Revised 2020 (Resolution 3)*

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF STEREOTACTIC/TOMOSYNTHESIS-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 care[1]. 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 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.

[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

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, lower cost, and similar accuracy [1-9].

Percutaneous biopsy techniques have decreased the number of benign surgical biopsies generated from breast imaging programs 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 lesions and is associated with low complication rates [10]. High-quality breast imaging evaluation is necessary to detect early or subtle breast lesions as well as 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 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, patient comfort, and the practitioner's experience [1].

Stereotactic guidance enables percutaneous placement of a needle within the breast to sample mammographically detected suspicious breast lesions. 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 lesion targeting and sampling, and effective methods of obtaining tissue for analysis [11-14]. Digital breast tomosynthesis (DBT) may be used with or without stereotactic guidance as another biopsy technique, either for findings visible only on DBT, or if preferred in certain cases over stereotactic guidance for mammographically visible findings, including calcifications, asymmetries, and especially architectural distortion. The imaging features and the histopathologic interpretations should be assessed for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations [1].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

Stereotactic and/or DBT-guided breast intervention is suitable for most mammographically depicted lesions, including microcalcifications, masses, asymmetries, and architectural distortions. DBT guidance may be used for findings that are amenable to mammographic stereotactic technique. For lesions seen only or better on DBT than on 2-D mammography, DBT-guided percutaneous biopsy is preferred if available [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 (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 [23]
    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 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, or plans to become pregnant in immediate future, etc) [24-27]
    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 or DBT-guided percutaneous sampling is an alternative to surgical biopsy in cases in which initial core biopsy results are nondiagnostic or discordant with imaging findings [1,28,29].

3. Presurgical localization

   Stereotactic- or DBT-guided localization may be used as an alternative to standard mammographic localization for mammographically identifiable lesions prior to surgical procedures [30]. Devices that may be placed using these guidance methods include wires and other localizing devices.

B. Contraindications

Inability to revisualize the target or breast lesion stereotactically at the time of the biopsy is a contraindication to stereotactic-guided breast intervention. Prior to the procedure, the patient should be asked about allergies, including metal allergies for clip placement. Patients may be asked whether they use medications, such as aspirin or other platelet inhibitors, anticoagulants, or other agents known to impact bleeding times, and whether they have a history of a bleeding diathesis. However, a report suggests that it is safe to proceed with biopsy when patients are anticoagulated [31]. Decisions regarding postponement or cancellation of a procedure or temporary cessation of anticoagulants can be made on a case-by-case basis at a programmatic level. The patient's weight (for prone table), compressed breast thickness, and ability to remain in the position required for the procedure 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 "Physician Qualifications for Stereotactic Breast Biopsy" [32,33]. 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 stereotatic- or DBT-guided breast procedures. DBT-guided breast procedures should be performed only by physicians who have completed the FDA mandated 8 hours of DBT training. Please refer to ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis (DBT) [22].

1. Initial qualifications

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

   The initial qualifications as outlined for Stereotactic Breast Biopsy Accreditation Program Requirements provide this foundation [33].

2. Maintenance of competence

   The physician should perform a sufficient number of procedures to maintain their skills. Continued competence should depend on participation in a quality control program as laid out under Section VIII in this practice parameter.

3. Continuing medical education (CME)

[2]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.

The physician's continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [34].

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 sample adequacy. The performing physician or, if unavailable, their qualified designated physician, is responsible for obtaining histopathologic results and determining concordance [1,28-30,35**]**. These results should be communicated to the referring physician and/or to the patient, as appropriate.

B. Qualified Medical Physicist

See the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Stereotactic/Tomosynthesis-Guided Breast Biopsy Systems.

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 [36**]**. Radiologic technologists should also have documented Category A continuing education units in stereotactic-guided breast intervention and must have participated in hands-on procedures under the guidance of a qualified physician or radiologic technologist [33]. For DBT-guided interventions, technologists also should have documented DBT training.

2. Maintenance of competence

Radiologic technologists should participate in stereotactic-guided breast interventions [33].

3. Continuing education (CE)

Radiologic technologists should be in compliance with the continuing education requirements of their certifying organization for the imaging modality for which they perform services [33].

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)

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 underMammography Quality Standards Act (MQSA) and only after adequate imaging evaluation, including orthogonal views, of the breast is performed. In some cases, it may be preferred to employ a combination of stereotactic and DBT guidance for tissue sampling. Appropriate documentation stating the use of stereotactic guidance, DBT guidance, or both, should be made.

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

Scout imaging is performed to confirm that the targeted lesion lies within the accessible area. The physician performing the procedure may decide on the best approach utilizing either stereotactic guidance, DBT guidance, or a combination of the two techniques, based on the ability to see the lesion and the needle during the biopsy. Prior to the procedure, the physician should be able to identify the significant lesion(s) on mammography (or DBT) 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. 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 should be prepared in conformity with the 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 proceduralist. (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 with magnification should be obtained to verify that the microcalcifications have been adequately sampled [1,35,37] prior to needle removal.

Placement of a tissue marker after biopsy is recommended, especially if a lesion may be difficult to see after the biopsy (eg, due to complete target removal or obscuration by postbiopsy change), for confirmation that the proper lesion has been sampled or if neoadjuvant chemotherapy is contemplated. When multiple lesions are present and biopsy of >1 suspicious lesion is performed, placement of markers with different characteristics 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 relative to the biopsy site. If the procedure is performed for a DBT-only visible finding, then postprocedure images should include DBT images.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [38].

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 (MLO), 90° 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 document the following:

1. Procedure performed
2. Designation of left or right breast
3. Description and location of the lesion
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, describing location of tissue marker with respect to the biopsied lesion
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 designated physician. When discordant, biopsy should be repeated by image-guided percutaneous method or surgical excision [1,28,29].
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. 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 [39-51]. However, controversies exist regarding

high-risk lesions, and care should be individualized when appropriate [52,53]. For malignant results, patients usually are referred to a surgeon or oncologist for consultation.

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

D. 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- and DBT-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 [54].

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 [55].

VII. EQUIPMENT QUALITY CONTROL

Refer to ACR stereotactic breast biopsy quality control manual [54].

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	• 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 or the qualified physician designee. Postbiopsy patient follow-up may be performed per radiologist discretion (in some cases at 6 or 12 months, for example) to detect and record any false-negative results.

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – Breast Imaging of the ACR Commission on Breast Imaging.

Reviewing Committee
Phoebe Freer, MD, Chair
Sarah M. Friedewald, MD
William R. Geiser, MS
Catherine S. Giess, MD
Jessica W.T. Leung, MD, FACR
John M. Lewin, MD, FACR
Linda Moy, MD
Mary S. Newell, MD, FACR
Liane E. Philpotts, MD, FACR
Dana H. Smetherman, MD, FACR

Committee on Practice Parameters – Breast Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Linda Moy, MD, Chair
Catherine S. Giess, MD, Vice-Chair
Phoebe Freer, MD
Sarah M. Friedewald, MD
Carolyn A. Haerr, MD
Lillian K. Ivansco, MD, MPH
Madison Kocher, MD
Cindy Lee, MD
John M. Lewin, MD, FACR
Haydee Ojeda-Fournier, MD
Karla A. Sepulveda, MD
Roberta M. Strigel, MD
Karen S. Zheng, MD

Dana H. Smetherman, MD, FACR, Chair, Commission on Breast Imaging
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Catherine J. Everett, MD, MBA, Chair
David Youmans, MD, FACR, Co-Chair
Jacqueline Anne Bello, MD, FACR
Priscilla F. Butler, MS, FACR
Terese I. Kaske, MD
Amy L. Kotsenas, MD, FACR
Paul A. Larson, MD, FACR
Jessica W.T. Leung, MD, FACR

Comments Reconciliation Committee

Richard Duszak Jr., MD, FACR
Kimberly N. Feigin, MD
Phoebe Freer, MD
Sarah M. Friedewald, MD
William R. Geiser, MS
Catherine S. Giess, MD
David W. Jordan, PhD
John M. Lewin, MD, FACR
Linda Moy, MD
Mary S. Newell, MD, FACR
Liane E. Philpotts, MD, FACR
Dana H. Smetherman, MD, FACR
Leonel A. Vasquez, MD, FACR

REFERENCES

1. Bassett L, Winchester DP, Caplan RB, et al. Stereotactic core-needle biopsy of the breast: a report of the Joint Task Force of the American College of Radiology, American College of Surgeons, and College of American Pathologists. CA Cancer J Clin 1997;47:171-90.
2. Brenner RJ, Bassett LW, Fajardo LL, et al. Stereotactic core-needle breast biopsy: a multi-institutional prospective trial. Radiology 2001;218:866-72.
3. Bruening W, Fontanarosa J, Tipton K, Treadwell JR, Launders J, Schoelles K. Systematic review: comparative effectiveness of core-needle and open surgical biopsy to diagnose breast lesions. Ann Intern Med 2010;152:238-46.
4. Parker SH, Burbank F, Jackman RJ, et al. Percutaneous large-core breast biopsy: a multi-institutional study. Radiology 1994;193:359-64.
5. Rovera F, Dionigi G, Marelli M, et al. Breast cancer diagnosis: the role of stereotactic vacuum-assisted aspiration biopsy. Int J Surg 2008;6 Suppl 1:S104-8.
6. White RR, Halperin TJ, Olson JA, Jr., Soo MS, Bentley RC, Seigler HF. Impact of core-needle breast biopsy on the surgical management of mammographic abnormalities. Ann Surg 2001;233:769-77.
7. Wolf R, Quan G, Calhoun K, Soot L, Skokan L. Efficiency of Core Biopsy for BI-RADS-5 Breast Lesions. Breast J 2008;14:471-5.
8. Elvecrog EL, Lechner MC, Nelson MT. Nonpalpable breast lesions: correlation of stereotaxic large-core needle biopsy and surgical biopsy results. Radiology 1993;188:453-5.
9. Gruber R, Walter E, Helbich TH. Impact of stereotactic 11-g vacuum-assisted breast biopsy on cost of diagnosis in Austria. Eur J Radiol 2011;77:131-6.
10. Lin LLY, Gao Y, Lewin AA, Toth HK, Heller SL, Moy L. Overstated Harms of Breast Cancer Screening? A Large Outcomes Analysis of Complications Associated With 9-Gauge Stereotactic Vacuum-Assisted Breast Biopsy. AJR Am J Roentgenol 2019:1-8.
11. Brenner RJ, Fajardo L, Fisher PR, et al. Percutaneous core biopsy of the breast: effect of operator experience and number of samples on diagnostic accuracy. AJR Am J Roentgenol 1996;166:341-6.
12. Koskela A, Berg M, Sudah M, et al. Learning curve for add-on stereotactic core needle breast biopsy. Acta Radiol 2006;47:454-60.
13. Liberman L, Benton CL, Dershaw DD, Abramson AF, LaTrenta LR, Morris EA. Learning curve for stereotactic breast biopsy: how many cases are enough? AJR Am J Roentgenol 2001;176:721-7.
14. Hendrick RE, Bassett LW, Feig SA, et al. *Mammography Quality Control Manual*. Reston, VA: American College of Radiology; 1999.
15. Ariaratnam NS, Little ST, Whitley MA, Ferguson K. Digital breast Tomosynthesis vacuum assisted biopsy for Tomosynthesis-detected Sonographically occult lesions. Clin Imaging 2018;47:4-8.
16. Bahl M, Maunglay M, D'Alessandro HA, Lehman CD. Comparison of Upright Digital Breast Tomosynthesis-guided versus Prone Stereotactic Vacuum-assisted Breast Biopsy. Radiology 2018:181788.
17. Patel BK, Covington M, Pizzitola VJ, et al. Initial Experience of Tomosynthesis-Guided Vacuum-Assisted Biopsies of Tomosynthesis-Detected (2D Mammography and Ultrasound Occult) Architectural Distortions. AJR Am J Roentgenol 2018;210:1395-400.
18. Schrading S, Distelmaier M, Dirrichs T, et al. Digital breast tomosynthesis-guided vacuum-assisted breast biopsy: initial experiences and comparison with prone stereotactic vacuum-assisted biopsy. Radiology 2015;274:654-62.

19. Shin K, Teichgraeber D, Martaindale S, Whitman GJ. Tomosynthesis-Guided Core Biopsy of the Breast: Why and How to Use it. J Clin Imaging Sci 2018;8:28.
20. Slanetz PJ, Brown AL, Bradley M, Karimova EJ. Tomosynthesis-Directed Coaxial Core Biopsy of Tomosynthesis-Detected Architectural Distortion: Indications and Logistics. Can Assoc Radiol J 2017;68:315-17.
21. Waldherr C, Berclaz G, Altermatt HJ, et al. Tomosynthesis-guided vacuum-assisted breast biopsy: A feasibility study. Eur Radiol 2016;26:1582-9.
22. American College of Radiology. ACR practice parameter for the performance of digital breast tomosynthesis (DBT) Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DBT.pdf?la=en. Accessed March 5, 2019.
23. D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA, et al. *ACR BI-RADS Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013*.
24. Helvie MA, Pennes DR, Rebner M, Adler DD. Mammographic follow-up of low-suspicion lesions: compliance rate and diagnostic yield. Radiology 1991;178:155-8.
25. Sickles EA. Periodic mammographic follow-up of probably benign lesions: results in 3,184 consecutive cases. Radiology 1991;179:463-8.
26. Varas X, Leborgne F, Leborgne JH. Nonpalpable, probably benign lesions: role of follow-up mammography. Radiology 1992;184:409-14.
27. Vizcaino I, Gadea L, Andreo L, et al. Short-term follow-up results in 795 nonpalpable probably benign lesions detected at screening mammography. Radiology 2001;219:475-83.
28. Dershaw DD, Morris EA, Liberman L, Abramson AF. Nondiagnostic stereotaxic core breast biopsy: results of rebiopsy. Radiology 1996;198:323-5.
29. Liberman L, Drotman M, Morris EA, et al. Imaging-histologic discordance at percutaneous breast biopsy. Cancer 2000;89:2538-46.
30. Riedl CC, Pfarl G, Memarsadeghi M, et al. Lesion miss rates and false-negative rates for 1115 consecutive cases of stereotactically guided needle-localized open breast biopsy with long-term follow-up. Radiology 2005;237:847-53.
31. Somerville P, Seifert PJ, Destounis SV, Murphy PF, Young W. Anticoagulation and bleeding risk after core needle biopsy. AJR Am J Roentgenol 2008;191:1194-7.
32. Updated physician qualifications for stereotactic breast biopsy. *Bulletin.* Vol 54. Reston, Va.: American College of Radiology; 1998:22-24.
33. American College of Radiology. ACR stereotactic breast biopsy accreditation program requirements. . Available at: https://www.acraccreditation.org/Modalities/Stereotactic-Breast-Biopsy Accessed January 22, 2019.
34. American College of Radiology. ACR practice parameter for continuing medical education (CME). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CME.pdf?la=en. Accessed January 24, 2019.
35. Jackman RJ, Marzoni FA, Jr., Rosenberg J. False-negative diagnoses at stereotactic vacuum-assisted needle breast biopsy: long-term follow-up of 1,280 lesions and review of the literature. AJR Am J Roentgenol 2009;192:341-51.
36. American College of Radiology. ACR practice parameter for the performance of screening and diagnostic mammography. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Screen-Diag-Mammo.pdf?la=en. Accessed January 232, 2018.
37. Liberman L, Evans WP, 3rd, Dershaw DD, et al. Radiography of microcalcifications in stereotaxic mammary core biopsy specimens. Radiology 1994;190:223-5.
38. American College of Radiology. ACR practice parameter for communication of diagnostic imaging findings. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CommunicationDiag.pdf?la=en. Accessed January 22, 2019.
39. Brem RF, Lechner MC, Jackman RJ, et al. Lobular neoplasia at percutaneous breast biopsy: variables associated with carcinoma at surgical excision. AJR Am J Roentgenol 2008;190:637-41.
40. Destounis SV, Murphy PF, Seifert PJ, et al. Management of patients diagnosed with lobular carcinoma in situ at needle core biopsy at a community-based outpatient facility. AJR Am J Roentgenol 2012;198:281-7.

41. Eby PR, Ochsner JE, DeMartini WB, Allison KH, Peacock S, Lehman CD. Frequency and upgrade rates of atypical ductal hyperplasia diagnosed at stereotactic vacuum-assisted breast biopsy: 9-versus 11-gauge. AJR Am J Roentgenol 2009;192:229-34.
42. Heller SL, Moy L. Imaging features and management of high-risk lesions on contrast-enhanced dynamic breast MRI. AJR Am J Roentgenol 2012;198:249-55.
43. Ingegnoli A, d'Aloia C, Frattaruolo A, et al. Flat epithelial atypia and atypical ductal hyperplasia: carcinoma underestimation rate. Breast J 2010;16:55-9.
44. Jackman RJ, Nowels KW, Shepard MJ, Finkelstein SI, Marzoni FA, Jr. Stereotaxic large-core needle biopsy of 450 nonpalpable breast lesions with surgical correlation in lesions with cancer or atypical hyperplasia. Radiology 1994;193:91-5.
45. Kohr JR, Eby PR, Allison KH, et al. Risk of upgrade of atypical ductal hyperplasia after stereotactic breast biopsy: effects of number of foci and complete removal of calcifications. Radiology 2010;255:723-30.
46. Liberman L, Cohen MA, Dershaw DD, Abramson AF, Hann LE, Rosen PP. Atypical ductal hyperplasia diagnosed at stereotaxic core biopsy of breast lesions: an indication for surgical biopsy. AJR Am J Roentgenol 1995;164:1111-3.
47. Liberman L, Tornos C, Huzjan R, Bartella L, Morris EA, Dershaw DD. Is surgical excision warranted after benign, concordant diagnosis of papilloma at percutaneous breast biopsy? AJR Am J Roentgenol 2006;186:1328-34.
48. Linda A, Zuiani C, Furlan A, et al. Radial scars without atypia diagnosed at imaging-guided needle biopsy: how often is associated malignancy found at subsequent surgical excision, and do mammography and sonography predict which lesions are malignant? AJR Am J Roentgenol 2010;194:1146-51.
49. Mahoney MC, Robinson-Smith TM, Shaughnessy EA. Lobular neoplasia at 11-gauge vacuum-assisted stereotactic biopsy: correlation with surgical excisional biopsy and mammographic follow-up. AJR Am J Roentgenol 2006;187:949-54.
50. Solorzano S, Mesurolle B, Omeroglu A, et al. Flat epithelial atypia of the breast: pathological-radiological correlation. AJR Am J Roentgenol 2011;197:740-6.
51. Sydnor MK, Wilson JD, Hijaz TA, Massey HD, Shaw de Paredes ES. Underestimation of the presence of breast carcinoma in papillary lesions initially diagnosed at core-needle biopsy. Radiology 2007;242:58-62.
52. Georgian-Smith D, Lawton TJ. Controversies on the management of high-risk lesions at core biopsy from a radiology/pathology perspective. Radiol Clin North Am 2010;48:999-1012.
53. Javitt MC. Diagnosis and management of high-risk breast lesions: Aristotle's dilemma. AJR Am J Roentgenol 2012;198:246-8.
54. Hendrick RE, Dershaw DD, Kimme-Smith C, et al. *Stereotactic Breast Biopsy Quality Control Manual*. Reston, VA: American College of Radiology; 1999.
55. Jackman RJ, Burbank F, Parker SH, et al. Stereotactic breast biopsy of nonpalpable lesions: determinants of ductal carcinoma in situ underestimation rates. Radiology 2001;218:497-502.

APPENDIX

ACR BI-RADS® ATLAS 5th Edition (BREAST IMAGING REPORTING AND DATA SYSTEM 2013 [23] (BI-RADS® Category 5)

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete – need additional imaging evaluation	Recall for additional imaging	N/A
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy

Category 3: Probably benign	Short-interval (6 month) follow-up or continued surveillance	>0% but ≤2% likelihood of malignancy
Category 4: Suspicious Category 4A: *Low suspicion* for malignancy Category 4B: *Moderate suspicion* for malignancy Category 4C: *High suspicion* for malignancy	Tissue diagnosis	>2% but <95% likelihood of malignancy >2% to ≤10% likelihood of malignancy >10% to ≤50% likelihood of malignancy >50% to <95% likelihood of malignancy
Category 5: Highly suggestive of malignancy	Tissue diagnosis	≥95% likelihood of malignancy
Category 6: Known biopsy-proven malignancy	Surgical excision when clinically appropriate	N/A

*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.

Development Chronology for This Practice Parameter
1996 (Resolution 2)
Revised 2000 (Resolution 41)
Revised 2005 (Resolution 45)
Amended 2006 (Resolution 34,35)
Revised 2009 (Resolution 28)
Revised 2014 (Resolution 6)
Revised 2016 (Resolution 36)
Revised 2020 (Resolution 3)