1990 (Res. 4)
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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

All mammography must be performed in concordance with the Mammography Quality Standards Act (MQSA) regulations. Nothing in this document should be construed to contradict those regulations.

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. It is essential that this examination be performed and interpreted with the highest quality possible. 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 should be performed by a qualified radiologic technologist with or without a physician in attendance.

III. PATIENT SELECTION

A. Indication

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 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 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.

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 healthcare provider.

D. The Augmented Breast

Facilities shall 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 is imaged as a screening or a diagnostic patient.

E. Pregnancy Policy

Screening mammography should be discouraged for pregnant patients.

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 the MQSA final rule as published by the FDA (see Appendix B).

If digital mammography equipment is used, refer to the ACR Practice Guideline for the Performance of Whole Breast Digital Mammography.

VI. SPECIFICATIONS OF THE EXAMINATION

The 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. When pathology is suspected, a recommendation for additional imaging studies, diagnostic mammography, or biopsy may be warranted.

Evaluation of the augmented breast should include, when possible, standard CC and MLO or lateral views as well as implant displacement views.

Women should be informed that a clinical breast examination is a complementary and recommended 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. Double Reading and Computer-Aided Detection

Double reading and computer-aided detection (CAD) may increase the sensitivity of mammography interpretation and may be utilized, realizing that cost and workforce issues make this difficult to accomplish at many facilities.

C. Film Labeling

All radiographic images should be labeled in accordance with the current ACR Mammography Quality Control Manual and the MQSA final rule. Image labeling should include the following information in a permanent, legible, and unambiguous manner and should be placed so as not to obscure anatomic structures:

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 for nondigital images.
7. Mammographic unit identification, if there is more than one unit in the facility.
8. View and laterality (placed on the image in a position near the axilla).

D. Viewing Issues

1. Viewboxes
   Viewboxes should provide a relatively high luminance level of at least 3,000 cd/m^2. This is generally higher than that necessary for viewing conventional radiographs. It is essential to exclude extraneous light, which reduces image contrast and limits maximum densities that can be seen. Film masking devices must be available. 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. 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 and monitors 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.

E. Film Retention

Original mammograms shall 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, or a longer period if mandated by state or local laws. 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.

F. Free Standing and Mobile Settings

Screening mammography may take place in radiology settings where there may not be a physician in attendance. Adequate supervision can be maintained in off-site facilities through professional feedback at least quarterly. 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 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 description of abnormalities detected by screening and recommendations for subsequent follow-up studies should be included in the report. Final reports should include the FDA-approved final assessment categories defined in the ACR Breast Imaging Reporting and Data System (BI-RADS® Atlas) 4th edition, 2003.

1. Mammographic assessment is incomplete
   Need additional imaging evaluation and/or prior mammograms for comparison [Category 0]
   This category has been assigned to incomplete evaluations. Additional mammography views, ultrasound, magnetic resonance imaging, or previous studies are necessary to assign a final assessment category.

2. Mammographic assessment is complete - final categories

Negative	[Category 1]
Benign finding(s)	[Category 2]
Probably benign finding(s)	[Category 3]
Suspicious abnormality	[Category 4]
Highly suggestive of malignancy	[Category 5]

A category 3, 4, or 5 assessment is usually not rendered from a screening mammogram, although in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. More commonly, patients with abnormalities in these groups 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.

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. The communication should be documented.

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 study no later than 30 days from the date of the mammographic examination. If assessments are "suspicious" or "highly suggestive of malignancy" the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

   b. For self-referred patients 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 healthcare provider when clinically indicated. 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 as soon as possible to the self-referred patient in a manner that ensures receipt and documentation of the report.

VIII. 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.

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 for screen-film mammography:

ACR Recommended and FDA Required Mammographic Quality Control Tests				
	Test	**Minimum Frequency**	**Required by MQSA***	**Timeframe for Corrective Action**
Technologist Tests	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
	Screen-Film Contact	Semi-annually	✓	Immediately
	Compression	Semi-annually	✓	Immediately
Medical Physicist Tests	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
	Average Glandular Dose	Annually	✓	Immediately
	Radiation Output Rate	Annually	✓	Within 30 days of the test date
	Measurement of Viewbox Luminance and Room Illuminance	Annually		

*Required under MQSA Final Rule.

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

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 (3.0 milligray). This applies to both screen-film and full-field digital mammography.

Medical Outcomes Audit

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 most practice situations it will not be possible to obtain follow-up information on all positive mammograms.

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APPENDIX A

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

(Taken directly from MQSA Final Regulations, Subpart B)

The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

A. Interpreting Physician

All physicians interpreting mammograms shall meet the following qualifications:

1. Initial Qualifications
   Unless the exemption in paragraph (A)(1)(3)(a) of this section applies, before beginning to interpret mammograms independently, the interpreting physician shall:
   a. Be licensed to practice medicine in a State.
   b. Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography;
      or
      Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (A) of this section.
   c. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category 1 and at least 15 of the category 1 hour shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to

mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

d. Unless the exemption in paragraph (A)(3)(b) of this section applies, have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

2. Continuing experience and education

All interpreting physicians shall maintain their qualifications by meeting the following requirements:

a. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (A)(1) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

b. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (A)(1) of this section were completed, the interpreting physician shall have taught or completed at least 15 category 1 continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category 1 continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and

c. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

d. Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (A)(2)(b) of this section, even if the course is taught multiple times during the previous 36 months.

3. Exemptions

a. Those physicians who qualified as interpreting physicians under paragraph (A) of this section of FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of paragraph (A)(2) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (A)(2)(a) of this section and the continuing experience and education requirements of paragraph (A)(2) of this section.

b. Physicians who have interpreted or multi-read at least 240 mammographic examinations under a diagnostic supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (A)(1)(d) of this section.

4. Re-establishing qualifications

Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall re-establish their qualifications before resuming the independent interpretation of mammograms, as follows:

a. Interpreting physicians who fail to meet the continuing experience requirements of paragraph (A)(1)(a) of this section shall:

i. Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

ii. Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physicians' total up to 960 examinations for the prior 24 months, whichever is less.

iii. The interpretation required under paragraph (A)(4)(a)(i) or (A)(4)(a)(ii) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.

b. Interpreting physicians who fail to meet the continuing education requirements of paragraph (A)(2)(b) of this section shall obtain a sufficient number of additional category 1 continuing medical education

credits in mammography to bring their total up to the required 15 credits in the previous 35 months before resuming independent interpretation.

B. Radiologic Technologists

All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements.

1. General requirements
   a. Be licensed to perform general radiographic procedures in a State; or
   b. Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and
2. Mammography requirements
   Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (B) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:
   a. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;
   b. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (B) of this section; and
   c. At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams.
3. Continuing education requirements
   a. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (B)(2) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.
   b. Units earned through teaching a specific course can be counted only once toward the 15 required in paragraph (B)(3)(a) of this section, even if the course is taught multiple times during the previous 36 months.
   c. At least six of the continuing education units required in paragraph (B)(3)(a) of this section shall be related to each mammographic modality used by the technologist.
   d. Requalification
   Radiologic technologists who fail to meet the continuing education requirements of paragraph (B)(3)(a) of this section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.
   e. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (B)(2)(c) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.
4. Continuing experience requirements
   a. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (B)(2) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.
   b. Requalification
   Radiologic technologists who fail to meet the continuing experience requirements of paragraph (B)(4)(a) of this section shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

C. Medical Physicists

All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall meet the following:

1. Initial qualifications
    a. Be state licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and
    b.
        i. Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;
        ii. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and
        iii. Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (C)(1) and (C)(3) of this section; or
2. Alternative initial qualifications
    a. Have qualified as a medical physicist under paragraph (C) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and
    b. Prior to the April 28, 1999, have:
        i. A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,
        ii. Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and,
        iii. Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirements. The training and experience requirements must be met after fulfilling the degree requirement.
3. Continuing qualifications
    a. Continuing education
    Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (C)(1) or (C)(2) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.
    b. Continuing experience
    Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (C)(1) or (C)(2) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.
    c. Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (C)(1) or (C)(2) of this section, the physicist must receive at

least 8 hours of training in surveying units of the new mammographic modality.

4. Re-establishing qualifications
   Medical physicists who fail to maintain the required continuing qualifications of paragraph (C)(3) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must re-establish their qualifications, as follows:
   a. Medical physicists who fail to meet the continuing educational requirements of paragraph (C)(3)(a) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.
   b. Medical physicists who fail to meet the continuing experience requirement of paragraph (C)(3)(b) of this section shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of paragraphs (C)(1) and (C)(3) of this section to bring their total surveys up to the required two facilities and six units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

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 the 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 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 physicians interpreting for the facility.