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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

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ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF SCREENING AND DIAGNOSTIC MAMMOGRAPHY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practice parameters, 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 practice parameters 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 practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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 practice parameters 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 practice parameters is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

The goal of mammography is the detection, characterization, and evaluation of findings suggestive of breast cancer and other breast diseases. Annual screening mammography of age-appropriate asymptomatic women is currently the only imaging modality that has been proven to significantly reduce breast cancer mortality [1-6]. A screening mammogram is an X-ray examination of the breast of an asymptomatic woman. A diagnostic mammogram is an X-ray examination of the breast of a patient with signs or symptoms of breast disease, a possible abnormality detected on screening mammography or other imaging, or who has prior mammography findings requiring imaging follow-up.

It is essential that all mammography be performed and interpreted with the highest quality possible [7]. All mammography in the United States must be performed in concordance with the Mammography Quality Standards Act (MQSA) legislation and regulations published by the Food and Drug Administration (FDA) [8]. Nothing in this document should be construed to contradict those regulations. In addition, mammography facilities should have policies and procedures in place for imaging patients with disabilities.

II. INDICATIONS

A. Screening Mammography [9,10]

1. Annually for asymptomatic women age 40 and older who are at average risk for breast cancer.
2. Asymptomatic women under age 40 who are at increased risk for breast cancer.
 - a. Woman with known mutation or genetic syndrome with increased breast cancer risk: yearly starting by age 30, but not before age 25.
 - b. Untested woman with a first-degree relative with known BRCA mutation: yearly starting by age 30, but not before age 25.
 - c. Woman with a 20% or greater lifetime risk for breast cancer based on breast cancer risk models: yearly starting by age 30, but not before age 25, or 10 years earlier than the age at which the youngest first-degree relative was diagnosed, whichever is later.
 - d. Woman with a history of chest (mantle) radiation received between the ages of 10 and 30: yearly starting 8 years after the radiation therapy, but not before age 25.
 - e. Woman with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in-situ (DCIS), invasive breast cancer, or ovarian cancer: yearly from time of diagnosis, regardless of age.
3. Age at which annual mammography screening should end.
 - a. There is no defined upper age limit at which mammography may not be beneficial.
 - b. Screening with mammography should be considered as long as the patient is in good health and is willing to undergo additional testing, including biopsy, if an abnormality is detected.
4. Self-referred woman
 - a. Women with no health care provider, who decline having a health care provider, or for whom the health care provider declines responsibility.
 - b. Direct access by individuals is permissible without requiring physician referral in advance. However, screening facilities that elect to accept self-referral patients must have procedures for referring them to a qualified health care provider if abnormal clinical or mammographic findings are present.
5. Self-requesting woman [11]
 - a. 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.
 - b. 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 [8].

6. Woman with breast augmentation
 - a. Asymptomatic women with breast implants may undergo screening mammography.
 - b. Facilities must have procedures in place to inquire whether patients have breast implants before a mammogram is performed.
 - c. If a facility does not provide implant imaging services, it should refer the patient to other facilities that provide such services.

B. Diagnostic Mammography

1. To assess certain clinical findings that may include a palpable abnormality, persistent focal area of pain or tenderness, bloody or clear nipple discharge, or skin changes.
2. A finding detected on screening mammography that requires further imaging evaluation. This could either be a call-back examination following an abnormal screening mammogram, or conversion of a screening mammogram to a diagnostic mammogram when an abnormality is detected at the time of the screening visit.
3. Short-interval follow-up for probably benign radiographic findings as defined by the [ACR Breast Imaging Reporting and Data System \(BI-RADS®\)](#) [12].
4. Asymptomatic patients previously treated for breast cancer may undergo screening or diagnostic mammography at the discretion of the facility [13].
5. Determination that a patient scheduled for screening mammography has a clinical problem, as noted above in section II.B.1. The facility should have a process whereby screening mammography can be converted to diagnostic mammography.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiologic technologists who work in mammography must meet the requirements in the Mammography Quality Standards Act (MQSA) final rule published by the Federal Drug Administration (FDA) [8].

IV. SPECIFICATIONS OF THE EXAMINATION

A. Screening Mammography

1. The screening examination should be limited to technically adequate craniocaudal (CC) and mediolateral oblique (MLO) views of each breast.
2. Additional views may be required to visualize breast tissue more effectively.
3. Evaluation of the augmented breast, whether done as a screening or a diagnostic examination, should include, when possible, standard CC and MLO views as well as implant displaced views in 2 projections [14].
4. The interpreting physician does not need to be present at the facility to monitor the examination when the patient is imaged.

B. Diagnostic Mammography

1. A diagnostic mammogram may include MLO, CC, and/or supplemental views to evaluate an area of clinical or radiographic concern.
2. Supplemental mammographic views might include spot compression, spot compression with magnification, tangential views, or other special views [14-19].
3. When selecting a view, the proximity of the area of concern to the image receptor should be considered [14].
4. Diagnostic mammography should be performed under the immediate supervision of the interpreting physician.²

C. 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)

D. Imaging Labeling

1. All radiographic images should be labeled in accordance with the current ACR Mammography Quality Control Manual [12].
2. 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 [8]:

Mammographic Image Identification
<ol style="list-style-type: none">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 screen-film and computed radiography 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).

² Immediate supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure. Immediate supervision may also be accomplished via telemammography as long as the interpreting physician is immediately available.

E. Markers

Markers may be used to identify areas of clinical concern or for other situations that could impact an appropriate interpretation (e.g., raised skin lesions, palpable findings, postsurgical changes). The facility should adopt a policy requiring consistent use of two different shapes of radiopaque devices for palpable and skin lesions, respectively. In addition, there should be an indication of the type of underlying lesion marked by every radiopaque device (palpable versus skin lesion), either as a permanent annotation on the appropriate mammographic image(s) or as a description in the mammography report [12].

F. Viewing Issues

1. Screen-film images should be viewed in accordance with the ACR Mammography Quality Control Manual [14].
2. Images acquired from digital mammographic systems should be viewed in accordance with the [ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography](#) [20].

G. 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 increased sensitivity is usually at the expense of decreased specificity and increased recall and biopsy rates.

H. Image Retention in Accordance with MQSA Regulations

For information regarding image retention, see the Mammography Quality Standards Act Final Regulations and Additions to Policy Guidance [8].

I. Comparison with Prior Breast Imaging Studies

1. Comparison with available prior breast imaging studies is an important part of mammography [16,21].
2. Digitized images of previously obtained screen-film mammograms may be used for comparison purposes if the interpreting physician deems that acceptable [15].
3. If previous breast imaging studies are needed for assessing mammographic findings, an attempt should be made to obtain them.
4. Facilities must be able to provide images of original high diagnostic quality to other mammography facilities or to referring physicians in accordance with MQSA regulations [8].

V. DOCUMENTATION AND COMMUNICATION OF RESULTS

A. The Mammographic Report

1. The mammography 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.
2. The type of examination (screening or diagnostic) and clinical or radiographic concern(s) that prompted the examination should be acknowledged.

3. Overall final assessment of findings should be based on all imaging studies performed up to that day. In addition, they must be classified according to the FDA-approved final assessment categories [8] and should follow the categories defined in the ACR BI-RADS[®] 4th edition, 2003 [12] (or any subsequent revisions). The BI-RADS[®] provides a framework for reporting, lesion assessment, imaging-pathologic correlation, quality improvement, and medical outcomes auditing.
4. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) and consistent with the MQSA final rule published by the FDA [8].
5. BI-RADS[®] Category 0 assessments are assigned to incomplete evaluations, in which 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 should either arrange for a cooperating facility to perform the examinations or refer the patient to one.
6. A category 3, 4, or 5 assessment is not recommended for a screening mammogram, even though in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. Rather, all patients with screening abnormalities should be given a BI-RADS[®] category 0 assessment and recalled for further diagnostic studies [12]. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) and be consistent with the MQSA final rule published by the FDA [8].

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. Direct communication with the patient and/or health care provider should be documented permanently in the medical records, preferably in the mammography 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, when 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 may 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.

VI. EQUIPMENT SPECIFICATIONS

Mammography equipment (screen-film and digital) must meet the MQSA regulations published by the FDA [8]. Equipment used for diagnostic mammography must have magnification and spot-compression capability. The [ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography](#) provides additional guidance for digital mammography acquisition and display equipment [20].

VII. MOBILE AND TELEMAMMOGRAPHY SETTINGS

A. 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 practice parameters.

B. 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 adequate image quality before any mammograms are performed at each location [8,14].

C. Diagnostic telemammography can be performed without a physician on site. However, since diagnostic evaluation often includes correlation of ultrasound and clinical findings, this practice is not optimal and may result in additional patient imaging at a site where the radiologist is actually present. Thus, diagnostic telemammography should be used only when there are access issues, to facilitate patient care. If it is done, supervision must be directed from off-site while the physician is immediately available to furnish assistance and direction throughout the examination. The mammography offered must follow ACR practice parameters and the MQSA final rule as published by the FDA [8] with strict adherence to documented protocols.

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)

http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

Nationally developed guidelines, such as the ACR’s [Appropriateness Criteria](#)[®], should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently[®] for children (www.imagegently.org) and Image Wisely[®] for adults (www.imagewisely.org) websites. These

advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

IX. 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 website (<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 regulations published by the FDA [8]. The current ACR Mammography Quality Control Manual is a reference resource that provides guidance [14]. Accreditation by the ACR Mammography Accreditation Program (MAP) documents compliance with the requirements in this section. 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 of peripheral devices such as monitors and laser film printers).

The ACR Subcommittee on Mammography Quality Assurance is currently working on a standardized digital mammography QC manual, in conjunction with the FDA that will be applicable to all manufacturers.

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 [22]. This applies to both screen-film and full-field digital mammography [8,14].

D. Medical Outcomes Audit

The MQSA regulations require that each facility establishes and maintains a mammography medical outcomes audit program [12,23,24] to follow up positive mammographic assessments (BI-RADS[®] categories 4 and 5). In addition, the ACR strongly recommends follow-up of category 0 assessments to correlate pathology results with the interpreting physician's findings [8,12,25]. This program must be designed to ensure reliability, clarity, and accuracy in the interpretation of mammograms. Each facility must have a documented policy for collecting outcomes data on biopsied cases interpreted by its physicians, both 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. The ACR National Mammography Database provides benchmarking for outcomes data including cancer detection rates, positive predictive value rates, and recall rates [26].

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