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Revised 2014 (Resolution 6)*

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF
STEREOTACTIC-GUIDED BREAST INTERVENTIONAL PROCEDURES

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the 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

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.
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.

I. INTRODUCTION

Image-guided core needle biopsy (CNB) has become the procedure of choice for most image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, less cost, and similar accuracy [1-9].

High-quality breast imaging evaluation is necessary to detect early or subtle breast lesions. Several imaging modalities are commonly available and in clinical use for image-guided breast interventions, including stereotactic guidance, ultrasound (US), and magnetic resonance imaging (MRI). The choice of guidance technique will depend on lesion visualization and accessibility, availability of the imaging modality, efficiency, safety, and the practitioner’s experience [1].

Stereotactic guidance enables percutaneous placement of a needle within the breast to sample mammographically detected suspicious breast lesions. This technique, along with the other methods of image-guided biopsy, has changed the management of breast disease. Percutaneous biopsy techniques have decreased the number of benign surgical biopsies generated from mammography programs and have decreased the number of surgical procedures needed to treat breast cancer [3,5-7].

Minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast lesions under appropriate circumstances.

Successful use of stereotactic-guided breast interventional procedures relies on high-quality imaging, expertise in lesion recognition and patient selection, experience in stereotactic-guided techniques for accurate lesion localization and sampling, and effective methods of obtaining tissue for analysis [10-13]. The imaging assessment and the cytopathologic or histopathologic interpretations should be correlated for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations [1].

II. INDICATIONS/CONTRAINDICATIONS

A. Indications

Stereotactic-guided breast intervention is suitable for most mammographically depicted lesions, including microcalcifications, masses, asymmetries, and architectural distortions.

Indications for stereotactic-guided breast intervention include, but are not limited to, the following:

1. Biopsy for primary diagnosis (see Appendix) of:
   a. Lesions that are assessed as highly suggestive of malignancy in the Breast Imaging Reporting and Data System, Breast Imaging Atlas (BI-RADS®) Category 5 [14].
   b. Lesions that are assessed as suspicious abnormalities (BI-RADS® Category 4).
   c. Lesions that are assessed as probably benign (BI-RADS® Category 3) when there are valid clinical indications or when short-interval imaging follow-up would be difficult or unreasonable [15-18].
   d. Multiple suspicious lesions, particularly in a multifocal or multicentric distribution, to facilitate treatment planning.
   e. Lesions seen on mammography that correlate with suspicious areas of enhancement present on contrast-enhanced breast MRI.
2. Repeat biopsy

Repeat stereotactic-guided percutaneous sampling is an alternative to surgical biopsy in cases when the initial core biopsy results are nondiagnostic or are discordant with the imaging findings [1,19,20].

3. Presurgical localization

Stereotactic-guided localization may be used as an alternative to standard mammographic localization for mammographically identifiable lesions prior to surgical procedures [21]. Localization may be performed with wire, needle-wire combination, or radioactive seeds.

B. Contraindications

Inability to visualize the target or breast lesion mammographically is a contraindication to stereotactic-guided breast intervention. For lesions that are equally well seen on mammography and ultrasound, ultrasound guidance is preferred. Prior to the procedure, the patient should be asked about allergies, use of medications such as aspirin, anticoagulants, or other agents known to impact bleeding times, and whether there is a history of a bleeding diathesis. The patient’s weight (for prone table) and ability to remain in the position required for the procedure should also be assessed in determining the appropriateness of the procedure for that patient.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Stereotactic-guided breast biopsy procedures should be performed by physicians who meet the “Physician Qualifications for Stereotactic Breast Biopsy” [22,23]. Stereotactic breast biopsies may be performed in either collaborative or independent settings.²

Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactic-guided breast procedures. Prior to the stereotactic procedure, the physician should be able to identify the significant lesion(s) on mammography so that the correct area of the breast is localized or biopsied. This is particularly important when small field-of-view imaging equipment is used.

1. Initial qualifications

a. In both collaborative and independent settings, the radiologist should initially meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography.

b. The physician must also have 3 hours of Category 1 CME didactic instruction in stereotactic-guided breast intervention and have performed at least 3 hands-on stereotactic breast biopsy procedures under the supervision of a qualified radiologist [23]. Completion of a residency or fellowship program that includes instruction in stereotactic breast biopsy procedures is also acceptable.

c. In independent settings, the radiologist should also have 15 hours of Category 1 CME in breast imaging and disease.

d. Nonradiologist physicians must meet the criteria in 1b and 1c above. Additionally, they must have 4 hours of Category 1 CME in medical radiation physics and must have evaluated³ 480 mammograms every

²The following definitions are taken from the ACR Stereotactic Breast Biopsy Accreditation Program Requirements: A collaborative setting is one where both radiologists and surgeons (or other physicians) conduct stereotactic breast biopsy procedures. An independent setting is one where either radiologists or other physicians (typically surgeons) conduct stereotactic breast biopsies.
2 years in consultation with a physician who has the qualifications specified in the Mammography Quality Standards Act (MQSA).

2. Maintenance of competence

In both collaborative and independent settings, the physician should perform at least 36 image-guided breast biopsies in the prior 36 months; at least 9 of these must be stereotactic breast biopsies [23].

3. Continuing medical education

In both collaborative and independent settings, the physician should complete 15 hours of CME (half of which must be Category 1) in the prior 36 months specific to breast imaging [23].

4. Responsibilities for assessment of concordance

The physician who performs the procedure (either the radiologist or, in the collaborative setting, the surgeon) is responsible for determining adequacy of sampling. The physician or, if unavailable, his/her MQSA-qualified physician designee, is responsible for obtaining histopathologic results and determining concordance [1,19-21,24]. These results should be communicated to the referring physician and/or to the patient, as appropriate.

B. Qualified Medical Physicist

1. Initial qualifications

Medical physicists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography. In addition medical physicists should have performed at least 1 hands-on stereotactic breast biopsy unit survey under the guidance of a medical physicist qualified to perform such surveys [23].

2. Maintenance of competence

Medical physicists should perform at least 2 stereotactic breast biopsy unit surveys every 2 years [23].

3. Continuing medical education

Medical physicists should obtain 3 hours of CME in stereotactic breast biopsy unit physics every 3 years [23].

C. Radiologic Technologist

1. Initial qualifications

Radiologic technologists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography. Radiologic technologists should also have 3 hours of Category A continuing education units in stereotactic-guided breast intervention and must have participated in at least 5 hands-on procedures under the guidance of a qualified physician or radiologic technologist [23].

2. Maintenance of competence

Radiologic technologists should participate in at least 24 stereotactic-guided breast interventions every 2 years [23].

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3 Evaluation means review of the mammographic images films in direct consultation with an MQSA-qualified interpreting physician and/or independent review of mammograms with the authenticated mammographic report.
3. Continuing medical education

Radiologic technologists should be in compliance with the continuing education requirements of their certifying organization for the imaging modality for which they perform services [23].

IV. SPECIFICATIONS OF THE PROCEDURE

A. Prior to the Procedure

The written or electronic request for a stereotactic-guided breast intervention examination 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)

The decision to perform a stereotactic-guided breast interventional procedure should be made by the physician only after adequate imaging evaluation, including orthogonal views, of the breast is performed.

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented [1].

Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings (See http://www.jointcommission.org/standards_information/up.aspx for more information.).

The organization should have processes and systems in place for reconciling differences in staff responses during the “time out.”

B. Procedure Technique

The breast is compressed between the image receptor and the compression plate. Imaging is performed to confirm that the targeted lesion lies within the area of accessibility. Lesion targeting should be performed by the physician performing or supervising the procedure. The computer-generated coordinates are then transferred to the stereotactic targeting device, and the skin entry site is prepared.

The field in which the procedure is to be performed should be prepared in conformity with the principles of cleanliness to minimize the risk of infection.

Documentation of appropriate needle positioning for sampling or localization should be obtained as part of the medical record.

When the biopsy is performed for microcalcifications, magnification image of the core biopsy specimens should be obtained to verify that the microcalcifications have been sampled [1,24,26].
Following performance of stereotactic-guided breast biopsy, a tissue marker should be placed at the biopsy site whenever a lesion may be difficult to see after the biopsy (eg, complete removal of the target or a subtle target), when needing confirmation that the proper lesion has been sampled, or if neoadjuvant chemotherapy is contemplated. When multiple lesions are present and biopsy of more than 1 suspicious lesion is performed, placement of markers of different shapes should be considered.

To minimize hematoma formation, the skin entry site and the region of needle sampling should be adequately compressed until hemostasis is achieved.

Postprocedure mammography should be performed in 2 orthogonal views to document tissue marker position, and the report should state the position in relation to the biopsy site.

V. DOCUMENTATION

Permanent records of stereotactic-guided breast interventions should be documented in retrievable image storage format.

A. Image labeling should include permanent identification, containing 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 left or right breast
6. Annotation of mammographic view (eg, craniocaudal, mediolateral oblique (MLO), 90 degree mediolateral (ML))
7. Technologist’s identification number or initials

Physician identification may be included on the permanent image record.

B. The physician’s report of stereotactic-guided breast intervention procedures should include the following:

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion
4. Safety timeout having been performed
5. Approach used
6. Type and amount of local anesthesia
7. Skin incision, if made
8. Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc)
9. Number of specimen cores or samples, if applicable
10. Specimen images, if performed, and their results
11. Tissue marker placement, if performed
12. Complications and treatment, if any
13. Postprocedure mammography, if obtained, documenting tissue marker placement and location of the marker with respect to the biopsied lesion

C. Postprocedure patient follow-up should consist of the following:

1. Documentation of any delayed complications and treatment administered
2. A determination of concordance of pathology results with imaging findings. When discordant, biopsy should be repeated by stereotactic guidance or surgical excision [1,19,20].
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis. Surgical consultation is usually recommended for high-risk lesions known to be subject to upgrade, including atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ), radial scar, and, to a lesser degree, papilloma [27-39]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate [40,41]. For malignant results, patients are usually referred for consultation to a surgeon or oncologist.

4. Record of communications with the patient and/or referring physician.

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

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

VI. EQUIPMENT SPECIFICATIONS

Radiographic equipment used for stereotactic-guided breast intervention procedures includes prone and add-on systems. The equipment should be calibrated by the manufacturer, and the medical physicist should complete verification of calibration and acceptance testing upon installation [42,43].

Several needle biopsy devices are available for stereotactic-guided procedures, including automated core needles, vacuum-assisted devices, and other tissue biopsy systems. The choice of biopsy device depends on the type of lesion as well as the operator’s experience. However, vacuum-assisted devices of 11 gauge and larger have been shown to be most effective in the performance of stereotactic biopsy for microcalcifications [44].

VII. EQUIPMENT QUALITY CONTROL

Refer to ACR stereotactic breast biopsy quality control manual [43].

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (http://www.acr.org/guidelines).

A documented quality control program with procedure manuals and records should be maintained for stereotactic-guided breast interventions. Imaging findings and pathologic interpretations should be correlated. Results of stereotactic-guided breast interventions should be monitored.

The following records should be maintained for the facility, practice, and individual physicians:

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of stereotactic biopsies needing repeat biopsy, categorized by reason and type of biopsy:
<table>
<thead>
<tr>
<th>Reason for Repeat Biopsy</th>
<th>Data</th>
</tr>
</thead>
</table>
| Insufficient sample      | • Total number of cases  
                           | • Number with repeat biopsy  
                           | • Final pathology results |
| Discordance              | • Total number of cases  
                           | • Number with repeat biopsy  
                           | • Final pathology results |
| High-risk lesions        | • Total number of cases  
                           | • Number with repeat biopsy  
                           | • Final pathology results |

Imaging findings and pathologic interpretation should be correlated by the physician who performs the biopsy. Postbiopsy patient follow-up should be performed to detect and record any false-negative and false-positive results.

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APPENDIX

ACR BI-RADS® ATLAS, BREAST IMAGING REPORTING AND DATA SYSTEM [14]

Mammography Assessment Categories

A. Mammographic Assessment Is Incomplete

Category 0: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison

There is a finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this assessment category may be used in a diagnostic mammography report, such as when US equipment or personnel are not immediately available, or when the patient is unable or unwilling to wait for completion of a full diagnostic examination. A recommendation for additional imaging evaluation includes the use of spot-compression (with or without magnification), special mammographic views, and US. Category 0 should not be used for diagnostic breast imaging findings that warrant further evaluation with MRI. Rather, the interpreting physician should issue a final assessment in a report that is made before the MRI examination is performed.

In most circumstances and when feasible, if a mammography examination is not assessed as negative or benign, the current examination should be compared with prior examination(s). The interpreting physician should use judgment on how vigorously to attempt obtaining prior examinations, given the likelihood of success of such an endeavor and the likelihood that comparison will affect the final assessment. In this context, it is important to note that comparison with previous examination(s) may be irrelevant when a finding is inherently suspicious for malignancy.

Category 0 should be used for prior image comparison only when such comparison is required to make a final assessment. When category 0 is used in the context of awaiting prior examinations for comparison, there should be in place a tracking procedure guaranteeing with 100% reliability that a final assessment will be made within 30 days (preferably sooner) even if prior examinations do not become available. Some mammography practices may reasonably choose never to use category 0 in the context of awaiting prior examinations simply because they do not have a 100% reliable tracking procedure. If a mammography examination is assessed as category 0 in the context of awaiting prior examinations and then the prior examinations do become available, an addendum to the initial mammography report should be issued, including a revised assessment. For auditing purposes, the revised assessment should replace the initial assessment.
B. Mammographic Assessment Is Complete – Final Assessment Categories

Category 1: Negative

There is nothing to comment on. This is a normal examination.

Category 2: Benign

Like category 1, this is a normal assessment, but here the interpreter chooses to describe a benign finding in the mammography report. Involuting calcified fibroadenomas, skin calcifications, metallic foreign bodies (such as core biopsy and surgical clips), and fat-containing lesions (such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas) all have characteristically benign appearances and may be described with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcification, implants, or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy. On the other hand, the interpreter may choose not to describe such findings, in which case the examination should be assessed as negative (category 1).

Note that both category 1 and category 2 assessments indicate that there is no mammographic evidence of malignancy. Both should be followed by the management recommendation for routine mammography screening. The difference is that category 2 should be used when describing one or more specific benign mammographic findings in the report, whereas category 1 should be used when no such findings are described (even if such findings are present).

Category 3: Probably Benign

A finding assessed using this category should have a \( \leq 2\% \) likelihood of malignancy, but greater than the essentially 0% likelihood of malignancy of a characteristically benign finding. A probably benign finding is not expected to change over the suggested period of imaging surveillance, but the interpreting physician prefers to establish stability of the finding before recommending management limited to routine mammography screening.

There are several prospective clinical studies demonstrating the safety and efficacy of periodic mammographic surveillance instead of biopsy for specific mammographic findings. Three specific findings are validated as being probably benign (noncalcified circumscribed solid mass, focal asymmetry, and solitary group of punctate calcifications). These studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (category 3) assessment; hence, it is recommended not to render such an assessment in interpreting a screening mammography examination. The practice of rendering category 3 assessments directly from screening examination also has been shown to result in adverse outcomes: 1) unnecessary follow-up of many lesions that could have been promptly assessed as benign, and 2) delayed diagnosis of a small number of cancers that otherwise may have been smaller in size and less likely to be advanced in stage. Also, these studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by robust scientific data, although there are two single-institution studies that do report successful outcomes for palpable lesions. Finally, because evidence from these studies indicates the need for biopsy rather than continued surveillance when a probably benign finding increases in size or extent, it is not prudent to render a category 3 assessment when a finding that otherwise meets “probably benign” imaging criteria is either new or has increased in size or extent.

While the vast majority of probably benign findings are managed with an initial short-interval follow-up (6 months) examination followed by additional examinations until long-term (2- or 3-year) stability
is demonstrated, there may be occasions in which a biopsy is done instead (patient preference or overriding clinical concern).

Category 4: Suspicious

This category is reserved for findings that do not have the classic appearance of malignancy but are sufficiently suspicious to justify a recommendation for biopsy. The ceiling for category 3 assessment is a 2% likelihood of malignancy and the floor for category 5 assessment is 95%, so category 4 assessments cover the wide range of likelihood of malignancy in between. Thus, almost all recommendations for breast interventional procedures will come from assessments made using this category. By subdividing category 4 into 4A, 4B, and 4C, as recommended in Guidance chapter of the ACR BI-RADS® Atlas and using the cut points indicated therein, it is hoped that patients and referring clinicians will more readily make informed decisions on the ultimate course of action.

Category 5: Highly Suggestive of Malignancy

These assessments carry a very high probability (≥95%) of malignancy. This category initially was established to involve lesions for which 1-stage surgical treatment was considered without preliminary biopsy, in an era when preoperative wire localization was the primary breast interventional procedure. Nowadays, given the widespread acceptance of imaging-guided percutaneous biopsy, 1-stage surgery is rarely, if ever, performed. Rather, current oncologic management almost always involves tissue diagnosis of malignancy via percutaneous tissue sampling to facilitate treatment options, such as when sentinel node biopsy is included in surgical management or when neoadjuvant chemotherapy is administered prior to surgery. Therefore, the current rationale for using a category 5 assessment is to identify lesions for which any non-malignant percutaneous tissue diagnosis is automatically considered discordant, resulting in the recommendation for repeat (usually surgical) biopsy.

Category 6: Known Biopsy

This category is reserved for examinations performed after biopsy proof of malignancy (imaging performed after percutaneous biopsy but prior to complete surgical excision), in which there are no mammographic abnormalities other than the known cancer that might need additional evaluation.

*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.

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