ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF SCREENING 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 on 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. It should be recognized, therefore, 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 asymptomatic women has been shown to reduce breast cancer mortality. The principles of quality for mammography do not differ basically from those applicable to other radiological examinations. Key points to be considered are the criteria for credentialing professionals, 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.
II. DEFINITION AND GOAL

Screening mammography is a radiological examination to detect unsuspected breast cancer in asymptomatic women. This examination may be performed without a physician in attendance.

III. PATIENT SELECTION

A. Indication

Screening mammography is indicated in asymptomatic women at least 40 years of age. It is reasonable to institute screening mammography at an earlier age in women with high-risk factors. Some women may not be candidates for screening mammography (see the ACR Practice Guideline for the Performance of Diagnostic Mammography).

B. Frequency

Asymptomatic women at least 40 years of age should have an annual mammographic screening examination.

It is unclear at what age, if any, women cease to benefit from screening mammography. Because this age is likely to vary with the individual depending on her 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.

C. Self-Referral

For screening mammography, the term "self-referred" is defined as a woman who refers herself for medical services and who does not have an identified referring physician or other healthcare 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 such patients must have procedures for referral to a qualified physician who has agreed to assume clinical responsibility.

D. Pregnancy Policy

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding with the study (Res. 24, 1995).

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiological technologists who work in mammography must meet the Mammography Quality Standards Act (MQSA) final rule as published by the Food and Drug Administration (FDA) (see Appendix A).

V. EQUIPMENT SPECIFICATIONS

Mammography equipment must meet MQSA final rule as published by the FDA (see Appendix B).

VI. SPECIFICATIONS OF THE EXAMINATION

The examination should ordinarily be limited to craniocaudal and mediolateral oblique 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. When pathology is suspected, a recommendation for additional imaging studies, diagnostic mammography, or biopsy may be warranted.

If a breast physical examination is not available at the screening site, women should be informed that physical examination is a complementary and necessary procedure.

A. Comparison with Prior Mammograms

An attempt should be made to obtain prior mammograms when the interpreting physician deems it necessary. Under the MQSA final rule, facilities must provide original films.

B. Film Labeling

Adequate documentation of the study is essential for high-quality patient care. All radiographic images should be labeled in accordance with the current ACR Mammography Quality Control Manual and MQSA final rule. Film labeling should include an identification label containing:

1. Facility name and location, including city, state, and zip code
2. Patient’s first and last names
3. Unique identification number and/or date of birth
4. Examination date
5. Technologist’s initials (or identification number)
6. Cassette (screen) number
7. Mammographic unit identification
8. View and laterality
C. Viewing Issues

1. Viewboxes
Viewboxes should provide a relatively high luminance level. This is generally higher than that required for viewing conventional radiographs. It is essential to mask the area around the mammograms to exclude extraneous light, which reduces image contrast and limits maximum densities that can be seen. The facility shall make special lights for film illumination (e.g., hot lights capable of producing light levels greater than that provided by the viewbox) available to interpreting physicians. Film masking devices must be available. All viewboxes should be checked periodically to ensure that they are in optimal condition.

2. Viewing conditions
Contrast is extremely important in the mammographic image and is degraded by extraneous light. Viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. General lighting should be at a low level and diffuse.

D. Film Retention

Original mammograms shall be retained by a facility for a period of 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. Upon the written request of the patient, original films and copies of the report shall be transferred to a healthcare provider or to the patient directly.

E. Free-Standing and Mobile Settings

Screening mammography may take place in radiology settings where there may not be a physician in attendance. The mammography offered must follow all of the previously mentioned guidelines with strict adherence to documented protocols.

In addition, at each location, the mammography provider shall verify satisfactory performance of mobile mammography unit(s) using a test method that establishes the adequacy of the image quality before any mammograms are performed.

VII. DOCUMENTATION AND COMMUNICATION OF RESULTS

A. A definitive diagnosis is not usually rendered, although in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. More commonly, patients with abnormalities in the high-probability group will be recalled for further diagnostic studies. Reporting should be in accordance with the ACR Practice Guideline for Communication: Diagnostic Radiology and be consistent with the MQSA final rule.

A description of abnormalities detected by screening and recommendations for subsequent follow-up studies should be included in the report. The overall final assessment of findings shall be classified using the following categories defined in the ACR Breast Imaging Reporting and Data System (BI-RADS®), 3rd ed., 1998.

1. Assessment is incomplete
   Incomplete needs additional imaging evaluation
   [Category 0]

   This category has been assigned to incomplete evaluations. Additional mammography views, ultrasound, or previous studies are necessary to assign a final assessment category.

2. Assessment is complete - final categories
   - Negative [Category 1]
   - Benign finding [Category 2]
   - Probably benign finding [Category 3]
   - Suspicious abnormality [Category 4]
   - Highly suggestive of malignancy [Category 5]

   Follow-up diagnostic imaging studies should be done under the direct supervision of a qualified mammography physician.

B. Communication of Mammography Results to Healthcare Providers

1. When the patient has a referring healthcare provider or has named a healthcare provider, the facility shall:
   a. Provide a written report of the mammography examination, including the name of the patient and an additional patient identifier, to that healthcare provider as soon as possible, but no later than 30 days from the date of the mammography examination; and
   b. Make reasonable attempts to communicate with the healthcare provider as soon as possible, if the assessment is "suspicious" or "highly suggestive of malignancy." If the healthcare provider is unavailable, a report
should be given to the responsible designee of the healthcare provider.

2. Written Communication to Patients
   a. The facility shall send or give directly to all patients a written summary, in lay terms, of the results of the screening study no later than 30 days from the date of the mammographic examination.
   b. For self-referred patients (patients who do not name a healthcare 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. Reports in the categories of “needs additional imaging evaluation”, “probably benign short-interval follow-up”, “suspicious abnormality”, or “highly suggestive of malignancy” should be communicated to the self-referred patient in a manner that ensures receipt and documentation of the report. The report should indicate a need for further consultation with a physician, and a follow-up contact with the patient should be made to determine that she has consulted a physician for follow-up care.

VIII. QUALITY CONTROL PROGRAM

A documented quality control program with procedure manuals and logs must be maintained and be in compliance with the MQSA final rule. The current ACR Mammography Quality Control Manual should be followed for guidance. The manual includes the following tests:

A. Technologist's Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Darkroom cleanliness</td>
<td>Daily</td>
</tr>
<tr>
<td>2. Processor quality control</td>
<td>Daily*</td>
</tr>
<tr>
<td>3. Mobile unit quality control</td>
<td>Daily*</td>
</tr>
<tr>
<td>4. Screen cleanliness</td>
<td>Weekly</td>
</tr>
<tr>
<td>5. Viewboxes and viewing conditions</td>
<td>Weekly</td>
</tr>
<tr>
<td>6. Phantom images</td>
<td>Weekly*</td>
</tr>
<tr>
<td>7. Visual checklist</td>
<td>Monthly*</td>
</tr>
<tr>
<td>8. Repeat analysis</td>
<td>Quarterly*</td>
</tr>
<tr>
<td>9. Analysis of fixer retention in film</td>
<td>Quarterly*</td>
</tr>
<tr>
<td>10. Darkroom fog</td>
<td>Semiannually*</td>
</tr>
<tr>
<td>11. Screen-film contact</td>
<td>Semiannually*</td>
</tr>
<tr>
<td>12. Compression</td>
<td>Semiannually*</td>
</tr>
</tbody>
</table>

B. Medical Physicist's Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mammographic unit assembly evaluation</td>
<td>Annually*</td>
</tr>
<tr>
<td>2. Collimation assessment</td>
<td>Annually*</td>
</tr>
<tr>
<td>3. Evaluation of system resolution</td>
<td>Annually*</td>
</tr>
<tr>
<td>4. Automatic exposure control (AEC) system performance assessment</td>
<td>Annually*</td>
</tr>
<tr>
<td>5. Uniformity of screen speed</td>
<td>Annually*</td>
</tr>
<tr>
<td>6. Artifact evaluation</td>
<td>Annually*</td>
</tr>
<tr>
<td>7. Image quality evaluation</td>
<td>Annually*</td>
</tr>
<tr>
<td>8. kVp accuracy/reproducibility</td>
<td>Annually*</td>
</tr>
<tr>
<td>9. Beam quality assessment (half-value layer measurement)</td>
<td>Annually*</td>
</tr>
<tr>
<td>10. Breast entrance exposure, AEC reproducibility, average glandular dose, and radiation output rate</td>
<td>Annually*</td>
</tr>
<tr>
<td>11. Measurement of viewbox luminance, room illuminance, and color temperature</td>
<td>Annually</td>
</tr>
</tbody>
</table>

*Required under MQSA Final Rule.

Accreditation by the ACR Mammography Accreditation Program (MAP) would document compliance with the requirements in this section.

B. Radiation Dose

The average glandular dose delivered during 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. This applies to both screen-film and full-field digital mammography.

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure reliability, clarity, and accuracy for the interpretation of mammograms. Analysis of these outcome data shall be made individually and collectively for all interpreting
physicians at a facility at least annually. It is understood that in some practice situations it will not be possible to obtain follow-up information on all positive mammograms.

ACKNOWLEDGEMENTS

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REFERENCES


APPENDIX A

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Interpreting Physician

Initial qualifications:

Be licensed to practice medicine

and

Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada;

or

Have at least 3 months (2 months if initially qualified before April 28, 1999) of documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection.

and

Have 60 hours of documented Category I continuing medical education (CME) in mammography (40 hours if initially qualified before April 28, 1999), at least 15 of which must have been acquired in the 3 years immediately prior to the physician meeting his/her initial requirements.

and

Have interpreted mammograms from examinations of 240 patients within the 6 months immediately prior to the physician's qualifying date or in any 6 months within the last 2 years of residency, if the physician becomes board certified at his/her first possible opportunity.

and

The interpreting physician must receive at least 8 hours of training in any mammographic modality (e.g., digital) for which he or she was not previously trained before beginning to use that modality.

Continuing Experience:

Continue to interpret or multi-read at least 960 mammographic examinations over a 24-month period.

Continuing Education:

Earn at least 15 Category I CME hours in a 36-month period, at least six of which must be related to each mammographic modality used.

B. Medical Physicist

Initial Qualifications:

Either be licensed or approved by a state.

or

Be certified in Diagnostic Radiological or Imaging Physics by the ABR or the American Board of Medical Physics.

and

Either have a master's degree or higher in a physical science, 20 semester hours of physics, 20 contact hours of training in conducting surveys of mammography facilities, and experience in conducting mammography surveys of at least 10 units and at least 1 facility.

or

By April 28, 1999, have qualified as a medical physicist under the interim regulations, have a bachelor's degree or higher in a physical science, 10 semester hours of physics, 40 contact hours of training in conducting surveys of mammography facilities, and experience in conducting mammography surveys of at least 20 units and at least one facility.

and

Before surveying units of any mammographic modality (e.g., digital), the medical physicist must have at least 8 hours of training with that modality.
Continuing Experience:

Survey at least two mammography facilities and a total of at least six mammography units within a 24-month period.

Continuing Education:

Earn at least 15 CME hours/continuing education units (CEU’s) in a 36-month period, which includes hours of training appropriate to each mammographic modality for which physics services are provided.

C. Radiologic Technologist

Initial Qualifications:

Have general certification from the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists.

or

Be licensed to perform general radiographic procedures in a state. (Technologists are not required to have passed the ARRT special competency examination in mammography.)

and

Technologists initially qualifying on or after April 28, 1999 must meet the mammography-specific training requirements by having at least 40 hours of documented training in mammography, including:

1. Training in breast anatomy and physiology, positioning and compression, quality-assurance / quality-control techniques, and imaging of patients with breast implants.
2. Performance of a minimum of 25 mammography examinations under direct supervision of an appropriate MQSA-qualified individual.
3. At least 8 hours of training in using any mammographic modality (e.g., digital) before beginning to use that modality independently.

Continuing Experience:

Perform at least 200 mammography examinations in a 24-month period.

Continuing Education:

Earn at least 15 CEUs in a 36-month period that must include at least 6 CEUs in each mammographic modality used.

APPENDIX B

EQUIPMENT SPECIFICATIONS

A. Prohibited Equipment

Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in Section 1020.31(f)(3) of the Federal Register.

B. General

All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to Section 1010.2 of the Federal Register as meeting the applicable requirements of Sections 1020.30 and 1020.31 of the Federal Register in effect at the date of manufacture.

C. Motion of Tube-Image Receptor Assembly

1. The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.
2. The mechanism ensuring compliance with C.1 above shall not fail in the event of power interruption.

D. Image Receptor Sizes

1. Systems using screen-film image receptors shall provide, at a minimum, operation with image receptors of 18 x 24 cm and 24 x 30 cm.
2. Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.
3. Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

E. Beam Limitation and Light Fields

1. All systems shall have beam-lighting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.
2. For any mammography system with a light beam that passes through the X-ray beam-lighting device, the light shall provide an average illumination of not less than 160 lux (15 foot

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candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

F. Magnification

1. Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.
2. Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

G. Focal Spot Selection

1. When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.
2. When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.
3. When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

H. Compression

All mammography systems shall incorporate a compression device.

1. Application of compression. Effective October 28, 2002, each system shall provide:
   a. An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and
   b. Fine adjustment compression controls operable from both sides of the patient.
2. Compression paddle.
   a. Systems shall be equipped with different size compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs H.2.d and H.2.e below.
   b. Except as provided in paragraph H.2.c below, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.
   c. Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.
   d. The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.
   e. The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

I. Technique Factor Selection and Display

1. Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere [mA] and/or time) shall be available.
2. The technique factors (peak tube potential in kilovolt [kV] and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.
3. Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

J. Automatic Exposure Control

1. Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided (e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations).
2. The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.
   a. The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
   b. The selected position of the detector shall be clearly indicated.
3. The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.
K. X-Ray Film

The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

L. Intensifying Screens

The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

M. Film Processing Solutions

For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

N. Lighting

The facility shall make special lights for film illumination (e.g., hot lights capable of producing light levels greater than that provided by the viewbox) available to interpreting physicians.

O. Film Masking Devices

Facilities shall ensure that the film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.