THE SNM PROCEDURE GUIDELINE FOR BREAST SCINTIGRAPHY WITH BREAST-SPECIFIC GAMMA CAMERAS 1.0

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic 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, the Society of Nuclear Medicine cautions 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, an approach that differs from the guidelines, 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 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 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 guidelines 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 guidelines is to assist practitioners in achieving this objective.
I.  INTRODUCTION

The intention of this guideline is to assist breast imaging practitioners in patient selection for, performance, interpretation, and reporting of $^{99m}$Tc-sestamibi breast-specific gamma imaging (BSGI).

II.  GOALS

The goal of Breast-specific gamma imaging (BSGI) performed with a high-resolution, small field-of-view, breast optimized gamma camera after intravenous administration of $^{99m}$Tc-sestamibi is to detect breast malignancies and is therefore classified under the CPT codes 78800 – 78804 Radiopharmaceutical Localization of Tumor or Distribution of Radiopharmaceutical Agent(s).

III.  DEFINITIONS

See SNM Procedure Guideline for General Imaging

IV.  EXAMPLES OF CLINICAL AND RESEARCH INDICATIONS

A.  Breast scintigraphy is addressed in the ACR’s Appropriateness Criteria Panel on Breast Imaging, The American College of Surgeons Consensus Conference III (1-2) and the Institute for Clinical Systems Improvement Diagnosis of Breast Disease

B.  Patients with recently detected breast malignancy (3-5)

1.  Evaluating the extent of disease (initial staging)
2.  Detecting multicentric, multi-focal, or bilateral disease
3.  Assessing response to neoadjuvant chemotherapy
4.  Breast scintigraphy is addressed in the ACR’s Appropriateness Criteria Panel on Breast Imaging.

C.  Patients at high risk for breast malignancy (6-8)

1.  Suspected recurrence
2.  Limited mammogram or previous malignancy was occult on mammogram

D.  Patients with indeterminate breast abnormalities and remaining diagnostic concerns (3,4,9,10)

1.  Nipple discharge with abnormal mammogram and/or sonographic abnormality with or without contrast ductography.
2.  Bloody nipple discharge with normal mammogram and/or ductogram
3.  Significant nipple discharge with unsuccessful ductogram
4.  Evaluation of lesions when patient reassurance is warranted (BIRADS 3)
5.  Evaluation of lesions identified by other breast imaging techniques, palpable or non-palpable
6.  Evaluation of palpable abnormalities not demonstrated by mammography or ultra-sound
7.  Evaluation of multiple masses demonstrated on breast imaging
8.  To aid in biopsy targeting
9.  Evaluation of diffuse or multiple clusters of microcalcifications
10.  Evaluation of breasts for occult disease in cases of axillary lymph node metastases with unknown primary
11. Unexplained architectural distortion
12. Evaluation of suspicious mammographic finding seen on one view only
13. Evaluation of enhancing areas seen on MRI to increase specificity

E. **Patients with technically difficult breast imaging** *(4,7-9,11,12)*
   1. Radiodense breast tissue
   2. Implants, free silicone, or paraffin injections compromising the mammogram

F. **Patients for whom Breast MRI would be indicated** *(1,13-15)*
   1. MRI is diagnostically indicated, but not possible
      a. implanted pacemakers or pumps
      b. ferromagnetic surgical implants
      c. risk of nephrogenic systemic fibrosis response to gadolinium.
      d. body habitus exceeding the inside of the MRI bore
      e. patients with breasts too large to be evaluated within the breast coil
      f. patients with acute claustrophobia
      g. other factors limiting compliance with a prescribed MRI study.

   2. As an alternative for patients who meet MRI screening criteria: BRCA1, BRCA2 mutations; parent, sibling, or child BRCA+; Lifetime risk of 20-25% established; chest radiation between ages 10 and 30

G. **Monitor neoadjuvant tumor response in patients undergoing preoperative chemotherapy** *(16-18)*
   1. Determine the impact of therapy
   2. Surgical planning for residual disease

V. **QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

   See Section V of SNM procedure guideline for general imaging 4.0

VI. **PROCEDURE/SPECIFICATIONS OF THE EXAMINATION**

A. **Request**
   1. Relevant imaging studies should be available for correlation.
   2. The interpreting physician should be aware of physical findings, symptoms and clinical history.
   3. The date of last menses or pregnancy and lactation status of the patient should be determined.
      a. BSGI should be performed between day 2 and day 12 of the patient’s cycle if possible.
      b. If pregnancy is possible, study should be delayed until onset of menses.
   4. Ideally, BSGI should be performed prior to interventional procedures. Breast scintigraphy (BSGI) is commonly used in pre-surgical planning and can effectively evaluate the remainder of the breast tissue in such cases. If performed within 2 weeks after a cyst aspiration/fine needle aspiration, or 3 to 4 weeks after a core or excisional biopsy it can produce false positive results at the interventional site. This effect is less likely if imaging is conducted within the first 72 hours after needle procedures.
B. Patient Preparation and Precautions

See Section VI of SNM Guideline on General Imaging 4.0.

1. No special preparation for the test is needed. A thorough explanation of the test should be provided by the technologist or physician.
2. The patient should remove all clothing and jewelry above the waist and should wear a mammography cape or gown.
3. Known hypersensitivity to $^{99m}$Tc-sestamibi is a contraindication.
4. Pregnancy is a contraindication.

C. Radiopharmaceutical

1. Approximately 925 MBq [25 mCi] of the radiopharmaceutical should be administered using an indwelling venous catheter or butterfly needle followed by 10 ml of saline to flush the vein.
2. When possible, administration of tracer should be via upper extremity vein on the opposite side of the breast with the suspected abnormality.

D. Protocol/Image Acquisition

1. Patient Position
   a. The patient is seated for the entire scan. Image positions should duplicate standard mammographic views according to the most recent mammogram.

2. Imaging
   a. Imaging begins 5–10 minutes after administration of the radiopharmaceutical.
   b. Planar images are acquired for 10 minutes each or 175K, (7 minutes minimum)
   c. Planar images should be acquired for each breast beginning with the side of the suspected abnormality if appropriate:
      • Right Craniocaudal
      • Left Craniocaudal
      • Right Mediolateral Oblique
      • Left Mediolateral Oblique

*If needed, additional images may be acquired according to the interpreting physician: 90 degree lateral (LM or ML), axillary tail (AT), cleavage view (CV), exaggerated craniocaudal (XCC), implant displacement (ID), Right Antero-posterior View (axilla), Left Antero-posterior View (axilla).

For lesions close to the chest wall, an extra craniocaudal image with minimum immobilization can help to ensure inclusion of posterior tissues, especially in women with breast tissue that resists compression.

3. Interventions
   Both a needle localization technique and an intra-operative lumpectomy technique using a gamma probe for guidance have been described in the medical literature to conduct biopsy. (19,20)
4. Processing
   a. Interpretation of the image should be done on a computer workstation as adjustment of the image contrast by the interpreting physician may be necessary.
   b. Various display parameters, including grayscale linear as well as color and logarithmic displays may be considered to optimize interpretation.
   c. If color scales are used, linear monochromatic (hot metal) are preferable to multi-color (rainbow).

E. Interpretation

1. Homogeneous uptake of the radio-pharmaceutical in the breast or axilla is consistent with a normal study. (BIRADS 1)
2. Patchy or diffusely increased radiopharmaceutical uptake in the breasts is usually a normal variant, especially when the distribution correlates with mammographic anatomy. (BIRADS 2)
3. Features suggestive of benign disease of the breast are diffuse or patchy uptake of mild to moderate intensity, often bi-lateral, with ill-defined boundaries.
4. Multiple patchy areas of uptake, mild to moderate intensity (BIRADS 3).
5. Small focal areas of increased radiopharmaceutical uptake in the breast or axilla (in the absence of radiopharmaceutical infiltration): equivocal result, consistent with malignancy, inflammation, atypia, fat necrosis. (BIRADS 4)
6. Intensity of focal uptake in malignant lesions is highly variable. Moderate-to-intense focal uptake with well-delineated contours is consistent with malignancy. (BIRADS 5)
7. Focal increased uptake (1 or more foci) in the ipsilateral axilla, in the presence of a primary lesion is strongly suggestive of axillary lymph node metastatic involvement (in the absence of radiopharmaceutical infiltration).
8. Masking of high-activity lesions in the breast can improve visualization of adjacent breast tissues. Masking can be performed by placing appropriately sized pieces of lead between the lesion and the detector. Both the masked and original images should be included in the final display.
9. Sources of Error
   a. Infiltration of the radiopharmaceutical administered in an arm vein may cause false-positive uptake in the axillary lymph nodes. Imaging of the injection site is helpful in evaluating the presence and extent of dose infiltration. This is particularly important if an unsuspected breast lesion is discovered on the same side as the injection. Motion of the breast relative to the detector will decrease the accuracy of the test.
   b. The sensitivity, specificity, and accuracy of this test depends upon several factors, including the size of the breast neoplasm being imaged. While the sensitivity of this test for subcentimeter tumors is high, around 95%, as with all radiologic examinations sensitivity decreases with lesion size.

VII. DOCUMENTATION/REPORTING

VII. A. Goals of a report

See Section VII.A of SNM Procedure Guideline for General Imaging 4.0
VII.B. Direct Communication

See ACR practice guidelines for communication.
See Section VII. B of SNM Procedure Guideline for General Imaging 4.0

VII.C. Written Communication

See ACR practice guidelines for communication
See Section VII.C of SNM Procedure Guideline for General Imaging 4.0

VII.D Contents of the report

See Section VII.D of SNM Procedure Guideline for General Imaging 4.0 for content of each section

1. Study Identification
2. Clinical Information
3. Procedure Description
4. Description of Findings
   See previous section on interpretation
5. Impression

The report to the referring physician should indicate the most likely diagnosis and should recommend appropriate follow-up as with any breast imaging study, using BIRADS classification.

6. Comments

VIII. EQUIPMENT SPECIFICATION

A. High-resolution small field-of-view gamma camera
B. A symmetric energy window should be centered over the 140-keV photo-peak of $^{99m}$Tc unless otherwise specified by the manufacturer.

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

A. Routine scintillation camera quality control should be performed as described in the Society of Nuclear Medicine Procedure Guideline for General Imaging.

*** Note –Some of the devices developed for this procedure are based on a pixilated design (both digital and scintillator element types) and not a single crystal design. The QC and QA of these
devices may require additional or modified testing procedures to maintain proper operation. The manufacturer’s manuals should be reviewed in addition to these guidelines.

B. Quality control measures and radiation safety precautions should be followed as described in the Society of Nuclear Medicine Procedure Guidelines for Use of Radiopharmaceuticals.

X. RADIATION SAFETY IN IMAGING

*See Section X of the SNM Procedure Guideline for General Imaging version 4.0.*

**Radiation Dosimetry – Adults**

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Administered Activity MBq (mCi)</th>
<th>Organ Receiving the Largest Radiation Dose mGy/MBq (rad/mCi)</th>
<th>Effective Dose mSv/MBq (rem/mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{99m}$Tc -Sestamibi-rest$^1$</td>
<td>0.039 Gallbladder (0.14)</td>
<td>0.009</td>
<td></td>
</tr>
<tr>
<td>$^{99m}$Tc -Sestamibi-stress$^1$</td>
<td>0.033 Gallbladder (0.12)</td>
<td>0.0079 (0.029)</td>
<td></td>
</tr>
<tr>
<td>$^{99m}$Tc-Tetrofosmin-rest$^2$</td>
<td>0.027 Gallbladder (0.10)</td>
<td>0.0069 (0.026)</td>
<td></td>
</tr>
<tr>
<td>$^{99m}$Tc-Tetrofosmin-stress$^2$</td>
<td>0.027 Gallbladder (0.10)</td>
<td>0.0069 (0.026)</td>
<td></td>
</tr>
<tr>
<td>$^{18}$FDG$^1$</td>
<td>0.13 Urinary bladder (0.48)</td>
<td>0.019 (0.070)</td>
<td></td>
</tr>
</tbody>
</table>

1 ICRP 80
2 ICRP 106

Radiation Dosimetry in Children

(5 year old)

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Administered Activity MBq (mCi)</th>
<th>Organ Receiving the Largest Radiation Dose mGy/MBq (rad/mCi)</th>
<th>Effective Dose mSv/MBq (rem/mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{99m}$Tc-Sestamibi -rest$^1$</td>
<td></td>
<td>0.10 Gallbladder (0.37)</td>
<td>0.028</td>
</tr>
<tr>
<td>$^{99m}$Tc-Sestamibi -stress$^1$</td>
<td></td>
<td>0.086 Gallbladder (0.32)</td>
<td>0.023</td>
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<tr>
<td>$^{99m}$Tc -Tetrofosmin-rest$^2$</td>
<td></td>
<td>0.073 Gallbladder (0.27)</td>
<td>0.021</td>
</tr>
<tr>
<td>$^{99m}$Tc -Tetrofosmin-stress$^2$</td>
<td></td>
<td>0.073 Gallbladder (0.27)</td>
<td>0.021</td>
</tr>
<tr>
<td>$^{18}$FDG$^1$</td>
<td></td>
<td>0.34 Urinary bladder (1.3)</td>
<td>0.056</td>
</tr>
</tbody>
</table>


$^{99m}$Tc-Sestamibi: Dose estimates to the fetus were provided by Russell et al. (1997). No information about possible placental crossover of this compound was available for use in estimating fetal doses.

$^{99m}$Tc MIBI-rest:
### $^{99m}$Tc MIBI-stress

<table>
<thead>
<tr>
<th>Stage of Gestation</th>
<th>Fetal Dose $^{99m}$Tc MIBI-stress</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mGy/MBq $(\text{rad}/\text{mCi})$</td>
</tr>
<tr>
<td>Early</td>
<td>0.012 (0.044)</td>
</tr>
<tr>
<td>3 months</td>
<td>0.0095 (0.035)</td>
</tr>
<tr>
<td>6 months</td>
<td>0.0069 (0.026)</td>
</tr>
<tr>
<td>9 months</td>
<td>0.0044 (0.016)</td>
</tr>
</tbody>
</table>

$^{99m}$Tc tetrofosmim: Dose estimates to the fetus were provided by Russell et al. (1997). No information about possible placental crossover of this compound was available for use in estimating fetal doses. Separate estimates were not given for rest and exercise subjects.

<table>
<thead>
<tr>
<th>Stage of Gestation</th>
<th>Fetal Dose $^{99m}$Tc tetrofosmim</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mGy/MBq $(\text{rad}/\text{mCi})$</td>
</tr>
<tr>
<td>Early</td>
<td>0.0096 (0.036)</td>
</tr>
<tr>
<td>3 months</td>
<td>0.0070 (0.026)</td>
</tr>
<tr>
<td>6 months</td>
<td>0.0054 (0.020)</td>
</tr>
<tr>
<td>9 months</td>
<td>0.0036 (0.013)</td>
</tr>
</tbody>
</table>

$^{18}$FDG: Dose estimates to the fetus were provided by Russell et al. (1997)$^3$, but were updated by Stabin to account for placental crossover, as observed in a published study$^4$.

The Breastfeeding Patient

ICRP Publication 106, Appendix D suggests that no interruption is needed for breastfeeding patients administered $^{99m}$Tc MIBI, $^{99m}$Tc Tetrofosmin, or $^{18}$FDG.

XI. ACKNOWLEDGEMENTS

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XII. BIBLIOGRAPHY/REFERENCES


XIII. BOARD OF DIRECTORS APPROVAL DATES

Version 1.0       June 4, 2010