

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

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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter 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 and approval. The practice parameters 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 parameter and technical standard by those entities not providing these services is not authorized.

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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

Minimally invasive image-guided core-needle biopsy (CNB) has become the procedure of choice for most breast findings requiring tissue diagnosis. Image-guided percutaneous biopsy has similar accuracy to surgical biopsy and several advantages over surgery including patient convenience, faster recovery, lower cost, superior cosmesis, and a lower complication rate.[1-9].

Percutaneous biopsy techniques have decreased the number of benign surgical biopsies and have decreased the number of surgical procedures needed to treat breast cancer [3,5-7]. Therefore, minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast findings visible on imaging [10]. High-quality diagnostic breast imaging evaluation is necessary to detect early or subtle breast abnormalities and to accurately target these lesions for image-guided biopsy. Several imaging modalities are commonly available and in clinical use for image-guided breast interventions, including stereotactic or digital breast tomosynthesis (DBT) guidance, ultrasound (US), and magnetic resonance imaging (MRI). The choice of guidance technique will depend on the visualization and accessibility of the finding(s), availability of the imaging modality, efficiency, safety, patient comfort, and the practitioner's experience [1].

Stereotactic guidance enables percutaneous placement of a needle within the breast to sample suspicious breast findings visible on mammography. Successful use of stereotactic-guided breast interventional procedures relies on high-quality imaging, expertise in breast imaging feature analysis, experience in stereotactic-guided techniques for accurate targeting and sampling, and effective methods of obtaining tissue for analysis [11-14]. Guidance using stereotaxis and/or DBT may be used, selecting the imaging that most accurately visualizes and targets findings demonstrated on DBT or mammography, or in certain cases of mammographically visible findings, including calcifications, asymmetries, architectural distortion, and mass(es) not visualized by ultrasound. The imaging features and the histopathologic interpretations should be assessed for concordance by the radiologist performing the biopsy. Records should be kept to document results and management recommendations and subsequent communication with patients and/or providers [1].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

Stereotactic and/or DBT-guided breast intervention is suitable for most mammographically depicted findings, including microcalcifications, masses not visualized by US, asymmetries, and architectural distortions. DBT guidance may be used for findings that are amenable to mammographic stereotactic technique. For findings seen only or better on DBT than on 2-D mammography, DBT-guided percutaneous biopsy is preferred[15-21]. In some cases, a combination of tomosynthesis and stereotactic guidance may be optimal. Please refer to [ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis \(DBT\)](#) [22].

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

1. Biopsy for primary diagnosis of:

- a. Findings with a Breast Imaging Reporting and Data System (BI-RADS)[®] assessment either suspicious (BI-RADS[®] Category 4) or highly suggestive of malignancy (BI-RADS[®] Category 5) [23].
- b. Finding(s) assessed as probably benign (BI-RADS[®] Category 3 [23]) when biopsy is preferable to short-term interval follow-up based on shared decision making with the patient [24] or when there are valid clinical indications for biopsy or when short-interval imaging follow-up would be difficult or unreasonable (eg, if the patient has a synchronous known breast cancer, is awaiting organ transplantation, is scheduled to undergo imminent elective breast surgery, or plans to become pregnant in the immediate future, etc.) [25-28].
- c. Multiple suspicious findings, particularly in a multifocal or multicentric distribution, to facilitate treatment planning including additional findings in patients with a known malignancy (BI-RADS[®] Category 6) where results will affect treatment planning [23].

d. Findings seen on mammography that correlate with suspicious areas of enhancement on contrast-enhanced breast MRI or contrast-enhanced mammography [64].

2. Repeat biopsy

Repeat stereotactic or DBT-guided percutaneous CNB is an alternative to surgical biopsy in some cases in which initial percutaneous CNB results are nondiagnostic or discordant with imaging findings [1,29,30].

3. Presurgical localization

Stereotactic- or DBT-guided localization may be used as an alternative to standard mammographic localization for mammographically identifiable findings before surgical procedures [31]. Devices that may be placed using these guidance methods include wires and nonwire localizing devices (eg, radar or radiofrequency reflectors or magnetic or radioactive "seeds"). Details of presurgical localization including the device types are given in the [ACR Practice Parameter for the Performance of Preoperative Image-Guided Localization in the Breast](#) [32].

B. Contraindications

Inability to revisualize the target finding stereotactically or with DBT at the time of the biopsy is a contraindication to stereotactic or DBT-guided breast intervention. Before the procedure, the patient should be asked about allergies, including metal allergies for clip placement. The patient's weight (for prone table), compressed breast thickness, and ability to remain in the position required for the biopsy also should 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 [ACR Stereotactic Breast Biopsy Accreditation Program](#) requirements[35]. Stereotactic breast biopsies may be performed in either collaborative or independent settings[35]. [1] Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactic- or DBT-guided breast procedures. DBT-guided breast procedures should be performed only by physicians who have completed the Food and Drug Administration (FDA) mandated DBT training. Please refer to [ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis \(DBT\)](#) [22].

[1]The following definitions are taken from the ACR Stereotactic Breast Biopsy Accreditation Program Requirements: A collaborative setting is one in which both radiologists and surgeons (or other physicians) conduct stereotactic breast biopsy procedures. An independent setting is one in which either radiologists or other physicians (typically surgeons) conduct stereotactic breast biopsies.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

1. Initial Qualifications

Training in mammographic image interpretation, medical physics, and specific hands-on training in the performance of stereotactic/DBT-guided biopsy are imperative for successful performance of this procedure.

The initial qualifications as outlined in the [ACR Stereotactic Breast Biopsy Accreditation Program Requirements](#) provide this foundation [35].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

2. Maintenance of Competence

Physicians must perform a sufficient number of overall procedures to maintain their skills. Continued competence should depend on participation in a quality improvement program. Consideration should be given to the physician's lifetime practice experience.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

3. Continuing Medical Education (CME)

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [36].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

4. Responsibilities for assessment of concordance

Concordance is the agreement of the imaging and histopathological findings such that the histopathology satisfactorily explains the imaging findings. The physician who performs the procedure (either the radiologist or, in the collaborative setting, another physician) is responsible for determining sample adequacy. The performing physician or, if unavailable another Mammography Quality Standards Act (MQSA)-qualified designated physician, is responsible for obtaining histopathologic results and determining concordance [1,29-31,37]. These results should be communicated to the referring physician and/or to the patient and documented.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Qualified Medical Physicist

See the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Stereotactic/Tomosynthesis-Guided Breast Biopsy Systems](#) [38].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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](#) [39] and the [ACR Stereotactic Breast Biopsy Accreditation Program Requirements](#) [35]. Radiologic technologists should also have documented Category A continuing education (CE) units in stereotactic-guided breast intervention and must have participated in hands-on procedures under the guidance of a qualified physician or radiologic technologist [35]. For DBT-guided interventions, technologists also should have documented DBT training.

2. Maintenance of competence

Radiologic technologists should participate in a sufficient number of stereotactic/DBT-guided breast interventions to maintain their skills [35].

3. CE

Radiologic technologists should be in compliance with the CE requirements of their certifying organization for the imaging modality for which they perform services [35].

IV. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for stereotactic/tomosynthesis-guided examination of the breast should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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 scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

IV. SPECIFICATIONS OF THE PROCEDURE

A. Prior to the Procedure

The decision to perform a stereotactic- or DBT-guided breast interventional procedure should be made by a physician who is qualified under the MQSA and only after adequate diagnostic imaging evaluation, of the breast is performed. The physician should meet the initial qualifications specified in the [ACR Practice Parameter for Performance of Screening and Diagnostic Mammography](#) [39] or should review the mammographic findings with a physician who has the qualifications specified in the FDA MQSA Final Regulations [40].

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]. Patients should be asked about the use of medications, such as anticoagulants, antiplatelet agents, or other agents known to impact bleeding, and whether they have a history of a bleeding diathesis. However, multiple studies support the safety of performing image-guided CNB of the breast while patients are taking antithrombotic therapy because the clinically significant bleeding risk is low [33,41-44]. Therefore, the routine cessation of antithrombotic medications before CNB of the breast is unnecessary. Management of patients with known bleeding diatheses should be determined on a case-by-case basis.

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 <https://www.jointcommission.org/standards/universal-protocol/> for more information).

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

IV. SPECIFICATIONS OF THE PROCEDURE

B. Procedure Technique

Scout imaging is performed to confirm that the targeted finding lies within the accessible area. The physician performing the procedure may decide on the best approach, using either stereotactic guidance, DBT guidance, or a combination of the two techniques, based on target conspicuity and needle visualization during the biopsy. Before the procedure, the physician should be able to identify the relevant finding(s) on mammography (or DBT) so that the correct area of the breast is biopsied or localized. This is particularly important when small field-of-view imaging equipment is used. Lesion targeting should be performed by the physician performing and/or supervising the procedure.

The breast, the field in which the procedure is to be performed, and the physician performing the procedure must adhere to established principles of infection control.

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

medical record, usually consisting of paired prefire stereotactic images or DBT image showing the device in the breast approaching the target. Postfire imaging usually is obtained at the discretion of the physician performing the procedure. (If the device is placed in nonfire or not in fire mode, paired stereotactic images or DBT image with the needle in its final prebiopsy position should be obtained.)

When the biopsy is performed for microcalcifications, specimen radiograph(s) with magnification should be obtained to verify that the microcalcifications have been adequately sampled [[1,37,45](#)] before needle removal.

Placement of a tissue marker after biopsy is recommended, especially if a targeted finding may be difficult to see after the biopsy (eg, due to complete removal or obscuration by postbiopsy change) for confirmation that the proper finding has been sampled or if neoadjuvant chemotherapy is contemplated. When multiple findings are present and biopsy of more than one suspicious finding is performed, placement of markers with 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. Once hemostasis is achieved, a sterile dressing should be applied to the entry site.

Postprocedure mammography should be performed in orthogonal views (typically craniocaudal and 90° lateral views) to document tissue marker position, the presence of a hematoma (if applicable), and whether there is any residual finding. The report should state the marker's position relative to the biopsy site. If the procedure is performed for a DBT-only visible finding, then postprocedure images should include orthogonal DBT images.

V. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings \[46\]](#).

Permanent records of stereotactic- and DBT-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, 90° mediolateral)
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 document the following:

1. Procedure performed
2. Designation of left or right breast
3. Description and location of the finding(s)
4. Informed consent is obtained
5. Safety time-out having been performed
6. Approach used
7. Type and amount of local anesthesia
8. Skin incision, if made
9. Needle gauge and device type (spring-loaded, vacuum-assisted, etc)
10. Number of specimen cores or samples acquired, if applicable
11. Specimen images, if performed, and findings

12. Use of stereotactic guidance, DBT guidance, or both
13. Tissue marker type/shape, if placed
14. Complications and treatment, if any
15. Postprocedure mammography, if obtained, documenting tissue marker placement and location of the tissue marker with respect to the biopsied finding
16. Other information may include presence or absence of residual target calcifications or mammographic abnormality for future localization and follow-up purposes.

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

1. Documentation of any delayed complications and treatment administered.
2. Determination of concordance of pathology results with imaging findings by the physician who performed the procedure or the MQSA-qualified designated physician. When discordant, biopsy should be repeated by image-guided percutaneous method or surgical excision [1,29,30].
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis. Surgical consultation usually is recommended for high-risk lesions known to be subject to upgrade to malignancy at excision, unless the high-risk lesion is felt to be incidental (ie, the high-risk pathology is not the explanation for the biopsied target). These lesions include atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ), radial scar, complex sclerosing lesion, phyllodes tumor, and, to a lesser degree, papilloma [47-59]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate [60,61]. For malignant results, patients usually are referred to a surgeon or oncologist for consultation.
4. Process for documentation and communication of biopsy results, concordance, and subsequent recommendations to the patient and/or referring provider.

D. Retention of the procedure images, including specimen images, 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- and DBT-guided breast intervention procedures includes prone and add-on upright systems. The equipment should be calibrated by the manufacturer, and the medical physicist should complete verification of calibration and acceptance testing upon installation [62].

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 [63].

VII. EQUIPMENT QUALITY CONTROL

Refer to [ACR Stereotactic Breast Biopsy Quality Control Manual](#) [62].

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 *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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 biopsy type:

Reason for Repeat Biopsy	Data
Insufficient sample	<ul style="list-style-type: none"> · Total number of cases · Number with repeat biopsy · Final pathology results
Discordance	<ul style="list-style-type: none"> · Total number of cases · Number with repeat biopsy · Final pathology results
High-risk lesions	<ul style="list-style-type: none"> · Total number of cases · Number with repeat biopsy · Final pathology results

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