBILE, AND TELEMAMMOGRAPHY SETTINGS

Screening mammography may take place in radiology settings where there may not be an interpreting physician in attendance. Adequate technical supervision can be maintained in such facilities through periodic, at least quarterly, review by the supervising radiologist. This review should include clinical image quality and quality assurance procedures, all quality control documentation, and a determination that safe operating procedures are used. The mammography services provided must follow all of the previously mentioned guidelines with strict adherence to documented protocols. The supervising radiologist should provide constructive feedback to the technologist on all areas that need improvement.

If mammography is performed in a mobile setting, the mammography quality control technologist must verify satisfactory performance of the mobile unit using a test method that establishes the adequacy of the image quality before any mammograms are performed at each location [6,12].

With telemammography, diagnostic mammography may be performed in settings where there may not be an interpreting physician on-site and supervision is directed from off-site. The mammography offered must follow ACR guidelines and the MQSA final rule as published by the FDA [6] with strict adherence to documented protocols.

## XI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as “as low as reasonably achievable (ALARA).”

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR

Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

## XII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

### A. General

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (<http://www.acr.org/guidelines>).

### B. Quality Control

A documented quality control program with procedure manuals and logs must be maintained and be in compliance with the MQSA final rule published by the FDA [6]. The current ACR Mammography Quality Control Manual is a reference resource that provides guidance [12]. The required and recommended tests for screen-film mammography are listed in the appendix. Accreditation by the ACR Mammography Accreditation Program (MAP) documents compliance with the requirements in this section. For digital mammography, the quality control program must be substantially the same as that recommended by the digital manufacturer [6].

### C. Radiation Dose

The average glandular dose delivered by a single craniocaudal view of a 4.2-cm thick, compressed breast consisting of 50% glandular and 50% adipose tissue must not exceed 0.3 rad (3.0 milligray), although it is generally much lower [20]. This applies to both screen-film and full-field digital mammography [6,12].

### D. Medical Outcomes Audit

Each facility must establish and maintain a mammography medical outcomes audit program [8,21,22] to follow up positive mammographic assessments (BI-RADS® categories 4 and 5). In addition, follow-up of category 0 assessments is encouraged to correlate pathology results with the interpreting physician's findings [6,23]. This program must be designed to ensure reliability, clarity, and accuracy in the interpretation of mammograms. Analysis of these outcomes data must be performed for all interpreting physicians at a facility, individually and collectively, at least annually. It is understood that in most practice situations it will not be

possible to obtain follow-up information on all positive mammograms.

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### Drafting Committee

Lawrence W. Bassett, MD, Chair

Carl J. D'Orsi, MD

Roberta A. Jong, MD

Carol H. Lee, MD

Barbara S. Monsees, MD

Priscilla F. Butler, MS

### Joint Committee on Breast Imaging

Lawrence W. Bassett, MD, Chair

Wendie A. Berg, MD, PhD

Robyn L. Birdwell, MD

R. James Brenner, MD, JD

Christopher E. Comstock, MD

Carl J. D'Orsi, MD

Nanette D. DeBruhl, MD

W. Phil Evans, III, MD

Lenore I. Everson, MD

Dione Marie Farria, MD

Jennifer A. Harvey, MD

Cheryl R. Herman, MD

Roberta A. Jong, MD

Stuart S. Kaplan, MD

Laura Liberman, MD

Mary C. Mahoney, MD

Ellen B. Mendelson, MD

Elizabeth A. Morris, MD

Jay R. Parikh, MD

Rachel A. Rabinovitch, MD

Eric L. Rosen, MD

Carol H. Lee, MD, Chair, Commission

### Comments Reconciliation Committee

Leonard Berlin, MD, Co-Chair

Thomas B. Fletcher, MD, Co-Chair

Harry C. Knipp, MD, Co-Chair

Debra L. Acord, MD

Lawrence W. Bassett, MD

Nancy A. Beauvage, MD

Carl J. D'Orsi, MD

Roberta A. Jong, MD

Mary M. Karst, MD

Alan D. Kaye, MD

Daniel B. Kopans, MD

David C. Kushner, MD

Paul A. Larson, MD

Carol H. Lee, MD

Lawrence A. Liebscher, MD

Barbara S. Monsees, MD

Lorenz T. Ramseyer, MD

Bonna Rogers-Neufeld, MD

J. Anthony Seibert, PhD

## REFERENCES

1. Smart CR, Hendrick RE, Rutledge JH, 3rd, Smith RA. Benefit of mammography screening in women ages 40 to 49 years. Current evidence from randomized controlled trials. *Cancer* 1995;75:1619-1626.
2. Tabar L, Chen HH, Fagerberg G, Duffy SW, Smith TC. Recent results from the Swedish Two-County Trial: the effects of age, histologic type, and mode of detection on the efficacy of breast cancer screening. *J Natl Cancer Inst Monogr* 1997;43-47.
3. Tabar L, Fagerberg G, Duffy SW, Day NE, Gad A, Grontoft O. Update of the Swedish two-county program of mammographic screening for breast cancer. *Radiol Clin North Am* 1992;30:187-210.
4. Lee CH, Smith RC, Levine JA, Troiano RN, Tocino I. Clinical usefulness of MR imaging of the breast in the evaluation of the problematic mammogram. *AJR* 1999;173:1323-1329.
5. Destouet J, Bassett L, Yaffe M, et al. The ACR's mammography accreditation program: ten years of experience since MQSA. *JACR* 2005;2:585-594.
6. Food and Drug Administration. *Mammography Quality Standards; Final Rule* [Available at: [http://www.fda.gov/CDRH/MAMMOGRAPHY/mqs\\_a-act.html](http://www.fda.gov/CDRH/MAMMOGRAPHY/mqs_a-act.html). Accessed September 25, 2007.
7. Bassett L, Hendrick E, Bassford TL, et al. U.S. Department of Health and Human Services. *Quality determinants of mammography: clinical practice guideline no. 13*. Vol AHCPR publication no. 95-0632. Rockville, Md: Agency for Health Care Policy and Research; 1994.
8. D'Orsi C, Bassett L, Berg W, et al. *ACR Breast Imaging Reporting and Data System (BI-RADS Atlas)*. 4th ed. ed. Reston, Va: American College of Radiology; 2003.
9. Kopans DB, Moore RH, McCarthy KA, et al. Should women with implants or a history of treatment for breast cancer be excluded from mammography screening programs? *AJR* 1997;168:29-31.
10. Kopans DB. *Breast Imaging: Fetal Radiation Exposure*. Philadelphia, Pa: Lippincott Williams & Wilkins; 1998;17:445.
11. Sechopoulos I, Suryanarayanan S, Vedantham S, D'Orsi C, Karella A. Radiation dose to organs and tissues from mammography: a computational approach. *Radiology* 2008;246:434-443.

12. Hendrick RE, Bassett L, Botsco MA, et al. *Mammography Quality Control Manual*. Reston, Va: American College of Radiology; 1999.
13. Faulk RM, Sickles EA. Efficacy of spot compression-magnification and tangential views in mammographic evaluation of palpable breast masses. *Radiology* 1992;185:87-90.
14. Feig SA. The importance of supplementary mammographic views to diagnostic accuracy. *AJR* 1988;151:40-41.
15. Pisano ED, Gatsonis C, Hendrick E, et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. *N Engl J Med* 2005;353:1773-1783.
16. Department of Health and Human Services, Food and Drug Administration. *Policy Guidance Help System* [Available at: <http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM>. Accessed August 28, 2007.]
17. Burnside ES, Sickles EA, Sohlich RE, Dee KE. Differential value of comparison with previous examinations in diagnostic versus screening mammography. *AJR* 2002;179:1173-1177.
18. IHE Consistent Presentation of Images Profile [Available at: <http://www.ihe.net/mammo/going-digital-mammography.cfm>. Accessed August 28, 2007.]
19. IHE Audit Trail & Node Authentication. Available at: [http://wiki.ihe.net/index.php?title=main\\_page](http://wiki.ihe.net/index.php?title=main_page). Accessed August 28, 2007.
20. Haus AG, Yaffe MJ, Feig SA, et al. Relationship between phantom failure rates and radiation dose in mammography accreditation. *Med Phys* 2001;28:2297-2301.
21. Rosenberg RD, Yankaskas BC, Abraham LA, et al. Performance benchmarks for screening mammography. *Radiology* 2006;241:55-66.
22. Sickles EA, Miglioretti DL, Ballard-Barbash R, et al. Performance benchmarks for diagnostic mammography. *Radiology* 2005;235:775-790.
23. Sickles EA. Quality assurance: how to audit your own mammography practice. *Radiol Clin North Am* 1992;30:265-275.

**Suggested Reading** (Additional articles that are not cited in the document but that the committee recommends for further reading on this topic)

24. Brenner RJ. Asymmetric densities of the breast: strategies for imaging evaluation. *Semin Roentgenol* 2001;36:201-216.
25. Brenner RJ. Medicolegal aspects of breast imaging. *Radiol Clin North Am* 1992;30:277-286.
26. DeBruhl ND, Bassett LW, Jessop NW, Mason AM. Mobile mammography: results of a national survey. *Radiology* 1996;201:433-437.
27. Dean JC, Ilvento CC. Improved cancer detection using computer-aided detection with diagnostic and

- screening mammography: prospective study of 104 cancers. *AJR* 2006;187:20-28.
28. D'Orsi CJ, Debord MD. Communication issues in breast imaging. *Radiol Clin North Am* 1995;33:1231-1245.
29. Eklund GW, Cardenosa G. The art of mammographic positioning. *Radiol Clin North Am* 1992;30:21-53.
30. Eklund GW, Cardenosa G, Parsons W. Assessing adequacy of mammographic image quality. *Radiology* 1994;190:297-307.
31. Evans WP. Breast masses: appropriate evaluation. *Radiol Clin North Am* 1995;33:1085-1108.
32. Hendrick RE. Mammography legislation. In: Bassett LW, Jackson V, eds. *Diagnosis of Diseases of the Breast*. Philadelphia, Pa: WB Saunders; 1997:149-150.
33. Hendrick RE, Chrvala CA, Plott CM, Cutter GR, Jessop NW, Wilcox-Buchalla P. Improvement in mammography quality control: 1987-1995. *Radiology* 1998;207:663-668.
34. IHE Radiology Technical Framework. *Mammography image (MAMMO) profile*. [www.ihe.net/Technical\\_Framework/upload/IHE\\_Rad\\_1344TF\\_Suppl\\_MAMMO\\_T1\\_2006-04-13.pdf](http://www.ihe.net/Technical_Framework/upload/IHE_Rad_1344TF_Suppl_MAMMO_T1_2006-04-13.pdf). Accessed February 23, 2007.
35. Institute of Medicine. Developing technologies for the early detection of breast cancer. In: Nass SJ, Henderson C, Lashop JC, eds. *Mammography and Beyond*. Washington, DC: National Academy Press; 2001:1-14.
36. Jackson VP. Diagnostic mammography. *Radiol Clin North Am* 2004;42:853-870.
37. Karssemeijer N, Otten JD, Verbeek Al, et al. Computer-aided detection versus independent double reading of masses on mammograms. *Radiology* 2003;227:192-200.
38. Lanyi M. Differential diagnosis of microcalcifications. In: Friedrich M, Sickles EA, eds. *Radiological diagnosis of breast diseases*. Berlin, Germany: Springer-Verlag; 1997:89-136.
39. Pisano ED, Yaffe MJ. Digital mammography. *Radiology* 2005;234:353-362.
40. Seo BK, Pisano ED, Kuzniak CM, et al. The positive predictive value for diagnosis of breast cancer full-field digital mammography versus film-screen mammography in the diagnostic mammographic population. *Acad Radiol* 2006;13:1229-1235.
41. Sickles EA. Breast masses: mammographic evaluation. *Radiology* 1989;173:297-303.
42. Sickles EA. Management of probably benign breast lesions. *Radiol Clin North Am* 1995; 33:1123-1130.
43. Sickles EA. Periodic mammographic follow-up of probably benign lesions: results in 3,184 consecutive cases. *Radiology* 1991;179:463-468.
44. Sickles EA. Practical solutions to common mammographic problems: tailoring the examination. *AJR* 1988;151:31-39

## APPENDIX

The following table applies to screen-film mammography only. For full-field digital mammography, the FDA requires that the facility's quality assurance program be substantially the same as the quality assurance program recommended by the image receptor (i.e., digital detector) manufacturer. Mammography facilities should refer to their digital manufacturer's quality control (QC) manual for a list of the required QC tests (including tests for peripheral devices such as monitors and laser film printers).

ACR-Recommended and FDA-Required Mammographic Quality Control Tests				
	Test	Minimum Frequency	Required by MQSA	Timeframe for Corrective Action
<b>Technologist Tests</b>	Darkroom cleanliness	Daily		
	Processor quality control	Daily	✓	Immediately
	Mobile unit QC	Daily	✓	Immediately
	Screen cleanliness	Weekly		
	Viewboxes and viewing conditions	Weekly		
	Phantom images	Weekly	✓	Immediately
	Visual checklist	Monthly		
	Repeat analysis	Quarterly	✓	Within 30 days of the test date
	Analysis of fixer retention in film	Quarterly	✓	Within 30 days of the test date
	Darkroom fog	Semi-annually	✓	Immediately
<b>Medical Physicist Tests</b>	Screen-film contact	Semi-annually	✓	Immediately
	Compression	Semi-annually	✓	Immediately
	Mammographic unit assembly evaluation	Annually	✓	Within 30 days of the test date
	Collimation assessment	Annually	✓	Within 30 days of the test date
	Evaluation of system resolution	Annually	✓	Within 30 days of the test date
	AEC system performance	Annually	✓	Within 30 days of the test date
	Uniformity of screen speed	Annually	✓	Within 30 days of the test date
	Artifact evaluation	Annually	✓	Within 30 days of the test date
	Image quality evaluation	Annually	✓	Immediately
	kVp accuracy and reproducibility	Annually	✓	Within 30 days of the test date
	Beam quality assessment	Annually	✓	Within 30 days of the test date
	Breast exposure and AEC reproducibility	Annually	✓	Within 30 days of the test date

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\*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

### Development Chronology for this Guideline

2008 (Resolution 24)