SNMMI Procedure Standard / EANM Practice Guideline for Molecular Breast Imaging with Dedicated Gamma-Cameras

Carrie B. Hruska*[1], Christinne Corion*[2,3], Lioe-Fee de Geus-Oei[3,4], Beatriz E. Adrada[5], Amy M. Fowler[6,7,8], Katie N. Hunt[1], S. Cheenu Kappadath[9], Patrick Pilkington[10], Lenka M. Pereira Arias-Bouda**[3,11], Gaiane M. Rauch**[5,12]

[1]Department of Radiology, Mayo Clinic, Rochester, MN, USA
[2]Department of Surgery, Haaglanden Medical Center, The Hague, Netherlands
[3]Department of Radiology, Leiden University Medical Center, Leiden, Netherlands
[4]Biomedical Photonic Imaging Group, University of Twente, Enschede, Netherlands
[5]Department of Breast Imaging, The University of Texas MD Anderson Cancer Center, Houston, TX, USA
[6]Department of Radiology, University of Wisconsin, Madison, WI, USA
[7]Department of Medical Physics, University of Wisconsin, Madison, WI, USA
[8]University of Wisconsin Carbone Cancer Center, Madison, WI, USA
[9]Department of Medical Physics, The University of Texas MD Anderson Cancer Center, Houston, TX, USA
[10]Department of Nuclear Medicine, University Hospital 12 de Octubre, Madrid, Spain
[11]Department of Nuclear Medicine, Alrijne Hospital, Leiderdorp, Netherlands
[12]Department of Abdominal Imaging, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

*joint first authors
**joint senior authors

PREAMBLE

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) is an international scientific and professional organization founded in 1954 to promote the science, technology, and practical application of nuclear medicine. The European Association of Nuclear Medicine (EANM) is a professional non-profit medical association that facilitates communication worldwide between individuals pursuing clinical and research excellence in nuclear medicine. The EANM was founded in 1985. SNMMI and EANM members are physicians, technologists, and scientists specializing in the research and practice of nuclear medicine.

The SNMMI and EANM will periodically define new guidelines for nuclear medicine practice to help advance the science of nuclear medicine and to improve the quality of service to patients throughout the world. Existing practice guidelines will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline, representing a policy statement by the SNMMI/EANM, has undergone a thorough consensus process in which it has been subjected to extensive review. The SNMMI and EANM recognize that the safe and effective use of diagnostic nuclear medicine imaging requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline by those entities not providing these services is not authorized.

These guidelines are an educational tool designed to assist practitioners in providing appropriate care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, both the SNMMI and the EANM caution against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, there is no implication that an approach differing from the guidelines, standing alone, is below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines.

The practice of medicine includes both the art and the science of 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 guidelines will not ensure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This document provides an update to the previous SNMMI Practice Guideline for Breast Scintigraphy for Breast-Specific Gamma Systems (*1*).

Nuclear medicine methods for imaging of the breast have been in clinical use since the 1990s, beginning with the technique of breast scintigraphy or “scintimammography”, which was performed with 99mTc-sestamibi and general purpose gamma cameras with NaI detectors (*2*). Since that time, gamma camera systems dedicated for breast imaging have emerged in the market. These dedicated systems, including some that employ semiconductor detectors rather than NaI scintillators, offer improved image quality over conventional scintimammography, leading to new clinical applications and unique guidelines specific to dedicated systems.

The term “molecular breast imaging (MBI)” has been generally used to describe imaging with dedicated gamma camera systems that detect single-photon emitting radiotracers (also previously referred to as breast specific gamma imaging [BSGI]), as well as imaging with dedicated coincidence detection systems that detect positron-emitting radiotracers (referred to as dedicated breast positron emission tomography [DbPET] or positron emission mammography [PEM]) (*3-5*). In this Joint SNMMI Procedure Standard/ EANM Practice Guideline, MBI refers to use of a dedicated gamma camera for planar imaging of the breast, following intravenous injection of 99mTc-sestamibi.

99mTc-sestamibi is FDA-approved as a second line diagnostic drug after mammography to assist in evaluation of breast lesions and EMA-approved for detection of suspected breast cancer when mammography is equivocal, inadequate or

indeterminate. However, in current clinical practice, MBI is frequently used for other indications as well, including screening; due to advances in technology that have improved count sensitivity, MBI is commonly performed at administered activities between 300 and 600 MBq, which is substantially lower than the amount listed in the package inserts (740-1110 MBq per FDA and 700-1000 MBq per EMA). 99mTc-tetrofosmin has also been used for evaluation of breast lesions (*6*).

Results from MBI have been shown useful for detection and monitoring of breast cancer, particularly in settings where conventional modalities of mammography and ultrasound are considered insufficient or where breast MRI is recommended but not feasible. Because MBI provides information on the functional behavior of tumors, it can reveal breast cancers masked by dense fibroglandular tissue on mammography. MBI is well-tolerated by patients, has few contraindications, is associated with low costs, and has a fast interpretation learning curve (*7,8*). MBI also offers the option for MBI-guided biopsy.

II. GOALS

The goals of this guideline are to provide an update on current clinical indications for MBI, to discuss the advantages and disadvantages of MBI and describe the MBI examination procedure. The qualifications and responsibilities of personnel involved, the equipment used with MBI, and the image acquisition protocol are also discussed.

III. COMMON CLINICAL INDICATIONS

Common indications for MBI include, but are not limited to, problem solving for indeterminate imaging findings, breast cancer staging, monitoring response to neoadjuvant therapy, breast cancer screening, and surveillance for breast cancer recurrence, as described in more detail below. Guidance on MBI indications has also been provided by American College of Radiology (*9*).

A. Problem solving

MBI has been proven useful in patients with indeterminate breast abnormalities and remaining diagnostic concerns after physical examination and conventional radiologic work up with mammography and ultrasound. MBI has been studied as a tool for directing management of benign and low suspicion findings. Use of MBI in other problem solving scenarios is still being studied (*6,10-15*).

B. Local Staging

In patients recently diagnosed with breast cancer, MBI may be used to evaluate the extent of disease and to determine additional sites in case of multifocal, multicentric as well as contralateral disease (*6,16-22*). MBI may be especially useful in case of discrepancies between clinical and radiological findings or indeterminate radiological findings due to challenging conventional imaging (e.g., mammographically dense breast) and when MRI is contraindicated or unavailable.

C. Treatment response monitoring

MBI can be used to evaluate disease extent before and after neoadjuvant chemotherapy (*23,24*). Data have shown MBI to provide similar evaluation of disease extent to that acquired with MRI. Other studies have examined whether the change in tumor size or uptake on MBI could provide prognostic information that predicts tumor response to therapy (*25,26*). Investigations to standardize 99mTc-sestamibi response criteria, to optimize timing and frequency of imaging, and to examine variability in response with tumor subtypes are ongoing.

D. Screening and surveillance

As a screening tool, MBI has been useful in detecting mammographically-occult breast cancer in women with dense breast tissue (heterogeneously or extremely dense on mammography(*27*)) and in women at elevated risk for breast cancer who are unable to undergo breast MRI screening (*28-33*).

MBI may be used in surveillance for recurrence in women with personal history of breast cancer, especially women whose previous breast cancer was occult on mammography or women who have dense breasts. MBI can help to differentiate between scar tissue and recurrence of disease in patients who underwent surgery, radiotherapy or biopsy (*34*).

E. Additional Uses

MBI has shown usefulness as a supplement to mammography in patients with difficult conventional imaging, such as patients with mammographically dense breasts, implants and free silicone. MBI has been used as an alternative to MRI when breast MRI is contraindicated or unavailable (*9,34*).

IV. CONTRAINDICATIONS

A. Pregnancy

MBI should be postponed during pregnancy if possible. Because 99mTc-sestamibi is known to cross the placental barrier, the fetus may be exposed to radiation if a pregnant patient undergoes MBI – see section XI.

B. Allergic reaction to 99mTc-sestamibi

Allergic reaction to 99mTc-sestamibi is rare and typically mild – see Section VI.C. Nevertheless, if a patient presenting for MBI has a known history of hypersensitivity or allergic reaction to 99mTc-sestamibi, an alternative test to MBI should be considered. If MBI is still pursued, special precautions such as premedication may be warranted to prevent allergic reaction.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

As this is a joint SNMMI procedure Standard/EANM Practice Guideline the qualifications and responsibilities of personnel will contain both the American/Canadian and the European rules and expectations.

A. Physician

In the U.S. and Canada, MBI examinations should be performed under the supervision of and interpreted by a physician certified in Nuclear Medicine or Radiology by the applicable accrediting board, such as the American Board of Nuclear Medicine, the American Board of Radiology, the Royal College of Physicians and Surgeons of Canada, Le College des Medecins du Quebec, or the equivalent.

In Europe, MBI examinations should be performed by or under supervision of a physician specialized in Nuclear Medicine or Nuclear Radiology and certified by the accrediting boards. The certified nuclear medicine physician who authorizes the study and signs the report is responsible for the procedure according to national laws and rules.

The physician should participate in maintenance of certification in the field of radiology or nuclear medicine.

B. Technologist

MBI examinations should be performed by a Nuclear Medicine Technologist that is registered/certified in Nuclear Medicine by the Nuclear Medicine Technology Certification Board (NMTCB), American Registry of Radiologic Technologists (ARRT), or the Canadian Association of Medical Radiation Technologists (CAMRT) or the equivalent. The Nuclear Medicine Technologist works under the supervision of the Physician as outline above. Nuclear medicine technologists who perform MBI should receive additional training in mammographic positioning techniques (*35*). Alternatively, if U.S. state regulations allow, MBI examinations may be performed with radiopharmaceutical administration by a nuclear medicine technologist and image acquisition by a certified mammography technologist.

In Europe the examination should be executed by qualified registered/certified nuclear medicine technologists (*36*).

C. Medical Physicist

The medical physicist should oversee instrumentation quality control, protocol development, and image processing of MBI examinations. The medical physicist should be able to practice independently in the subfield of nuclear medicine physics. Qualifications are as stated in the SNMMI Procedure Standard for General Imaging (*37*).The SNMMI recommends that Medical Physicists be certified in the appropriate subfield(s) by the American Board of Science in Nuclear Medicine or by the American Board of Radiology, or the equivalent.

The EANM states that a certified Medical Physics Expert (MPE) is responsible for the quality assurance of MBI systems that are in clinical use and also for the identification of possible malfunctions of these systems. The MPE is also responsible for the optimal implementation of procedures considering national and international radiation protection safety standards both for patients and personnel.

VI. PROCEDURE/SPECIFICATIONS OF THE EXAMINATION

A. Request for MBI

1. Other relevant imaging, such as recent mammogram, should be made available for correlation with the MBI.

2. The interpreting physician should be aware of physical findings, symptoms, and clinical history.

3. The patient's pregnancy and lactation status, date of last menses, and use of hormonal therapies should be determined.

    i. If pregnancy is possible, the study should be delayed until the onset of menses or until a negative pregnancy test is obtained.

    ii. Reporting of the patient's menopausal status, phase of menstrual cycle, and any exogenous hormone therapy use may aid in radiologist's interpretation with regard to background parenchymal uptake (BPU). Premenopausal women may benefit from scheduling imaging during the follicular phase of their menstrual cycle (typically before day 14) to minimize BPU. In patients currently taking hormone therapy, BPU may be elevated.

4. Ideally, MBI should be performed before interventional procedures, such as biopsy, because 99mTc-sestamibi may accumulate at sites of inflammation that may confound interpretation. However, MBI may still be performed after intervention as it can effectively evaluate the remainder of the ipsilateral breast tissue and the contralateral breast.

5. Care should be taken in scheduling MBI adjacent to other nuclear medicine studies or therapies that may interfere with imaging (*35*). In particular, MBI should not be scheduled within 24 h prior to a breast sentinel lymph node localization with a radiotracer.

B. Patient preparation and precautions

1. A thorough explanation of the test should be provided by the technologist or physician.

2. Patients should be encouraged to drink water prior to the MBI examination to stay hydrated for intravenous injection.

3. Although not required, patient fasting (no calorie intake) for approximately 3 h prior to MBI may increase uptake of 99mTc-sestamibi in breast tissue by reducing splanchnic and hepatic blood flow (*38*). If fasting is used, special considerations may be needed for diabetic patients.

4. The patient should change into a gown, removing all clothing from the waist up, to better facilitate imaging.

5. Deodorants, lotions, powders, and jewelry (such as necklaces) do not need to be removed for the MBI examination.

6. Although not required, warming the patient's upper torso by wrapping a warm blanket around the patient's shoulders for at least 5 min prior to injection may increase peripheral blood flow and further increase uptake of 99mTc-sestamibi in breast tissue (*38*).

7. Confirmation of no current pregnancy should be obtained from female patients of child-bearing capacity, according to local institutional procedures – see Sections IV and XI.

8. Confirmation of no previous allergic reaction to 99mTc-sestamibi should be obtained.

9. For patients who are breastfeeding, no interruption is necessary – see Section XI (*39*).

C. Radiopharmaceutical

1. Two single-photon radiopharmaceuticals, 99mTc-sestamibi and 99mTc-tetrofosmin are EMA-approved for breast imaging indications. 99mTc-sestamibi is also FDA-approved for breast imaging. In current practice, 99mTc-sestamibi is most commonly used.

2. 99mTc-sestamibi should be administered using an indwelling venous catheter or butterfly needle followed by 10 mL of saline to flush the vein.

3. When possible, the tracer should be administered via an upper-extremity vein on the opposite side of the suspected abnormality.

4. Administered activity

    i. MBI has previously been performed with general purpose gamma cameras and administered activities of 740 to 1100 MBq of 99mTc-sestamibi per the FDA approval or 700 to 1100 MBq per the EMA approval. However, the improved count sensitivity of modern MBI systems now facilitate lower administered activity, with many practices now administering 300 MBq or less.

ii. MBI performed with modern dedicated MBI systems, using approximately 300 MBq (8 mCi) of 99mTc-sestamibi, will typically attain adequate count density with an acquisition time 7 to 10 min per view. Administered activity and acquisition time may vary depending on equipment used and practice preference.

iii. For MBI-guided biopsy procedures, a higher administered activity of 600-800 MBq (16-22 mCi) may be considered to ensure optimal visibility of the target and allow shorter acquisition time (*40*).

5. 99mTc-sestamibi has been found to adhere to certain types of plastic syringe walls (*41*). Care in selection of a syringe with low 99mTc-sestamibi adsorption is advised to minimize residual activity. If warranted, residual activity should be measured after injection to obtain an accurate assessment of the net administered activity.

6. Adverse events from 99mTc-sestamibi are rare (1 to 6 events per 100,000; < 0.006%) and can include allergic reaction but are typically mild in severity (e.g., flushing, rash, injection site inflammation, or brief metallic taste) (*42,43*).

7. 99mTc-sestamibi clears from the bloodstream within 2 to 3 min and is taken up largely by first-pass extraction, with minimal redistribution. 99mTc-sestamibi uptake in breast tissue has minimal physical decay and minimal washout over a typical examination time (<1 h). Thus MBI acquisition may begin approximately 5 min after injection and minor delays between injection and imaging are not problematic (*35*).

D. Protocol/ image acquisition

1. A detailed guide for MBI technologists has been previously published (*35*).

2. Technologists should verify with the patient the indication for the examination and ask the patient if she has any areas of breast concern. If applicable, the affected side should be imaged first in case the patient cannot tolerate the entire examination. The technologist should confirm that the area of concern will be included in the imaging field of view.

3. Breast positioning

   i. The patient should be seated during the scan time. A specialized chair, such as those designed for seated mammography, is recommended.

   ii. Support the patient’s back with pillows as needed to make the scanning time as comfortable as possible.

iii. The patient's breast should be placed in direct contact with the gamma camera detector and light compression applied to immobilize the breast during image acquisition.

4. Imaging

   i. Imaging may begin within 5 min of injection (section VI.C.7).

   ii. Planar imaging should be acquired in 2 standard views: cranio-caudal (CC) and mediolateral oblique (MLO), analogous to mammographic views. For single-head systems, CC view is acquired with the detector under the breast, and the MLO view is acquired with the detector at approximately 45° oblique on the lateral side of the breast. If needed, additional views may be acquired.

   iii. Typical image acquisition time is between 7 to 10 min per view. The necessary acquisition time to achieve acceptable image quality will depend on administered activity and specifics of the MBI system, including gamma camera sensitivity and detector pixel size. For MBI detectors with 1.6 mm or 2.5 mm detector elements, it is suggested to select an acquisition time that will achieve at least 30 counts per pixel or 50 counts per pixel, respectively, in areas of normal breast tissue.

   iv. Images should be labeled with laterality ("left" or "right"). Radioactive Co-57 markers may be used.

5. Processing

   For the correct interpretation of the images a computer workstation should be available which enables simultaneous display of the MBI and recent mammogram. Adjustment of the image contrast by the interpreting physician may be necessary.

   Display parameters, including gray scale linear display and color logarithmic display can be used in order to optimize interpretation.

E. Interpretation

1. Relevant information listed below should be considered in the interpretation.
   i. The indication for MBI, clinical problems, history of breast interventions, risk factors and menopausal state should be listed.
   ii. If there are any limitations (e.g., suboptimal positioning, or artifacts) which are felt to affect the image interpretation, these must be reported.
   iii. Correlation should be made with other available relevant imaging, such as mammography, and clinical findings.

2. A validated molecular breast imaging lexicon for interpretation has previously been published (*8,44*). This lexicon should be utilized when describing and interpreting imaging findings. The predictive value of MBI lexicon features is being examined (*45-47*).
    i. Background parenchymal uptake (BPU) is defined as the degree of radiotracer uptake within the breast parenchyma in comparison to subcutaneous fat. BPU is assessed visually as photopenic, minimal/mild, moderate, or marked.
    ii. If a lesion is identified, the intensity of uptake within the lesion (photopenic, mild, moderate or marked), mass or non-mass uptake, and the distribution are described.
    iii. The location and size of any finding are described by the quadrant or clock face position, as well as depth or distance from the nipple.
    iv. Lesion size is measured on the image where the finding is best visualized. By definition, *x* is the longest lesion measurement, *y* is orthogonal to *x* on the same image, and *z* is orthogonal to *x* and *y* on the image not used to measure *x* and *y.*
    v. Associated findings such as nipple, axillary, or vascular uptake should be described.

3. The final assessment and management recommendations should be provided on every MBI examination.
    i. Assessment categories parallel those of the Breast Imaging Reporting and Database System (BI-RADS)(*27*) and are described as Category 0 (incomplete, needs additional imaging); Category 1 (negative, routine follow-up); Category 2 (benign, routine follow-up); Category 3 (very low likelihood of malignancy); Category 4 (Suspicious, consider biopsy); Category 5 (highly suggestive of malignancy, take appropriate action); and Category 6 (known malignancy, take appropriate action).
    ii. The assessment is based on the level of suspicion by the interpreting radiologist based on lesion distribution, intensity, and morphology.
    iii. When a final assessment of 1 or 2 is given, no further imaging is necessary.
    iv. Category 0 should be avoided, similar to breast MRI interpretation, and an assessment corresponding to the level of suspicion provided when possible.
        a. All category 0, 3, 4, or 5 lesions undergo diagnostic mammography and/or ultrasound.
        b. If a correlate is identified on mammography or ultrasound, biopsy can be performed with guidance from one of those modalities.
        c. If no correlate is identified on conventional imaging for a category 3 finding, short-interval follow-up MBI, typically in 6 months, is recommended. If the lesion decreases in size and/or intensity on follow-up, it is considered benign. If it increases in size and/or intensity, MRI or MBI guided biopsy is performed. If it remains the same, continued follow-up at 12 and 24 months after the initial MBI is recommended.

d. For category 4 or 5 lesions, MBI guided biopsy or MRI are recommended when conventional imaging does not show a correlate.

F. Interventions

MBI devices with stereotactic biopsy guidance capability are available. Common indications for MBI-guided biopsy include:

1. Suspicious MBI abnormalities which are occult on mammography and (targeted) ultrasound.
2. Mammographic abnormalities, occult on US but 99mTc-sestamibi avid, when stereotactic mammographically-guided biopsy is technically challenging.
3. Cases of lesions recommended for MRI-guided biopsy that cannot be performed (e.g., MRI-guided biopsy is not available, is technically challenging, or attempted and unsuccessful).

For a detailed description of the MBI-guided biopsy methodology, the following papers can be advised (*40,48-50*).

G. Limitations and pitfalls

1. Motion of the breast relative to the detector may result in image blurring, making small lesions more difficult to detect.

2. Small lesions, especially less than 5 mm, are difficult to detect with current MBI technology.

3. Posterior lesions close to the chest wall may be difficult to include in the MBI field of view. The axilla cannot be reliably imaged with planar MBI acquisitions due to positioning limitations.

4. Due to the smaller field of view of MBI cameras relative to mammography, additional views may be needed for patients with larger breasts.

5. False positive uptake of 99mTc-sestamibi is associated with the following etiologies:

    i. Benign lesions (e.g. fibroadenomas, papillomas, fat necrosis, pseudoangiomatous stromal hyperplasia)

    ii. Atypical lesions (e.g. atypical ductal hyperplasia, atypical lobular hyperplasia) and lobular carcinoma in situ

    iii. Normal axillary or intramammary lymph nodes

iv. Inflammation following biopsy, surgery, or external beam radiation therapy

v. Background parenchymal uptake that may fluctuate with menstrual cycle or exogenous hormone use

6. Extravasation of the tracer injection may result in areas of abnormal uptake in ipsilateral lymph nodes (*51*).

VII. DOCUMENTATION / REPORTING

The report should provide the referring physician with an answer to the specific clinical questions and must contain the following:

1. The clinical indication for requesting MBI
2. Relevant clinical information
3. The administrated dose of the radiopharmaceutical used and injection site.
4. History of previous examinations
5. Findings
6. Impression to include assessment category and recommendation for further management

Additional information specific to the MBI interpretation should be included in the report as described above – see Section VI.E.

VIII. EQUIPMENT SPECIFICATIONS

A. MBI systems have included both single and dual detector for data acquisition under mammography configurations. A single-detector system comprising pixelated NaI elements coupled to position-sensitive photomultiplier tubes has been previously referred to as “BSGI”. More recently, MBI systems comprise dual-head cadmium zinc telluride (CZT) detectors with specialized collimation to improve spatial resolution and count sensitivity.

B. MBI systems should be specifically designed for dedicated breast imaging. Compared to conventional gamma cameras, MBI systems have a compact design with minimal dead space at the detector-chest wall edge to allow placement of the breast directly on the surface of the gamma camera in a manner analogous to mammography.

C. MBI systems should have a mechanism to allow breast immobilization.

D. MBI systems should be capable of detecting 140 keV gamma rays of 99mTc-sestamibi. The energy acceptance window may be symmetric or asymmetric with regard to the 140 keV photopeak, depending on manufacturer recommendations.

E. MBI systems may be equipped with a biopsy attachment (*40,49,50*).

IX. QUALITY CONTROL

A. An MBI quality control program should be established and maintained under the direction of a qualified medical physicist.

B. Acceptance testing of MBI systems should be performed to verify equipment performance specifications from manufacturer

C. Annual physics testing should be performed to verify MBI system performance and stability, as required by the sites accrediting body (e.g., The Joint Commission or American College of Radiology). See for example, AAPM Report No. 177 - Acceptance Testing and Annual Physics Survey Recommendations for Gamma Camera, SPECT, and SPECT/CT Systems (*52*). Some of the devices are based on a pixelated design and not a single crystal design. The quality control of these devices may require additional or modified testing to maintain proper operation.

D. Daily uniformity testing of the MBI system should be conducted before imaging patients to assess that system uniformity and bad pixel correction are within manufacturer specifications (typically, integral uniformity should be 5% or less). Uniformity calibrations should be performed when integral uniformity is out of range, per manufacturer recommendations. Daily uniformity flood scans should be repeated after calibrations to ensure that uniformity falls within range. See SNMMI Procedure Standard for General Imaging for additional information (*37*).

E. Local and state guidelines may also mandate additional quality control testing.

F. A guide for quality control procedures and recommended routine testing of MBI equipment has been previously published (*53*).

X. PATIENT EDUCATION

A. Patients undergoing MBI should receive a thorough explanation of the examination prior to radiopharmaceutical administration and commencement of imaging. Patient education materials and preparation instructions, if necessary, may be provided prior to the MBI appointment.

B. Patient education includes describing the injection of 99mTc-sestamibi and the rare potential for mild side effects (see Section VI.C), explaining the imaging procedure, and informing the patient examination results will be communicated.

C. When the patient arrives for MBI, the technologist or other staff member should explain the examination to the patient in person, verify that the patient is not pregnant, and give breastfeeding instructions if necessary.

D. Patient-focused information about MBI is provided by SNMMI at DiscoverMI.org (*54*).

XI. RADIATION SAFETY

A. Patient exposure considerations

See Section X of the SNMMI Procedure Standard for General Imaging (*37*).

99mTc-sestamibi emits gamma rays with principal photon energy of 140 keV and has a physical half-life of 6.01 h.

Dose estimates to adult patients and the fetus of pregnant patients are presented in Tables 1 and 2. For a typical administration of 296 MBq (8 mCi) 99mTc-sestamibi for MBI, the estimated dose to the breast is 1.1 mGy, the organ receiving the largest estimated dose is the gallbladder (11.5 mGy) and the effective dose is estimated as 2.1 to 2.7 mSv.

Regarding dose estimates to breastfeeding patients, ICRP Publication 106 (Annex D) suggests that no interruption is needed for breastfeeding patients administered 99mTc-sestamibi or 99mTc-tetrofosmin (*39*). However, due to possible free 99mTc pertechnetate it is advisable to interrupt the feeding for 4 h.

TABLE 1. Radiation dosimetry estimates in adults

Radiopharmaceutical	Radiation dose to the breast mGy/MBq (rad/mCi)	Organ receiving largest radiation dose mGy/MBq (rad/mCi)	Effective dose mSv/MBq (rem/mCi)
99mTc-sestamibi, resting subject	0.0038 (0.014)	Gallbladder: 0.039 (0.14)	0.0071* to 0.0090 (0.026 to 0.033)
99mTc-tetrofosmin, resting subject	0.0020 (0.0074)	Gallbladder: 0.036 (0.13)	0.0062* to 0.0080 (0.023 to 0.030)

Unless otherwise noted, data are from ICRP Publication 128 (55).
**An updated estimate of effective dose specific to female subjects was provided in (56).*

TABLE 2. Fetal dose from 99mTc-sestamibi (rest)

	Fetal dose	
Stage of gestation	**mGy/MBq**	**rad/mCi**
Early	0.015	0.055
3 mo	0.012	0.044
6 mo	0.0084	0.031
9 mo	0.0054	0.020

99mTc-sestamibi dose estimates to fetus are from Russell et al (57). No information about possible placental crossover of this compound was available for use in estimating fetal doses.

B. Personnel exposure considerations

The technologist total body radiation exposure depends on the administered activity, the imaging time per patient, and the patient workload. Assuming an administered activity of 296 MBq (8 mCi) 99mTc-sestamibi per patient and approximately 1 hour total patient contact time, the total body radiation dose of an MBI technologist who injects the radiopharmaceutical, performs breast positioning, and remains in the room with the patient during imaging is estimated to be <0.2 mrem per patient (*58*). For example, a modest technologist clinical workload of 1 MBI patient exam per day corresponds to an annual effective dose of ~48 mrem (0.48 mSv).

Exposure to radiologists and support staff performing MBI-guided biopsy has been reported as 0.03 mGy/h at a distance of 15 cm from the patient (*40*). Thus, estimated radiation exposure to a radiologist in close contact with the biopsy patient for 20 min is conservatively estimated at 0.01 mGy, which corresponds to an effective dose of 0.01 mSv.

C. MBI room shielding requirements

The standard shielding as used in a mammography exam room is typically sufficient for MBI.

XIII. REFERENCES

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XIV. APPROVAL

This Procedure Standard was approved by the Board of Directors of the SNMMI on (date).

XV. LIABILITY STATEMENT

This guideline summarizes the views of the EANM Oncology & Theranostics Committee and SNMMI. It reflects recommendations for which the EANM and SNMMI cannot be held responsible. The recommendations should be taken into context of good practice of nuclear medicine and do not substitute for national and international legal or regulatory provisions.

XVI. ACKNOWLEDGEMENTS

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