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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.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

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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 the only imaging modality 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 prior mammography findings requiring imaging follow-up. Digital breast tomosynthesis (DBT), a mammographic technique that creates thin-section reconstructed images of the breast tissue, may also be used in screening and/or diagnostic settings. DBT decreases the masking effect of superimposed normal tissue, allowing greater sensitivity and specificity to be attained [7]. This document will collectively refer to analog mammography, full-field digital mammography, and DBT as “mammography.”

It is essential that all mammography be performed and interpreted with the highest quality possible [8]. All mammography in the United States must be performed in accordance with the Mammography Quality Standards Act (MQSA) legislation and regulations published by the Food and Drug Administration (FDA) [9]. 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 [3,10-12]

1. Women undergoing screening mammography should be asymptomatic. If a woman has symptoms or clinical signs of breast disease, diagnostic mammography should be performed instead (see section II.B.).
2. For women at average risk for breast cancer, annual screening mammography starting at age 40 is recommended [1-6,13,14].
3. For women at high risk for breast cancer, annual screening mammography may commence at age 30 (or as specified in the scenarios below). This includes:
 - a. A woman with known genetic mutation or syndrome conferring increased breast cancer risk.
 - b. A woman who has not undergone genetic testing but has a first-degree relative with a BRCA mutation.
 - c. A woman with a 20% or greater lifetime risk for breast cancer based on breast cancer risk model(s).
 - d. A woman with a first-degree relative with breast cancer may commence screening 10 years earlier than the age at which the youngest first-degree relative was diagnosed (but not before age 30).
 - e. A woman with a history of chest (mantle) radiation received between the ages of 10 and 30 should begin screening 8 years after the radiation therapy, but not before age 25.
 - f. A woman with biopsy-proven lobular neoplasia or atypical ductal hyperplasia.
 - g. A woman with biopsy-proven ductal carcinoma in situ, invasive breast cancer, or ovarian cancer should begin screening at the time of diagnosis, regardless of age.
4. Asymptomatic women previously treated for breast cancer may undergo annual screening or annual diagnostic mammography, as determined by the imaging facility [15].
5. Lactating women may undergo screening mammography, depending on clinical context and underlying risk of breast cancer. Breast feeding and/or pumping immediately prior to the examination may help minimize any effect of lactation on mammographic density [16].
6. There is no defined upper age limit at which mammography ceases to be beneficial. Screening mammography should be considered as long as the patient is in good health, able to undergo the examination, and willing to undergo additional testing, including biopsy, if an abnormality is detected [14].

7. A woman may present for a screening mammogram without an advance order from a physician or health care provider.
 - a. A self-referred woman has no health care provider, declines to accept a health care provider chosen by the facility, or has a designated health care provider who declines responsibility.
 - b. A self-requesting woman comes for mammography on her own initiative, but provides the name of her physician or health care provider.
 - i. If the provider declines to accept the mammography report from the facility, the facility should treat the woman as if she were self-referred.
 - c. Direct access to screening mammography is permissible in these instances. However, screening facilities that elect to accept self-referred women (or self-requesting women whose providers decline responsibility) must have procedures for appropriate referrals to qualified medical providers if the screening process leads to additional diagnostic imaging, biopsy, or treatment not available at that facility [17].
8. Women 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 imaging services for women with breast implants, it should refer the patient to a facility that does.

B. Diagnostic Mammography

1. Diagnostic mammography is used to evaluate certain clinical breast findings, such as an area of palpable concern, a persistent focal area of pain or tenderness, skin/nipple changes, or suspicious nipple discharge.
2. A clinical breast finding may be elicited when a woman presents for a screening mammogram. If so, a diagnostic mammogram should be performed instead.
 - a. The facility should have a process for converting a screening mammogram to a diagnostic examination (which may comprise both mammography and targeted ultrasound).
3. Diagnostic mammography is used to evaluate abnormal imaging findings identified on screening mammography.
 - a. Occasionally, diagnostic mammography may be requested to characterize breast findings identified on imaging examinations not specific to the breast, such as computed tomography (CT), positron emission tomography/computed tomography (PET/CT), or magnetic resonance (MR) studies.
 - b. Diagnostic mammography may be indicated to further evaluate a finding identified on a breast MR examination, although targeted ultrasound is more commonly used in this setting.
4. Diagnostic mammography should be performed for follow-up evaluation of a mammographic finding assessed as “probably benign” at a prior diagnostic examination, as defined by the [ACR Breast Imaging Reporting and Data System \(BI-RADS®\)](#) [18].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiologic technologists who work in mammography must meet the requirements in the MQSA final rule published by the FDA [9].

IV. SPECIFICATIONS OF THE EXAMINATION

A. Screening Mammography

1. The screening examination should ideally be limited to technically adequate bilateral craniocaudal (CC) and mediolateral oblique (MLO) views. However, additional views may be required to visualize breast tissue more effectively.
 - a. Evaluation of the augmented breast should include, when possible, standard CC and MLO views as well as implant displaced views in 2 projections [19].
 - b. DBT may be performed.
 - i. Compared to standard mammography, DBT has been found to increase the number of cancers detected and to decrease the number of false-positive examinations [20]. These advantages have been found to be especially pronounced in certain populations, including women under age 50 and women with dense breast tissue [7,21,22]. However, interpretation time does increase.
 - ii. DBT may be used in women with implants. Its utility is limited on full views, thus is typically only performed on implant-displaced views [7].
2. 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 full CC, MLO, and/or supplemental views to evaluate an area of clinical or imaging concern.
 - a. Supplemental mammographic views may include spot compression, spot compression with magnification, tangential views, or other special views [19,23-26].
 - i. When determining which views to perform, the distance from the area of concern to the digital detector (or image receptor) should be minimized if possible [19].
 - b. DBT may be performed.
 - i. Lesion characterization may be improved with DBT, especially for noncalcified lesions, spiculated masses, and asymmetries [7].
2. Diagnostic mammography should be performed under the immediate supervision of the interpreting physician².

C. Request for Diagnostic Mammography

The written or electronic request for a diagnostic mammography examination evaluation 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 – revised in 2016, Resolution 12-b)

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 (see section VII.C).

D. Image Labeling

1. All mammographic images should be labeled in accordance with FDA requirements [27] and the ACR BI-RADS Atlas [18]. The FDA allows work stations used for final interpretation the ability to temporarily switch off the image identification information, provided that the standard or default setting shows the image identification information [28].
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 [9].

Mammographic Image Identification
<ol style="list-style-type: none">1. Facility name and location, including city, state, and zip code2. Patient's first and last names3. Unique identification number and/or date of birth4. Examination date5. Technologist's initials or identification number6. Cassette (screen) number for screen-film and computed radiography images7. Mammographic unit identification, if there is more than one unit in the facility8. Laterality and view, placed on the image in a position near the axilla

E. Markers

1. Radiopaque markers may be placed on the breast prior to imaging in order to identify areas of clinical concern (such as a palpable lump) or other entities that could affect interpretation (eg, raised skin lesions or postsurgical changes).
2. Facilities should require consistent use of radiographically distinct markers to indicate palpable areas of concern, skin lesions, and surgical scars. In addition, there should be an indication of the type of underlying lesion denoted by each marker, either as a permanent annotation on the appropriate mammographic image(s) or as a description in the mammography report [18]. It may also be helpful to record such findings on the patient's intake sheet and/or technologist worksheet.

F. Viewing Issues

1. 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](#) [29].
2. Screen-film images should be viewed in accordance with the 1999 ACR Mammography Quality Control Manual [19].

G. Double Reading and Computer-Aided Detection

Double reading and computer-aided detection 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/or biopsy rates [30].

H. Image Retention in Accordance with MQSA Regulations

For information regarding image retention, see the MQSA Final Regulations and Additions to Policy Guidance [31].

I. Comparison with Prior Breast Imaging Studies

1. Comparison with prior breast imaging studies is an important part of mammography interpretation [23,32,33].
2. If prior breast imaging studies are needed to assess mammographic findings, an attempt should be made to obtain them.
3. Digitized images of previously obtained screen-film mammograms may be used for comparison purposes if the interpreting physician deems them acceptable [34] .
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 [9].

V. DOCUMENTATION AND COMMUNICATION OF RESULTS

A. Documentation: Mammogram Report

1. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [35] and consistent with the MQSA final rule published by the FDA [9].
2. The mammogram report should:
 - a. State whether the mammogram is being performed as a screening or diagnostic examination
 - i. In the diagnostic setting, the clinical and/or imaging concern(s) that prompted the examination should be acknowledged.
 - b. Describe the patient’s mammographic breast density, using one of the four BI-RADS breast density categories.
 - c. Describe detected abnormalities and pertinent observations, using BI-RADS terminology whenever possible.
 - d. Establish level of suspicion of malignancy and provide final assessment, using BI-RADS terminology whenever possible.
 - e. Provide recommendations for patient management.
3. Overall final assessment of findings should be based on all imaging studies performed at that patient visit. In addition, they must be classified according to the FDA-approved final assessment categories [9] and should follow the categories defined in BI-RADS Atlas [18].
 - a. BI-RADS Category 0 assessments are assigned to incomplete evaluations, in which additional mammographic views, ultrasound, or previous studies are necessary to assign a final assessment category. When additional imaging is recommended, the facility should:
 - i. have the capacity to perform the recommended examination(s); or,
 - ii. arrange for a cooperating facility to perform the recommended examination(s); or,
 - iii. refer the patient to a facility able to perform the recommended examination(s).
 - b. A BI-RADS Category 3, 4, or 5 assessment is strongly discouraged for a screening mammogram, even though in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. Rather, patients with screening abnormalities should be given a BI-RADS category 0 assessment and recalled for further diagnostic studies [18].

B. Communication of Mammography Results to Health Care Providers³

1. A facility must provide the interpreting physician’s written report from the mammogram 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 [9].

³ If the patient is self-referred, or her named health care provider declines responsibility, see section V.C.3.

2. However, if the final 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, via either verbal communication or a written report.
 - a. If the health care provider is unavailable, the report should be given to that provider's responsible designee.
 - b. Direct verbal communication with the health care provider should be documented permanently in the medical records, preferably in the mammography report.
 - c. In all cases, the patient's health care provider must receive a written report, even if the results were verbally communicated [9].

C. Communication of Mammography Results to Patients

1. A facility must directly give or send each patient a written summary of her examination results, in lay terms, no later than 30 days from the date of the mammographic examination [9].
2. However, if the final assessment is a BI-RADS category 4 or 5, the facility should make a reasonable attempt to communicate directly with the patient as soon as possible. This should occur within 5 working days from the date of interpretation.
 - a. Direct verbal communication with the patient should be documented permanently in the medical records, preferably in the mammography report. If unsuccessful, the communication attempt may be documented.
 - b. In all cases, the facility must provide the patient with a written summary of her examination results, even if the results were verbally communicated [9].
3. For self-referred patients, the facility must directly give or send the patient both the physician's mammographic report and a written summary of her results in lay terms, no later than 30 days from the date of the mammographic examination.
 - a. 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.
 - i. Facilities must have procedures for referring such patients to a health care provider, with documentation that this has occurred. The radiologist may act as a referring physician if she/he is willing to accept responsibility for the patient's medical care, and the patient agrees.

VI. EQUIPMENT SPECIFICATIONS

Mammography equipment (digital and screen-film) must meet the MQSA regulations published by the FDA [9]. 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 [29].

VII. MOBILE AND TELEMAMMOGRAPHY SETTINGS

- A. If mammography is performed in a mobile setting, the mammography quality control (QC) 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 [9,19,36].
- B. Screening mammography may take place without an interpreting physician in attendance.
 1. The mammography services provided must follow all the practice parameters herein.
 2. Adequate technical supervision can be maintained in such facilities through periodic review by the supervising radiologist, performed quarterly at minimum. This review should include clinical image

quality and quality assurance procedures, all QC documentation, and a determination that safe operating procedures are used.

- C. Diagnostic mammography may be performed without the interpreting physician on site (“diagnostic telemammography”). However, because diagnostic evaluation often includes real-time correlation of mammographic, sonographic, and clinical findings, this practice is not optimal.
1. Diagnostic telemammography should be used only in circumstances of limited patient access, in order to facilitate patient care.
 2. If performed, the responsible physician should be immediately available to review images and provide direction throughout the examination.
 3. The mammography services offered must follow ACR practice parameters and the MQSA final rule as published by the FDA with strict adherence to documented protocols [9].

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 (<https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards>).

B. Quality Control

1. A documented QC program with procedure manuals and logs must be maintained and comply with the MQSA regulations published by the FDA [9].
 - a. Accreditation by the ACR Mammography Accreditation Program documents compliance with the requirements in this section.
2. Quality assurance for full-field digital mammography
 - a. The FDA requires that the facility's quality assurance program be substantially the same as the quality assurance program recommended by the image receptor (ie, digital detector) manufacturer. Mammography facilities should refer to their manufacturer's QC manual for a list of the required equipment tests (including tests of peripheral devices, such as monitors and laser film printers).
 - b. In 2016, the FDA approved an ACR alternative standard request [37] to allow mammography facilities to use the 2016 ACR Digital Mammography Quality Control Manual [36] and Digital Mammography Quality Control Phantom for routine QC of digital equipment instead of their manufacturer's QC manual.
3. Quality assurance for screen-film mammography
 - a. If screen-film mammography is used, the facility should follow the procedures and performance criteria outlined in the 1999 ACR Mammography Quality Control Manual [19].

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 mGy), although it is generally much lower [38]. This applies to both full-field digital and screen-film mammography [9,36]. DBT, when acquired in addition to standard full-field digital images for a screening examination, increases radiation dose; use of a reconstructed ("synthetic") image as a substitute for standard mammographic images may be employed to reduce radiation dose [7,39].

D. Medical Outcomes Audit

1. MQSA regulations require that each facility establishes and maintains a mammography medical outcomes audit program, designed to ensure reliability, clarity, and accuracy in the interpretation of mammograms [9,18,40,41].
2. An audit program allows each facility to follow up BI-RADS categories 4 and 5 assessments, and correlate pathology results with the interpreting physician's findings. In addition, the ACR also strongly recommends follow-up of BI-RADS category 0 assessments [9,18,42].
 - a. 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.
 - b. It is understood that in most practice situations it will not be possible to obtain follow-up information on all positive mammograms.

3. The ACR National Mammography Database provides benchmarks for outcomes data including recall rates, cancer detection rates and positive predictive values [43].

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