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Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2009 (Res. 28)*

ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF STEREOTACTICALLY GUIDED BREAST INTERVENTIONAL PROCEDURES

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 American College of Radiology 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. However, a practitioner who employs an approach substantially different from these guidelines 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 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

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.

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 techniques will depend on lesion visualization and access, availability of the imaging modality, efficiency, safety, and the practitioner's experience.

II. GENERAL PRINCIPLES

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.

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

Advantages of percutaneous procedures include:

- Reduced morbidity, with better cosmetic results and less scarring detectable on future breast imaging.
- Improved cost effectiveness with less time lost from normal activities.
- Accuracy comparable to open surgical biopsy.

Successful use of stereotactically guided breast interventional procedures relies on high-quality imaging, expertise in lesion recognition and patient selection, experience in stereotactically guided techniques for accurate lesion localization and sampling, and effective methods of obtaining tissue for analysis. 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.

III. INDICATIONS/CONTRAINDICATIONS

A. Indications

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

Indications for stereotactically 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) [1].
 - 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.
 - d. Multiple suspicious lesions, particularly in a multicentric distribution, to facilitate treatment planning.
 - e. Lesions seen on mammography that correspond to suspicious areas of

enhancement present on contrast enhanced breast MRI.

2. Repeat biopsy

Repeat stereotactically 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.

3. Stereotactically guided presurgical needle localization

Stereotactically guided needle localization may be used as an alternative to standard mammographic needle localization for mammographically identifiable lesions prior to surgical procedures.

B. Contraindications

Inability to visualize the target or breast lesion mammographically is a contraindication to stereotactically guided breast intervention. 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 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.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Stereotactically guided breast biopsy procedures should be performed by physicians who meet the "Physician Qualifications for Stereotactic Breast Biopsy" [2]. Stereotactic breast biopsies may be performed in either collaborative or independent settings¹.

Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactically 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

¹The 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.

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 Guideline for the Performance of Screening and Diagnostic Mammography](#).
- b. The physician must also have 3 hours of Category 1 CME didactic instruction in stereotactically guided breast intervention and have performed at least 3 hands-on stereotactic breast biopsy procedures under the supervision of a qualified radiologist. 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 and additionally have 4 hours of Category 1 CME in medical radiation physics and have evaluated² 480 mammograms every 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 24 stereotactically guided biopsies every 2 years.

3. Continuing medical education

In both collaborative and independent settings, the physician should obtain 3 hours of Category 1 CME in stereotactically guided breast intervention and related topics such as lesion targeting, imaging-pathology correlation, general needle biopsy information and techniques, or lesion-target assessment, every 3 years.

² Evaluation means review of the mammographic films in direct consultation with an MQSA-qualified interpreting physician and/or independent review of mammograms with the authenticated mammography report.

4. Responsibilities for assessment of concordance

The physician who performs the procedure is responsible for obtaining results of the cytopathologic or the histopathologic sampling to determine if the lesion has been adequately biopsied and is concordant or discordant with the imaging findings. 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 Guideline 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.

2. Maintenance of competence

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

3. Continuing medical education

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

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

D. Radiologic Technologist

1. Initial qualifications

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

2. Maintenance of competence

Radiologic technologists should participate in at least 24 stereotactically guided breast interventions every 2 years.

3. Continuing medical education

Radiologic technologists should obtain 3 hours of CME in stereotactically guided breast intervention every 3 years.

V. SPECIFICATIONS OF THE PROCEDURE

A. Prior to the Procedure

The written or electronic request for a stereotactically 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 stereotactically guided breast interventional procedure should be made by the physician

only after adequate imaging evaluation of the breast is performed.

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

Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team.
- Use active communication.
- Be briefly documented, such as in a checklist, and include at least:
 - Correct patient identity.
 - Correct side and site.
 - Agreement on the procedure to be done.
 - Correct patient position.
 - Availability of any special equipment or special requirements.

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.

Following performance of stereotactically guided breast biopsy, a tissue marker should be placed at the biopsy site whenever a lesion may be difficult to see after the biopsy (e.g., complete removal of the target or a subtle target), or when there is need to confirm that the proper lesion has been sampled, or if neoadjuvant chemotherapy is contemplated.

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.

VI. DOCUMENTATION

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

A. Image labeling should include permanent identification containing:

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 (e.g., craniocaudal (CC), mediolateral oblique (MLO), 90 degree lateral).
7. Technologist's identification number or initials.

Physician identification may be included on the permanent image record.

B. The physician's report of stereotactically guided breast intervention procedures should include:

1. Procedure performed.
2. Designation of the left or right breast.
3. Description and location of the lesion.
4. Approach used.
5. Type and amount of local anesthesia, if used.
6. Skin incision, if made.
7. Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc.).
8. Number of specimen cores or samples, if applicable.
9. Specimen radiographs, if performed and their results.
10. Tissue marker placement, if performed.
11. Complications and treatment, if any.
12. 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.
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis.
4. Record of communications with the patient and/or referring physician.

D. Reporting should be in accordance with the [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#).

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

VII. EQUIPMENT SPECIFICATIONS

Radiographic equipment used for stereotactically guided breast intervention procedures includes prone and add on systems. The equipment should be calibrated by the manufacturer at the time of installation. The medical physicist should complete verification of calibration and acceptance testing before use.

Several needle biopsy devices are available for stereotactically 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 [3].

VIII. EQUIPMENT QUALITY CONTROL

A. Technologist's Quality Control Tests [4]

1. Localization accuracy (daily before use on patients).
2. Darkroom cleanliness (daily if film used).
3. Processor quality control (QC) (daily if film used).
4. Phantom image (weekly).
5. Screen cleanliness (weekly if film used).
6. Viewboxes and viewing conditions (weekly if film used).
7. Hardcopy output quality (monthly digital only).
8. Visual checklist (monthly).
9. Analysis of fixer retention in film (quarterly if film used).
10. Compression (semiannually).

11. Repeat analysis (semiannually).
12. Screen film contact (semiannually if film used).
13. Darkroom fog (semiannually if film used).

B. Annual Medical Physicist Survey [4]

1. Stereotactic breast biopsy unit assembly.
2. Collimation assessment.
3. System limiting spatial resolution.
4. kVp accuracy and reproducibility.
5. Beam quality assessment (half-value layer measurement).
6. Automatic exposure control (AEC) system or manual exposure performance assessment.
7. Screen speed uniformity (screen-film) or digital receptor uniformity.
8. Breast entrance exposure, average glandular dose, and exposure reproducibility.
9. Image quality evaluation.
10. Artifact evaluation.
11. Localization accuracy.

IX. 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 elsewhere in the ACR Practice Guidelines and Technical Standards book.

A documented quality control program with procedure manuals and records should be maintained for stereotactically guided breast interventions. Imaging findings and pathologic interpretations should be correlated.

Results of stereotactically 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:

Reason for Repeat Biopsy	Data
Insufficient sample	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results. •
Discordance	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results.
Cellular atypia, radial scar	<ul style="list-style-type: none"> • Total number of cellular atypia cases. • Total number of radial scar cases (CNB only). • Number of repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • Final pathology results.
Other	<ul style="list-style-type: none"> • Total number of cases. • Number with repeat biopsy performed by core. • Number with repeat biopsy performed by excision. • 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.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the ACR Practice Guidelines and Appropriateness Criteria Committee of the Commission on Breast Imaging.

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APPENDIX

ACR BREAST IMAGING REPORTING AND DATA SYSTEM (BI-RADS®), BREAST IMAGING ATLAS

Assessment Categories

A. Mammographic Assessment Is Incomplete

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

Finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to, the use of spot compression, magnification, special mammographic views, and ultrasound.

Whenever possible, if the study is not negative and does not contain a typically benign finding, the current examination should be compared to previous studies. The radiologist should use judgment in how vigorously to attempt obtaining previous studies. Category 0 should only be used for old film comparison when such comparison is required to make a final assessment.

B. Mammographic Assessment Is Complete – Final Categories

Category 1 - Negative

There is nothing to comment on. The breasts are symmetric and no masses,

architectural distortion or suspicious calcifications are present.

Category 2 - Benign Finding(s)

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, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas all have characteristically benign appearances, and may be labeled with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcifications, implants, or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.

Note that both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy. 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.

Category 3 - Probably Benign Finding – Initial Short-Interval Follow-Up Suggested

A finding placed in this category should have less than a 2% risk of malignancy. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability.

There are several prospective clinical studies demonstrating the safety and efficacy of initial short-term follow-up for specific mammography findings.

Three specific findings are described as being probably benign (the noncalcified circumscribed solid mass, the focal asymmetry and the cluster of round (punctate) calcifications; the latter is anecdotally considered by some radiologists to be an absolutely benign feature). All the published studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (Category 3) assessment; hence it is inadvisable to

render such an assessment when interpreting a screening examination. Also, all the published studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by scientific data. Finally, evidence from all the published studies indicates the need for biopsy rather than continued follow-up when most probably benign findings increase in size or extent.

While the vast majority of findings in this category will be managed with an initial short-term follow-up (6 months) examination followed by additional examinations until longer-term (2 years or longer) stability is demonstrated, there may be occasions where biopsy is done (patient wishes or clinical concerns).

Category 4 - Suspicious Abnormality: Biopsy Should Be Considered

This category is reserved for findings that do not have the classic appearance of malignancy but have a wide range of probability of malignancy that is greater than those in Category 3. Thus, most recommendations of breast interventional procedures will be placed within this category. By subdividing Category 4 into 4A, 4B, and 4C as suggested in the guidance chapter of the ACR Breast Image Reporting and Data System (BI-RADS® Atlas, it is encouraged that relevant probabilities for malignancy be indicated within this category so the patient and her physician can make an informed decision on the ultimate course of action.

Category 5 - Highly Suggestive of Malignancy - Appropriate Action Should Be Taken (almost certainly malignant)

These lesions have a high probability ($\geq 95\%$) of being cancer. This category contains lesions for which one-stage surgical treatment could be considered without preliminary biopsy. However, current oncologic management may require percutaneous tissue sampling as, for example, when sentinel node imaging is included in surgical treatment or when neoadjuvant chemotherapy is administered at the outset.

Category 6 - Known Biopsy – Proven Malignancy – Appropriate Action Should Be Taken

This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

*Guidelines and 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 guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline

1996 (Resolution 2)

Revised 2000 (Resolution 41)

Revised 2005 (Resolution 45)

Amended 2006 (Resolution 34,35)

Revised 2009 (Resolution 28)