ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF CONTRAST-ENHANCED 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 care[1]. 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 practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 the guidance in this document 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 purpose of this document is to assist practitioners in achieving this objective.

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[1] *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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

Contrast enhanced mammography (CEM) is a specialized mammographic examination that uses iodinated contrast with low- and high-energy X-rays to detect neovascularity associated with breast malignancies, conceptually similar to breast magnetic resonance imaging (MRI). FDA-approved for diagnostic imaging, current indications include the detection and characterization of breast cancer, assessment of local disease extent, evaluation of neoadjuvant treatment response, and guidance for biopsy and localization. Some centers also use CEM for supplemental screening, especially in women who have contraindication to breast MRI or who do not meet the ≥20% lifetime risk threshold to qualify for supplemental screening with breast MRI. CEM findings should be correlated with the clinical history, physical examination, and other available imaging modalities.

II. INDICATIONS AND CONTRAINDICATIONS

Current indications for CEM include, but are not limited to, the following:

1. Evaluation of an abnormality detected on screening mammography [1-4]
2. Evaluation of a palpable breast abnormality [5-7]
3. Evaluation of the extent of disease in patients with newly diagnosed breast cancer [8-12]
    a. Characterize and detect ipsilateral and contralateral ductal carcinoma in situ and invasive carcinoma
4. Assessment of response to neoadjuvant chemotherapy [13, 14]
5. Screening of intermediate risk women (15-20% lifetime risk) [15-17]
    a. Personal history of breast cancer
    b. Personal history of lobular carcinoma in situ or atypical ductal hyperplasia
    c. Family history of breast cancer
    d. Mammographically dense breasts
6. Supplemental screening of women at high risk, especially those with a contraindication to breast MRI

Contraindications:

1. Documented allergy to iodinated contrast
2. Renal impairment

For further information, see the ACR Manual on Contrast Media [18].

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 final rule published by the FDA [19]. Interpreting physicians should have knowledge and expertise in breast disease and breast imaging diagnosis. Facilities performing CEM should have the capacity to perform correlation with previous breast imaging examinations, directed breast ultrasound, CEM biopsy capability, or, if unavailable, MRI and MRI-guided intervention. Alternatively, if these services are not available at the facility performing CEM, the facility should create a referral arrangement with a cooperating facility that can provide these services. If any breast biopsy is performed based on findings on CEM, histopathologic results should be available to the interpreting physician as well as the procedural physician. The facility performing the biopsy should have the physician expertise to determine radiologic-pathologic concordance and the ability to report management recommendations in the biopsy report. For suspicious or indeterminate findings detected on the recombined images of the CEM that are occult on mammography and breast ultrasound, a CEM or MRI-guided biopsy should be performed.

The technologist, nurse, and/or other designated personnel involved with performing the examination is responsible for making the patient comfortable, preparing the patient for the examination, positioning the patient for the mammographic imaging, and monitoring the patient during and immediately after the examination for potential adverse reactions. For the intravenous (IV) administration of contrast material for CEM, qualifications for technologists performing IV injections should be in compliance with current ACR policy and existing operating procedures or manuals at the imaging facility. The technologist should be certified by the American Registry of Radiologic Technologists and have an unrestricted license within the state where the examination is being performed.

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for CEM 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 for the examination or a provisional diagnosis is helpful to allow for the proper performance and interpretation of the examination.

The request for the 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

stated scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

IV. SPECIFICATIONS OF THE EXAMINATION

A. Patient Selection and Preparation

The physician responsible for the CEM should supervise patient selection and preparation. Patients should be screened for possible contraindications for CEM as discussed in section II.

Patients without absolute contraindication to the administration of iodinated contrast media are candidates for CEM. In cases of relative contraindication to the administration of iodinated contrast medium, measures to reduce the possibility of contrast medium reactions or nephrotoxicity should be followed to the extent that the patient's condition allows or an alternative vascular imaging modality such as MRI should be considered [20]. When possible, patients should be well hydrated, and IV access should be established by either a nurse or technologist. A 22-gauge or larger IV catheter should be placed to accommodate an optimal rate of 2–3 mL/s of iodinated contrast media. All catheters used for the CEM examination should first be tested with a rapidly injected bolus of sterile saline to ensure that the venous access is secure and can accommodate the rapid bolus, minimizing the risk of contrast medium extravasations. The injection site should be monitored by medical personnel trained in the rapid recognition of IV extravasations. Department procedures for care of IV extravasations should be documented and applied if necessary.

IV. SPECIFICATIONS OF THE EXAMINATION

B. Equipment

CEM should be performed on a commercially available system that captures low-energy (ie, below the k-edge of iodine) and high-energy (ie, above the k-edge of iodine) images and has the software to generate the recombined images that will display the breast vascularity. The low-energy exposure typically uses a tube voltage of 25–34 kV and uses molybdenum, rhodium, or tungsten as the anode material and molybdenum, rhodium, or silver as filters [20]. The high-energy image is acquired using a tube voltage of 45–49 kV and a similar anode with titanium or copper as the filter [20]. The exposure time for each view varies based on breast composition and thickness.

A contrast medium power injector that allows programming of both the volume and flow rate is recommended, although a bolus injection by hand is acceptable. A low osmolarity iodine-based contrast material should be used. This contrast is injected before image acquisition for a total volume of 1–1.5 mL/kg of body weight with a maximum dose up to 150 mL, followed by a saline flush [20].

IV. SPECIFICATIONS OF THE EXAMINATION

C. Examination Technique

Facilities performing CEM should develop specific imaging protocols for the various CEM indications.

There are no studies reporting on optimal imaging parameters for CEM, such as contrast dose, injection rate, or time interval between contrast injection and image acquisition. However, there are generally accepted guidelines.

Imaging should begin no more than 2–2.5 minutes after administration of IV contrast and be completed within 10 minutes of injection [20]. The imaging protocol may vary depending on the indication but typically includes acquiring technically adequate unilateral or bilateral craniocaudal and mediolateral oblique views. Additional supplemental mammographic views (eg, mediolateral spot compression, magnification, or other views) may be acquired at the discretion of the interpreting radiologist and ideally should be completed within 10 minutes from the time of injection. The acquired images undergo processing to generate the low-energy and recombined images. All mammographic images should be labeled in accordance with FDA MQSA requirements [19] and the ACR BI-RADS Atlas [21].

The order of view acquisition is at the discretion of the interpreting radiologist. Some facilities start with imaging the symptomatic side and subsequently alternate images between the two sides when performing a bilateral study.

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should evaluate the accuracy of interpretation as well as the appropriateness of the indications for the examination. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, reported, and periodically reviewed to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures to ensure the confidentiality of the peer-review process.

IV. SPECIFICATIONS OF THE EXAMINATION

D. Interpretation

Using the BI-RADS lexicon for CEM, the interpreting radiologist will review low-energy images, which are equivalent to conventional 2-D full-field digital mammographic images, and the recombined images, which provide information regarding neovascularity.

IV. SPECIFICATIONS OF THE EXAMINATION

E. Facility Requirements

Appropriate emergency equipment with medications must be immediately available to treat adverse reactions associated with administered medications, including iodinated-based contrast agents. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Facility staff should be trained in the use of emergency equipment and medications in accordance with the ACR Manual on Contrast Media [18].

Each facility should establish and maintain a medical outcome audit program to follow up positive assessments and to correlate pathology results with the interpreting physician's findings. If the facility does not perform CEM-guided or MRI-guided intervention, it should have access to correlative pathology results from the accredited facility with which it has a referral arrangement. As above, such audits should encompass interpretation accuracy and examination appropriateness. Facilities should use the BI-RADS final assessment codes and terminology for reporting and tracking outcomes. The BI-RADS Atlas contains guidance on monitoring outcomes and conducting audits [21]. Summary statistics and comparisons generated for each physician and for each facility should be reviewed annually by the lead interpreting physician.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [22].

Reporting of CEM should adhere to reporting structure outlined in the ACR's BIRADS supplement for CEM [23].

VI. EQUIPMENT SPECIFICATIONS

Mammography equipment used for CEM must meet the MQSA regulations published by the FDA, including magnification and spot-compression capabilities for diagnostic mammography. The ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Mammography [24] provides additional guidance for digital mammography acquisition and display equipment.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers**,** 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 who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the ACR's Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). 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 periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, 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; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

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 *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education* on the ACR website (https://www.acr.org/Advocacy/Position-Statements/Quality-Control-and-Improvement).

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Development Chronology for this Practice Parameter

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