Adopted 2017 (Resolution 38)*

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF MOLECULAR BREAST IMAGING (MBI) USING A DEDICATED GAMMA CAMERA

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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole 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, ___ 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

This practice parameter has been developed to guide physicians performing and interpreting nuclear breast imaging studies using intravenous technetium-99m sestamibi and a dedicated gamma camera, referred to subsequently in this document as molecular breast imaging (MBI).

This technology has been referred to as both MBI and breast-specific gamma imaging (BSGI), depending on the type of camera used. For consistency, this document will use the term MBI to refer to these techniques, which use small field-of-view gamma cameras designed specifically for breast imaging using technetium-99m sestamibi.

In 1997, the Food and Drug Administration (FDA) approved the use of technetium-99m sestamibi for scintimammography, which used a conventional gamma camera to image the breast. Although scintimammography with conventional gamma cameras showed good sensitivity and specificity for larger tumors, its low sensitivity for tumors smaller than 15 mm does not meet current standards for breast imaging [1,2].

MBI requires the intravenous injection of technetium-99m sestamibi. Scintigraphic images are acquired while each breast is gently compressed (for immobilization) using conventional mammographic positioning. Typically, images are obtained of each breast in the craniocaudal (CC) and mediolateral oblique (MLO) projections. Each image is acquired for approximately 10 minutes or 175,000 counts (minimum of 7 minutes), for a total examination time of about 40 minutes. Two types of gamma cameras are currently available: 1) multicrystal array detectors using sodium iodide or cesium iodide and 2) cadmium zinc telluride (CZT) direct conversion detectors. These dedicated breast detector systems have higher sensitivity for detecting subcentimeter lesions compared with a single detector [3].

The FDA originally approved an administered activity of 740 to 1100 megabecquerels (MBq) (20 to 30 milllicuries [mCi]) of technetium-99m sestamibi. Currently, an administered activity of 300 to 555 MBq (8 to 15 mCi) is being used successfully by some facilities using the currently available camera systems [1,4,5].

MBI is a promising technique for evaluation of the breast. It has high sensitivity (95%) and specificity (80%) for detecting malignancy [6]. For malignant lesions <1 cm in size and ductal carcinoma in situ (DCIS), sensitivities are slightly lower at 84% and 88%, respectively [6]. One advantage of MBI is that its sensitivity is not affected by dense breast tissue. MBI in women with dense breasts shows improved sensitivity compared with mammography, improved specificity compared with ultrasound, and overall similar performance compared with magnetic resonance imaging (MRI) [7-10].

II.   INDICATIONS

The clinical indications for MBI are becoming better defined as more research data have become available. Particularly applicable when MRI is not feasible, potential indications currently include, but are not limited to:

A. Extent of Disease/Preoperative Staging in Newly Diagnosed Breast Cancer

Breast MRI is commonly employed as a supplemental modality to evaluate the extent of disease in newly diagnosed breast cancer patients. MBI can be useful in such patients who cannot undergo MRI. Although data for MBI are less robust than for MRI, studies have shown that, similar to MRI, MBI can identify mammographically occult, multifocal, and multicentric malignancy in newly diagnosed breast cancer patients [9,11-14]. In comparing the 2 modalities, MBI has a higher specificity and MRI has higher sensitivity for sub-centimeter cancers and DCIS [6,9,11-15]. However, it remains to be shown conclusively whether increased accuracy in determining the full extent of disease results in any reduction in recurrence rates or mortality following surgery, radiation, or systemic therapy.

MBI has limited anatomic coverage. Therefore, compared with MRI, its utility in loco-regional staging is inferior. Positioning for MBI is the same as for conventional mammography; thus, the extreme posterior

medial breast, chest wall, and axillae will be incompletely imaged. In contrast, MRI covers the entire breast, chest wall, level 1 and 2 axillary lymph nodes, and internal mammary lymph nodes.

B. Evaluation of Response to Neoadjuvant Chemotherapy

Neoadjuvant chemotherapy (NAC) in women with newly diagnosed breast cancer is often beneficial in decreasing tumor size in order to allow less extensive surgery and in assessing agent effectiveness. Imaging results guide surgical planning and assess treatment response. Breast MRI has superior accuracy in assessing residual disease compared with mammography, sonography, and palpation [16-18]. MBI has been proposed as comparable to MRI for this indication. Robust supporting data are not available; one study (n=122) found that MBI performed with comparable sensitivity and specificity to MRI in the assessment of residual tumor after NAC [19]. Likewise, there are limited data regarding the ability of MBI to predict early treatment response to NAC [25,26]. MBI can be used in this setting when patients cannot tolerate MRI.

C. Detection of Local Breast Cancer Recurrence

Early detection of breast cancer recurrence is important in improving survival [19]. Mammography is the first-line imaging modality to monitor women following breast conserving surgery. However, the detection of recurrence using mammography can be limited by morphologic changes in the post-treatment breast following surgery, radiation, and/or chemotherapy and within dense tissue. MRI has proven highly sensitive for detecting tumor recurrence and has a high negative predictive value for differentiating scar from recurrence [20-22]. Screening breast MRI, in addition to mammography, improves early detection of loco-regional recurrence and/or new primary tumors in these patients [23].

Given the similar sensitivities of MBI and MRI for detection of breast cancer, MBI may be useful in evaluating women with suspected local breast cancer recurrence. Although specific data on current MBI technology are lacking, previous studies evaluating scintimammography showed superior sensitivity for detecting recurrence compared with mammography, indicating that gamma camera imaging is not adversely affected by post-treatment morphologic changes in the breast [24,25]. Thus, some practices use MBI when such patients cannot undergo MRI.

D. Evaluation for Primary Breast Cancer in Women with Metastases or Metastatic Axillary Lymphadenopathy of Unknown Primary

Although this scenario is uncommon, breast cancer patients may present with axillary or distant metastatic disease without evidence of a primary malignancy within the breasts on mammography, sonography, or clinical examination. MRI is useful for detecting the occult primary malignancy [26]. There are no current studies evaluating MBI for this indication. However, in light of its similar performance in comparison with MRI for cancer detection, it is anticipated that MBI may be a reasonable option for such patients who cannot undergo MRI.

E. Breast Cancer Screening

Mammography is the first line tool for breast cancer screening in women at all risk levels. However, mammography has known limitations, including decreased sensitivity in dense breast tissue and lower sensitivity compared with breast MRI in high risk women (>20% to 25% lifetime risk of breast cancer) [27]. The addition of screening breast MRI is recommended for high risk women and may be considered for women with a 15% to 19% lifetime risk [28]. Approximately 15% of patients cannot undergo MRI for a variety of reasons, including claustrophobia, renal disease (not on dialysis), certain metallic implants, and body habitus [29,30]. The comparable sensitivity for lesions ≥1 cm and improved specificity associated with MBI, combined with the lack of barriers associated with MRI (for some patients), make it a potential

screening option for high-risk women and for those with dense breasts who cannot undergo MRI. However, unlike MRI, MBI involves ionizing radiation [11].

The radiation absorbed dose and target organ distribution of MBI differ significantly from mammography. The differences in absorbed dose for MBI correspond to higher estimated lifetime attributable risks compared with mammography. These differences in risk must be carefully weighed against the benefits of MBI if it is to be used as a screening tool.

This risk to benefit ratio is affected by the administered activity of technetium-99m sestamibi and cancer detection rates; lower administered activities and high cancer detection rates result in a more favorable ratio. The traditional range of administered activities, 740 to 1100 MBq (20 to 30 mCi), may not offer an acceptable risk-to-benefit ratio. However, some practices are currently using administered activities as low as 300 MBq (8 mCi) [5]. Given that the effective dose of 2.6 mSv (for an administered activity of 300 MBq [8 mCi]) is below annual background radiation levels and is about twice that of a combined full-field digital mammography (FFDM)/digital breast tomosynthesis (DBT) screening examination, some advocate biennial MBI screening for women with dense breast tissue and/or elevated breast cancer risk [31]. However, this proposed paradigm represents the current best-case scenario, as not all sites are successfully using 300 MBq (mCi). For centers using 555 MBq (15 mCi), the effective dose will be higher than annual background levels and 4 times that of a combined FFDM/DBT screening examination (7 to 8 times that of a standard FFDM examination or a DBT examination that uses a synthetic planar component). Additionally (and imperative to consider), MBI administers radiation to the entire body, not just the breast as with digital mammography, so overall radiation dose needs to be taken into account in the screening setting. A recent analysis comparing the benefit to radiation risk ratio of mammography versus lower dose (300 MBq or 8 mCi) MBI for asymptomatic women with dense breasts showed higher benefit ratios with mammography for all 10-year age intervals examined (13 versus 5 for women aged 40 to 49 years; 82 versus 37 for women aged 70 to 79 years) [32]. Again, this represents a best-case scenario. The benefit to risk ratio for centers using higher doses is less favorable. It is estimated that an administered dose of 75 to 150 MBq (2 to 4 mCi) is required to achieve a benefit risk ratio comparable to mammography [33].

F. MBI as Adjunct to Conventional Breast Imaging for Problem Solving in Indeterminate Cases

Infrequently, mammographic findings may be indeterminate or difficult to localize for biopsy after a complete conventional mammographic and sonographic diagnostic evaluation. MRI can be useful in such cases as it may aid in lesion localization to improve biopsy targeting accuracy and boost confidence in a decision to follow questionable findings that are not amendable to biopsy.

MBI has also been proposed as useful in such cases when MRI is contraindicated or not available. A sparse amount of data is available to date supporting this indication. In 2012, Siegel and colleagues reported their institution's experience in using MBI for this indication. In their retrospective review (n=416), the majority (56%) of patients undergoing MBI for problem solving consisted of those with indeterminate mammographic asymmetries that were either seen on only 1 view, seen on 2 views with negative ultrasound, or multifocal asymmetries, including cases that were difficult to target for biopsy. Sixty-eight patients (14%) subsequently underwent biopsy based on MBI findings; 43% were malignant and 15% were high-risk lesions, with 29 false positive cases and 2 false-negative cases [34].

Weigert and colleagues subsequently reported a larger multicenter clinical patient registry analysis evaluating the impact of adjunctive imaging with MBI compared with ultrasound on patient management (n=1042). Management changes included proceeding to biopsy for positive adjunctive imaging and follow-up imaging or return to screening for negative imaging. A subset of 119 patients with indeterminate mammographic findings (BIRADS 0) was evaluated. Compared with ultrasound, MBI changed management in 92% of these patients, versus 40% for ultrasound. Performance measures of positive predictive value, false negative rate and accuracy for MBI were 50%, 0% and 84% compared with ultrasound 26%, 9% and 56% [35]. Additionally, they found that neither ultrasound or MBI provided sufficiently high negative predictive value

to obviate biopsy when biopsy was already recommended based on mammographic findings (BIRADS 4 and 5).

A limiting factor in the use of MBI for this indication includes the lack of biopsy capability for some of the MBI systems. Additionally, as with MRI, false-positives and false-negatives will occur; therefore, MBI cannot replace a standard diagnostic evaluation and a negative MBI examination should not obviate biopsy when suspicious mammographic or sonographic findings are present.

III.   RADIATION DOSIMETRY

The radiation absorbed dose to the patient during MBI is directly proportional to the administered activity of technetium-99m sestamibi. The originally recommended range was 740 to 1100 MBq (20 to 30 mCi). Currently, administered activities of 300 to 555 MBq (8 to 15 mCi) are being used with dedicated dual-detected gamma camera systems. It is possible to achieve diagnostic images with these lower administered activities [4], especially given improvements in CZT purity and collimators [4,5].

The average radiation absorbed dose to the breast with intravenous technetium-99m sestamibi is estimated to be approximately 0.07 mGy/mCi [36], which calculates to approximately 0.53 mGy for an administered activity of 300 MBq (8 mCi); this level is lower than the mean glandular dose for a 2-view screening mammogram of 2 mGy for a 5 cm thick compressed breast. However, because of the whole-body distribution of technetium-99m sestamibi, organs outside the breast receive radiation with MBI examinations. Organs that receive the highest doses are the large intestine wall, small intestine wall, kidneys, bladder wall, and gallbladder wall. The effective (whole-body) dose is estimated to be approximately 0.325 mSv/mCi, which calculates to approximately 2.6 mSv for an administered activity of 300 MBq (8 mCi) and 6.5 mSv for an administered activity of 740 MBq (20 mCi) [36]; these levels are higher than the effective (whole-body) dose from 2-view digital mammography (approximately 0.5 mSv). As a result, overall radiation dose needs to be taken into account when evaluating the risks of MBI. Injected activity should be consciously chosen, taking advantage of the sensitivity of the given system and adjusting the timing of acquisition with the ultimate goal of administering the lowest possible dose.

IV.   CONTRAINDICATIONS

A. Pregnancy

The ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [37].

B. Allergy

Allergy to technetium

V.   QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

MBI should be performed by qualified physicians. The physician should meet the qualifications outlined in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [38] or should review the mammographic, sonographic, and/or MRI findings with a physician who meets the qualifications specified in the FDA Mammography Quality Standards Act (MQSA) Final Regulations.

1. Initial qualifications

Training in medical physics, interpretation of MBI, and hands-on training are imperative to successful performance.

The initial qualifications outlined for the Nuclear Medicine Accreditation Program Requirements provide this foundation [39].

2. Maintenance of competence
   The physician should perform a sufficient number of examinations to maintain appropriate skills. Continued competence depends on participation in a quality control program as defined in section IX.

3. Continuing medical education
   The physician's continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education [40].

B. Qualified Medical Physicist

For qualifications of the Qualified Medical Physicist, see the ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography [41] and the ACR–AAPM Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras [42].

C. Radiologic Technologist

Technologists administering radiopharmaceuticals to the patient must meet the qualifications specified in the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [43]. Positioning patients and acquiring the images must be performed either by mammography technologists meeting the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [38] or by certified nuclear medicine technologists with special training in mammographic positioning techniques.

VI.   SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for molecular breast imaging 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 would be helpful and may at times be needed 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 state's scope of practice requirements. (ACR Resolution 35, adopted in 2006).

A. Radiopharmaceuticals

Technetium-99m sestamibi: There is increased uptake by breast malignancies, as these tumors generally have a higher metabolic rate than surrounding normal tissues.

Administered activities of 740 to 1100 MBq (20 to 30 mCi) are standard; however, an administered activity as low as 300 to 555 MBq (8 to 15 mCi) may be appropriate depending on the imaging system [4,5]. The lower dosage range improves the risk to benefit ratio [33]. The radiopharmaceutical is administered through an indwelling venous catheter or a butterfly needle, followed by 10 mL of saline to flush the vein. An upper

extremity vein on the contralateral side to a suspected abnormality is preferred; either side is acceptable for those having screening MBI.

B. Patient Factors

Although no special preparation is necessary, measures to promote sestamibi uptake are encouraged. For example, patients are asked to fast except for coffee, diet beverages, or water for 3 hours before the examination, and they are covered with a warm blanket while in the department [44].

A thorough explanation of MBI should be provided to the patient by the technologist or physician.

The patient should remove all clothing and jewelry above the waist. Wearing a mammography cape or gown is recommended.

Contraindications to MBI include pregnancy and known hypersensitivity to technetium-99m sestamibi.

C. Images

Imaging begins 5 to 10 minutes after intravenous administration of the radiopharmaceutical. Each image is acquired for approximately 10 minutes or 175,000 counts (minimum of 7 minutes).

The patient is seated for the examination. MBI views correspond to standard mammographic views.

The breast with the suspected abnormality is imaged first. Views include left craniocaudal, left mediolateral oblique, right craniocaudal and right mediolateral oblique. If needed, additional views may be acquired by the interpreting physician; they include 90 degree lateral (lateromedial or mediolateral), axillary tail, cleavage view, exaggerated craniocaudal view, left anteroposterior view (axilla), and right anteroposterior view (axilla). For lesions close to the chest wall, an extra craniocaudal image with minimal immobilization can help ensure inclusion of posterior tissues, especially in women with breast tissue that resists compression.

VII. EQUIPMENT SPECIFICATIONS

See the ACR–AAPM Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras [42].

VIII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [45].

The report should include the radiopharmaceutical used and the dosage and route of administration, as well as any other pharmaceuticals administered, including the dosages and routes of administration.

A. Image findings and pathologic interpretation should be correlated in a timely fashion by a qualified physician.

A standardized MBI lexicon has been proposed [46].

B. View performed and acquisition time per view

Permanent records of MBI should be documented in a retrievable image storage format. When appropriate, correlative mammography should be performed in conjunction with MBI.

C. Image labeling should include the following:

1. Patient's first and last names
2. Identifying number and/or date of birth
3. Examination date
4. Facility name and location
5. Designation of the left or right breast and specific view

D. Other information that can be entered on the permanent record includes the technologist's and physician's initials.

E. Retention of the procedure images, including specimen images if obtained, should be consistent with the facility's policies for retention of images and in compliance with federal and state regulations.

IX. 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

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals and that they are adhered to in accordance with ALARA. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol

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.

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).

X. 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 American College of Radiology (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)

ACKNOWLEDGEMENTS

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter
Adopted 2017