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RESOLUTION NO. 1

Ten Year Extension of Policy

WHEREAS, the ACR bylaws state that “All official actions and policies of the Council are effective for only ten years unless extended for an additional ten year period by the Council…,” and

WHEREAS, the various components of the College feel that the following policy should be extended for an additional ten year period; therefore

BE IT RESOLVED, that the following policies of the American College of Radiology be extended for an additional ten year period:

(a) C. COMMISSIONS AND COMMITTEES

1. APPOINTMENTS TO COMMISSIONS AND COMMITTEES

The Board of Chancellors shall regularly canvas all members to solicit the names of individuals who deserve consideration for and who would be interested in working on ACR Commissions and/or Committees.

Non-Members shall be used on College commissions and committees only when the talent needed is not available from the ACR membership; 1980, 1990, 2000, amended 2010 (Res. 39-a).

(b) C. COMMISSIONS AND COMMITTEES

2. REPRESENTATION OF RELATED ORGANIZATIONS

The ACR encourages inclusion of representatives of other radiological organizations as members on ACR commissions and committees; adopted 1980, 1990, 2000, amended 2010 (Res. 39-b).

(c) D. ANNUAL COUNCIL MEETING

5. EDUCATIONAL TOPICS FOR ACR MEETINGS

The Commission on Education and the Council Steering Committee, when planning educational sessions at the Annual Meeting, the Council Steering Committee and designated ACR commissions shall consider inclusion of topics deemed relevant to practice leadership and management, professional workforce development and diversity, along with quality and safety issues; adopted 2000, amended 2010 (Res. 39-c).

(d) A. EDUCATION

2. RESIDENT AND FELLOWSHIP TRAINING PROGRAMS

a. Medical Physics Residency Training Program
The American College of Radiology endorses the concept of a clinically oriented medical physics residency program which meets the requirements of the Commission on Accreditation of Medical Physics Education Programs (CAMPEP); adopted 1990, 2000, 2010 (Res. 1-a).

(e) A. EDUCATION

2. RESIDENT AND FELLOWSHIP TRAINING PROGRAMS

e. Residency Programs in Socioeconomics

The members of the American College of Radiology Council and all chapters reaffirm commitment to the socioeconomic education of residents and fellows. Directors of radiologic and radiation oncology residency programs shall strive to provide regular programs on socioeconomics and practice management. The program directors shall also encourage residents to attend ACR-sponsored educational meetings; 1990, 2000, amended 2010 (Res. 39-d).

(f) A. EDUCATION

4. MISCELLANEOUS EDUCATION POLICIES

b. Qualifications of Non-Physician Personnel Who Provide Radiologic and Radiation Oncologic Services

The American College of Radiology supports state licensure, certification or appropriate methods designed to assure the qualifications of all personnel who provide the technical aspects of medical imaging and/or radiation therapy procedures.

Non-physician personnel, may provide those aspects of radiological or therapeutic procedures for which they have appropriate education, training and experience as defined in the appropriate current American College of Radiology Practice Guideline(s) Parameters and Technical Standards, and then only under the supervision of a licensed physician(s) who has the qualifications described in those Practice Guideline Parameters and Technical Standards; 2000, amended 2010 (Res. 1-b).

Sponsored by: ACR Council Steering Committee
To support the resolution for **Ten Year Extension of Policy**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
RESOLUTION NO. 2

BE IT RESOLVED,
that the American College of Radiology adopt the ACR Practice Parameter for the Performance of Preoperative Image-Guided Localization in the Breast

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF PREOPERATIVE IMAGE-GUIDED LOCALIZATION IN THE BREAST

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

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.

PRACTICE PARAMETER 1

Preoperative Image-Guided Breast

2020 Resolution No. 2
I. INTRODUCTION

Preoperative image-guided localization of breast pathology before surgical resection is currently the standard of care for breast cancer and high-risk lesions. Localization devices guide appropriate excision and provide a surgeon with the best means to ensure complete removal of the target tissue. Preoperative localization with image-guided wire placement has been a standard of breast imaging diagnosis and treatment since its development in the 1970s [1]. Several recent advancements in nonwire localization (NWL) techniques minimize limitations of wire localization and have improved patient care and clinical workflow.

II. INDICATIONS

Presurgical localization in the breast may be performed for patients with selected indications including:

1. Biopsy-proven cancer
2. Biopsy-proven metastatic lymphadenopathy
3. High-risk lesions diagnosed at percutaneous biopsy
4. Imaging pathological discordance at core needle biopsy
5. Cases in which core needle biopsy is not an option or fails to provide a definitive histological diagnosis

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiological technologists who work in breast imaging must meet the requirements that are appropriate to the scope of their practice as outlined in the following documents or practice parameters:

2. ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures [3]
4. ACR Practice Parameter for the Performance of a Breast Ultrasound Examination [5]
7. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [8]

IV. SPECIFICATIONS OF THE PROCEDURE

Prior to localization, the radiologist should review all pertinent imaging examinations to determine the extent of disease. Review should determine whether biopsy markers deployed at the time of biopsy were placed in the appropriate position or whether they have migrated. In patients who have undergone neoadjuvant therapy, the original extent of disease and the visible residual are both important to consider. The localization may target a biopsy marker and/or the spectrum of breast imaging abnormalities: mass, calcifications, asymmetry, architectural distortion. If there is known malignancy, it is necessary to understand the extent of malignancy and its location with
respect to previously placed biopsy markers(s). More than one guidance device may be used to bracket the extent of disease [9,10]. The use of multiple localizing devices can decrease the number of procedures required to obtain clear lumpectomy margins and increase the rate of breast conservation versus mastectomy [9].

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. 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, including bedside procedures. The organization should have processes and systems in place for reconciling differences in staff responses during the time-out. The breast, imaging equipment, field in which the procedure is to be performed, and physician performing the procedure should be prepared in conformity with the principles of infection control.

A. Localization Techniques

1. Wire localizations

Preoperative wire localization using mammographic, sonographic, or Magnetic Resonance Imaging (MRI) guidance is optimally performed the day of surgery. The wire may be placed at the breast lesion, adjacent to the biopsy marker (if it lies at the site of the lesion), or at the postbiopsy hematoma if the lesion itself cannot be visualized and if a biopsy marker is not present. If ultrasound guidance is used to place the wire, marking the location of the lesion on the overlying skin with the patient in the supine operative position and measuring the depth of the lesion can assist the surgeon during excision. Tomosynthesis-guided localization is an emerging alternative that may be used by some vendors and practices and differs slightly in technique from standard orthogonal mammographic practice. Limitations of wire localizations include need for same day placement as surgery, imprecision that results from variability in positioning by the radiologist, and inadvertent wire displacement (during patient transfer, postprocedure mammography, or surgical positioning) [11].

2. NWLs

Alternative forms of preoperative localization that do not use wire and mitigate wire localization limitations are now available and include radioactive seed, radiofrequency reflector, and magnetic seed. These localization devices offer increased patient comfort and decreased risk of movement of the localizing device compared to wires. In addition, the devices can be placed before the day of surgery. This uncoupling of localization from the day of surgery provides flexibility to both the radiologist and surgeon in the localization and surgical procedures and less waiting time for patients [12-14]. All forms of NWL typically have two components: a single-use sterilized device preloaded into a needle introducer and a reusable console with dedicated handheld probe for detection of deployment by radiologist and surgical guidance by surgeon. The localizing device may be placed at the breast lesion, adjacent to the biopsy marker (if it lies at the site of the lesion), or at the postbiopsy hematoma if the lesion itself cannot be visualized and if a biopsy marker is not present. In addition to some type-specific limitations (outlined below), nonwire devices may be subject to imprecise positioning during placement or deployment.

a. Radioactive seed localization (RSL)

The radioactive seed placed for localization is composed of titanium and contains iodine-125. The radioactive seed is inserted through a needle with sonographic or mammographic guidance. Because the iodine-125–labeled seed half-life is 59.4 days, preoperative RSL using mammographic or sonographic guidance can be performed up to several days prior to surgery.

RSL programs require adherence to regulations for nuclear materials under the Nuclear Regulatory
PRACTICE PARAMETER

Commission (NRC). A lost radioactive seed is a reportable medical event, and an established protocol is needed to manage the event. In addition, a migrated radioactive seed in the breast must be recovered [1,11,14-18].

b. Radar reflector

Radar localization technology was introduced in 2014 and utilizes radar device as an alternative to wire or radioactive seed. The device is delivered to the desired target in the breast via a needle. The reflector is passive until activated with infrared light from the dedicated handheld probe. Once activated, the device reflects the radar signal, which is detected by the probe and recorded by the console. The console provides audible and visual indicators that increase in cadence and decrease in number as the probe is closer to the reflector. The reflector can be placed with guidance from mammography or ultrasound any time prior to surgery. There is no limitation on length of time the reflector can stay in the breast, providing the opportunity for placement prior to initiation of neoadjuvant therapy. Reflectors placed at significant depth or within a postbiopsy hematoma may not produce a detectable signal to the skin [1,18-20].

c. Magnetic seed

Magnetic seed localization technology was introduced in 2016. The localization device is made from stainless steel. The seed is not magnetic, but it is induced to become a magnet under the influence of the handheld probe that produces an alternating magnetic field that transiently magnetizes the seed. The seed is delivered into the breast via a needle. Once the needle tip is in the desired position, a stylet is advanced within the needle to deploy the seed. Similar to radar reflector, the console provides increasing audible and numeric feedback as the probe is in closer proximity to the seed. The seed can be placed with guidance from mammography or ultrasound any time prior to surgery. There is no restriction on length of time the reflector can remain in the breast, providing the opportunity for placement prior to initiation of neoadjuvant therapy. The device is not compatible for deployment under MRI guidance; however, the patient can have an MRI following deployment, albeit with significant artifact. Nonmagnetic surgical tools need to be used while the probe is in use, and certain stainless steel instruments may not be compatible with the system. Compared with wires and other NWL devices, the magnetic seed is more resistant to damage on deployment, following implantation, or with electrocautery during surgery. There is no limitation on depth placement of magnetic seeds for detectable signal [1,18,21-23].

In each of the NWL methods, more than one localizing device may be placed to bracket the full extent of disease in patients with large masses, masses with satellite nodules or accompanying microcalcifications extending from the mass, or segmental or linearly distributed microcalcifications alone. When two or more localizing devices are used, each manufacturer recommends a specific minimum distance between the devices in order to discriminate between them.

In general, postlocalization preoperative orthogonal mammograms should be obtained to depict the localization and to guide the surgeon in the operative procedure. However, in the rare occasion of young women undergoing ultrasound-guided localizations, some practices will only use ultrasound to document placement of localizing device. Radiologists may elect to annotate the target and specify the final relation of the localization device to the target for the surgeon on the postlocalization mammogram. In all forms of preoperative wire localization, communication with the surgeon may avoid misunderstanding and may take the form of a telephone call, written comments, or annotation of the images.

B. Specimen Imaging

Specimen radiography is essential to document removal of the target and localization device and provide guidance to the surgeon as to the adequacy of excision [24,25]. This should occur while the patient is still in the operating room.
so the surgeon can remove more tissue if warranted.

If the lesion is a single mass, particularly if it was mammographically occult, ultrasound of the specimen can be used to document mass removal [26]. If the lesion contains microcalcifications, either extending from a mass or alone, specimen radiography is better to evaluate the adequacy of excision. When tumor can be seen extending to the specimen margins on the specimen radiograph, there is a high positive predictive value for residual tumor in the breast. Conversely, the negative predictive value of clear margins on specimen radiography is low. Therefore, even though the tumor may not appear to extend to the margins of the resected specimen on the specimen radiograph, the residual tumor may still be present in the breast. This may be particularly true for noncalcified Ductal carcinoma in situ DCIS and infiltrating lobular carcinoma [27,28].

C. Targeted axillary dissection

In an effort to minimize morbidity from complete axillary dissection, targeted axillary dissection with removal of sentinel lymph node and the index biopsy-proven metastatic node has been reported in patients who have undergone neoadjuvant therapy [29]. If a patient converts to node-negative status after therapy, the patient can potentially be spared complete nodal dissection. In this procedure, a pathology-proven metastatic lymph node with biopsy marker may be localized following neoadjuvant therapy. Routine intraoperative lymphatic mapping is performed along with removal of the localized metastatic lymph node. This combined sentinel lymph node dissection with localized removal of metastatic lymph node has a false-negative rate for axillary staging below 5% and provides a potentially safe way to limit axillary surgery [30].

V. DOCUMENTATION

Permanent records of image-guided breast localizations should be documented in a 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

B. The physician’s report of image-guided localizations should include the following:

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion
4. Safety time-out having been performed
5. Approach used
6. Type and amount of local anesthesia
7. Skin incision, if made
8. Type of localization device
9. Confirmation of postprocedure mammogram documenting accurate localizing device placement and location with respect to the targeted lesion
10. Complications and treatment, if any
11. Confirmation of specimen imaging (if not detailed in a separate report)
C. Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [31].

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. 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).

VII. EQUIPMENT

Equipment requirements are outlined in the following practice parameters:

1. ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures [3]

ACKNOWLEDGMENTS

This practice parameter was developed 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.

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REFERENCES


*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
BE IT RESOLVED,
that the American College of Radiology adopt the ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures

Sponsored By: ACR Council Steering Committee

NOT FOR PUBLICATION, QUOTATION, OR CITATION

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. 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.

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.

PRACTICE PARAMETER 1 Stereo/Tomosynthesis- Breast Guided 2020 Resolution No. 3
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.

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 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 localization 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. 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 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. 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/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 when the in which initial core biopsy results are nondiagnostic or are discordant with the imaging findings [1,28,29].

3. Presurgical localization

Stereotactic-guided localization 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. Localization may be performed with wire, needle-wire combination, or radioactive seeds.

B. Contraindications

Inability to visualize 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 of 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 recent report suggested 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. For lesions that are equally well seen on mammography and ultrasound, ultrasound guidance is usually preferred.

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.  

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 FDA mandated 8 hours of DBT training. Please refer to ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis (DBT) [22].

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

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)

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 of sampling. The performing physician or, if unavailable, his/her 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


1. Initial qualifications

---

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.
Medical physicists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [36]. 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 [33].

2. Maintenance of competence

Medical physicists should at least 2 stereotactic breast biopsy unit surveys every 2 years [33].

3. Continuing medical education

Medical physicists should obtain 3 hours of CME in stereotactic breast biopsy unit physics every 3 years [33].

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 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 [33]. For DBT-guided interventions, technologists also should have documented DBT training.

2. Maintenance of competence

Radiologic technologists should participate in at least 24 stereotactic-guided breast interventions every 2 years [33].

3. Continuing medical education (CME)

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 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 an MQSA-certified physician who is qualified under Mammography 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

The breast is compressed between the image receptor and the compression plate. 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 computer-generated coordinates are then transferred to the stereotactic targeting device, and the skin entry site is prepared.

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, a magnification image of the core biopsy 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), of the target or a subtle target), when needing 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. Following performance of stereotactic-guided breast biopsy, a tissue marker should be placed at the biopsy site whenever
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 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 **include document** the following:

1. Procedure performed
2. Designation of the 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. **Gauge of Needle gauge** and **device type of device** (spring-loaded, vacuum-assisted, etc)
10. Number of specimen cores or samples **acquired**, if applicable
11. Specimen images, if performed, and **findings** their results
12. **Use of stereotactic guidance, DBT guidance, or both**
13. Tissue marker placement **type/shape**. If placed performed
14. Complications and treatment, if any
15. Postprocedure mammography, if obtained, documenting **tissue marker placement and describing** location of the tissue marker with respect to the biopsied lesion
16. Other information may include presence or absence of residual target calcifications or mammographically evident residual mass 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. A 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 the imaging guidance image-guided percutaneous method or surgical excision [1,28,29].
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 to malignancy at excision. These lesions include including 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 are usually referred for consultation 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 of biopsy:

<table>
<thead>
<tr>
<th>Reason for Repeat Biopsy</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient sample</td>
<td>• Total number of cases&lt;br&gt;• Number with repeat biopsy&lt;br&gt;• Final pathology results</td>
</tr>
<tr>
<td>Discordance</td>
<td>• Total number of cases&lt;br&gt;• Number with repeat biopsy&lt;br&gt;• Final pathology results</td>
</tr>
<tr>
<td>High-risk lesions</td>
<td>• Total number of cases&lt;br&gt;• Number with repeat biopsy&lt;br&gt;• Final pathology results</td>
</tr>
</tbody>
</table>

333 Imaging findings and pathologic interpretation should be correlated by the physician who performs the biopsy or the qualified physician designee. Postbiopsy patient follow-up should may be performed per radiologist discretion (in some cases at 6 or 12 months, for example) to detect and record any false-negative and false-positive 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.

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PRACTICE PARAMETER 9 Stereo/Tomosynthesis- Breast Guided 2020 Resolution No. 3
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REFERENCES


### APPENDIX

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

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Management</th>
<th>Likelihood of Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 0: Incomplete – need additional imaging evaluation</td>
<td>Recall for additional imaging</td>
<td>N/A</td>
</tr>
<tr>
<td>Category 1: Negative</td>
<td>Routine screening</td>
<td>Essentially 0% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 2: Benign</td>
<td>Routine screening</td>
<td>Essentially 0% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 3: Probably benign</td>
<td>Short-interval (6 month) follow-up or continued surveillance</td>
<td>&gt;0% but ≤2% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4: Suspicious</td>
<td>Tissue diagnosis</td>
<td>&gt;2% but &lt;95% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4A: Low suspicion for malignancy</td>
<td>Tissue diagnosis</td>
<td>&gt;2% to ≤10% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4B: Moderate suspicion for malignancy</td>
<td>Tissue diagnosis</td>
<td>&gt;10% to ≤50% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4C: High suspicion for malignancy</td>
<td>Tissue diagnosis</td>
<td>&gt;50% to &lt;95% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 5: Highly suggestive of malignancy</td>
<td>Tissue diagnosis</td>
<td>≥95% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 6: Known biopsy-proven malignancy</td>
<td>Surgical excision when clinically appropriate</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*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)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACOG–AIUM–SRU Practice Parameter for the Performance of Sonohysterography and Hysterosalpingo-Contrast-Sonography (HyCoSy)

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

Revised 2015 (Resolution 37) *

ACR–ACOG–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF SONOHYSTEROGRAPHY AND HYSTEROASALPINGO-CONTRAST-SONOGRAPHY (HyCoSy)

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. 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.

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.
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.

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications and Contraindications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the American College of Obstetricians and Gynecologists (ACOG), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician qualifications, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control and Patient Education vary among the 4 organizations and are addressed by each separately.

This practice parameter has been developed to assist qualified physicians performing saline infusion sonohysterography (SIS) and hysterosalpingo contrast sonography (HyCoSy); each procedure is addressed separately. Properly performed SIS sonohysterography and HyCoSy can provide information about the uterus, endometrium, and fallopian tubes. Additional studies may be necessary for complete diagnosis. Adherence to the following practice parameter will maximize the diagnostic benefit of each procedure. sonohysterography

Sonohysterography SIS is the evaluation of the endometrial cavity using the transcervical injection of sterile fluid. Various terms, such as saline infusion sonohysterography or hysterosonography, have been used to describe this technique. The primary goal of sonohysterography is to visualize the endometrial cavity in more detail than is possible with standard routine transvaginal endovaginal ultrasound (US) [1]. Sonohysterography may also be used to assess tubal patency [2]. The accuracy of SIS approaches hysteroscopy in detecting endometrial abnormalities [2,3]. An increase in the amount of free pelvic fluid at the end of the procedure indicates that at least one tube is patent.

HyCoSy, also known as sonosalpingography, is the US evaluation of tubal patency. Tubal patency is demonstrated by instilling contrast into the fallopian tubes via the endometrial cavity, with either direct visualization of fluid flowing through the various tubal segments and out of the tube or the accumulation of fluid in the cul-de-sac. An increase in the amount of free pelvic fluid at the end of the procedure indicates that at least one tube is patent. HyCoSy has been demonstrated to have an accuracy essentially equivalent to hysterosalpingogram (HSG) and chromoperturbation at laparoscopy [2,3].

II. INDICATIONS AND CONTRAINDICATIONS

A. Sonohysterography (SIS):

1. Indications [1,4-13]

Indications include, but are not limited to, evaluation of the following:

a) Abnormal uterine bleeding
b) Uterine cavity evaluation, especially relating to uterine leiomyomas, polyps, and synechiae, and cesarean scar niches [14]

c) Abnormalities detected on endovaginal transvaginal sonography, including focal or diffuse endometrial or intracavitary abnormalities

d) Congenital or acquired abnormalities of the uterus

e) Infertility [15-17]

f) Recurrent pregnancy loss

g) Suboptimal visualization of the endometrium by standard sonography endovaginal ultrasound

2. Contraindications

Sonohysterography should not be performed in a woman who is pregnant or who could be pregnant. In patients with regular cycles, this is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has essentially completely or almost completely ceased and but before the patient has ovulated. In a patient with regular cycles, sonohysterography should ideally not in most cases be performed prior to later than the 10th day of the menstrual cycle. Sonohysterography should not be performed in patients with a pelvic infection or unexplained pelvic tenderness which could be due to pelvic inflammatory disease. Active vaginal bleeding is not a contraindication to the procedure but may make the interpretation more challenging [18].

B. HyCoSy

1. Indications [15,16]

Indications include, but are not limited to, evaluation of the following:

a) Determination of tubal patency in patients desiring fertility [19]

b) Confirmation of tubal occlusion after sterilization procedures [20]

2. Contraindications

HyCoSy should not be performed in a woman who is pregnant or who could be pregnant. In patients with regular cycles, this is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has completely or almost completely ceased and before the patient has ovulated. HyCoSy should not be performed in patients with a pelvic infection or unexplained pelvic tenderness which could be due to pelvic inflammatory disease. The presence of a hydrosalpinx is not an absolute contraindication to HyCoSy [21]. HyCoSy should not be performed in the presence of active vaginal bleeding.

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document. ACR language is as follows:

See the ACR-SPR-SRU Practice Parameter for the Performing and Interpreting Diagnostic Ultrasound Examinations [22].

In addition, It is strongly recommended that the physician performing the study has must have spent a minimum of 3 months in documented formal training in the performance, interpretation, and reporting of US examinations of the female pelvis, reproductive system. Additionally, the physician should supervise and interpret US examinations of the female pelvis reproductive system on a regular basis and be familiar with techniques of cervical cannulation.
IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document. ACR language is as follows:

The written or electronic request for SIS and HyCoSy Sonohysterography 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)

V. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

A. Patient Preparation

Pelvic organ tenderness should be assessed during the preliminary transvaginal endovaginal sonogram. If the patient’s history or physical examination is concerning for active pelvic inflammatory disease, the SIS/HyCoSy examination should be deferred until an appropriate course of treatment has been completed. In the presence of nontender hydrosalpinges, consideration may be given to administering antibiotics at the time of the examination; in this case it is prudent to discuss the antibiotic regimen with the referring physician. A pregnancy test is advised when clinically indicated. Patients should be questioned about a latex allergy or a reaction to povidone-iodine betadine or other topical antiseptic (2%–4% chlorhexidine gluconate is a safe alternative [23,24]) prior to use of these products. In patients with regular cycles, a sonohysterogram or HyCoSy should be performed in the early follicular phase, as close to the end of the menstrual bleeding period as possible.

B. Procedure

1. SIS

A previous transvaginal endovaginal sonogram should be performed prior to performing an SIS. is useful for measurement of the endometrium and evaluation of the uterus, ovaries, and pelvic free fluid. A speculum is used to allow visualization of the cervix. The presence of unusual pain, lesions, or purulent vaginal or cervical discharge may require rescheduling the procedure pending further evaluation or treatment. The pre-SIS US allows identification of pertinent pelvic anatomy, may visualize other adnexal or ovarian abnormalities, and allows the unenhanced (with no fluid) assessment of the myometrium and endometrium. This study allows visualization of the orientation and flexion of the uterus, which may assist in placement of the catheters. Prior to insertion, the catheter should be flushed with sterile fluid to avoid introducing air during the study. After cleansing the external os, the cervical canal and/or uterine cavity should be catheterized using an aseptic technique and appropriate normal saline or other contrast fluid sterile fluid should be instilled slowly by means of manual injection under real-time sonographic imaging. Imaging should include real-time scanning of the endometrium and cervical canal [25,26]. Imaging may include evaluation of fallopian tube patency if indicated.
2. **HyCoSy**

A transvaginal sonogram should be performed prior to performing HyCoSy. The presence of unusual pain or purulent vaginal or cervical discharge may require rescheduling the procedure pending further evaluation or treatment. The preliminary US allows identification of pertinent pelvic anatomy and may visualize other adnexal or ovarian abnormalities. The preliminary study visualizes the orientation and flexion of the uterus, which may assist in placement of the catheters. A sonohysterogram (SIS) can be performed, as described above, immediately prior to HyCoSy. If performing an SIS, the catheter should be flushed with sterile fluid prior to insertion. After cleansing the external os, the cervical canal or uterine cavity should be catheterized using an aseptic technique, typically using a balloon catheter to avoid backflow of fluid during HyCoSy. Appropriate sterile fluid, with air, contrast, or foam, is instilled slowly by means of manual injection under real-time sonographic imaging \([19,25-27]\). Commercial devices that mix air and saline together to form the air-infused saline for HyCoSy are available. One can produce similar results by filling a 30-cc syringe with 15 cc of saline and 15 cc of air. Pushing the plunger while rocking the syringe up and down effectively infuses air with saline, which is easily seen on US.

C. **Contrast Agent**

1. **SIS**

Appropriate sterile fluid, such as Sterile normal saline should be used for sonohysterography. If the requesting physician is interested in tubal patency, then a sonosalpingogram can be offered using agitated saline \([28,29]\).

2. **HyCoSy**

Appropriate sterile fluid, such as normal saline infused with air or appropriate contrast medium, should be used for HyCoSy.

D. **Analgesics**

1. **SIS**

Nonsteroidal anti-inflammatory drugs (NSAIDS) may benefit some patients during SIS.

2. **HyCoSy**

Some authors advocate the use of nonsteroidal anti-inflammatories to reduce pain and potentially reduce tubal spasm, similar with HSG \([30-32]\).

E. **Images** \([33]\)

1. **SIS**

Precatheterization images should be obtained and recorded in accordance with the ACR-ACOG-AIUM-SPR-SRU Practice Parameter for the Performance of Ultrasound of the Female Pelvis \([34]\), in at least two planes, to demonstrate normal and abnormal findings. These images should include the thickest bilateral endometrial measurement, which includes the anterior and posterior endometrial thicknesses, obtained in a sagittal view.

It is recommended to instill fluid into the endometrial cavity with real-time US, ensuring adequate visualization. Once the uterine cavity is filled with fluid, A complete survey of the uterine cavity should be performed, and representative with images obtained to document normal and abnormal findings. Images should
include sagittal and transverse images of the endometrium, with measurement of each layer of the endometrium in the sagittal plane. One should also evaluate the endometrium for any asymmetry, irregularity, or presence of focal lesions. 3-D imaging may be helpful in the evaluation. If an intrauterine balloon catheter filled with saline is used for the examination, additional images should be obtained at the end of the procedure with the balloon deflated to fully evaluate the endometrial cavity, particularly the cervical canal and lower portion of the endometrial cavity, including a cesarean scar niche, if present.

The location of any focal lesions should be demonstrated in sagittal and transverse planes, or with 3-D imaging. The size, sonographic characteristics, and depth of penetration into the myometrium, in the case of submucous myomas, should be documented. The use of color Doppler or power Doppler sonography may be helpful in evaluating the vascularity of an intrauterine abnormality. Tubal patency

3-D imaging, specifically reconstructed coronal plane imaging, is also useful in the assessment of Mullerian duct anomalies and for preoperative mapping of myomas [35,36].

2. HyCoSy

Precatheterization images of the pelvis should be obtained and recorded in accordance with the ACR-ACOG-AIUM-SPR-SRU Practice Parameter for the Performance of Ultrasound of the Female Pelvis [34].

It is recommended to instill fluid into the endometrial cavity with real-time US, ensuring adequate visualization. If SIS is performed prior to HyCoSy, images are obtained as described above. Prior to instilling contrast for HyCoSy, the uterus is imaged in a transverse plane, visualizing both cornua simultaneously. Contrast is then instilled under direct US visualization, assessing the passage of contrast through the courses of the fallopian tubes, including the interstitial and isthmic portions, the ampulla, and passage of contrast from the fimbria. Accumulation of contrast in the pelvis is consistent with at least one patent tube. Rotating the patient on each hip may assist in demonstrating tubal patency. Various authors have found power Doppler and 3-D imaging helpful in evaluating tubal patency [37,38]. The lack of tubal patency should be considered with swirling of contrast in the cornual regions of the endometrium. Tubal spasm may result in a similar appearance [39].

F. Postprocedure Care

The imaging or referring physician should discuss the SIS sonohysterogram and/or HyCoSy findings with the patient. The patient should be told to expect may experience leaking of fluid after the procedure that could may be blood-tinged or may have a similar color as the cleaning solution. The patient should be instructed to contact their physician if the symptoms such as fever, persistent pain, or unusual bleeding develop following the procedure. The patient should be told to expect leaking of fluid after the procedure that may be blood-tinged or may have a similar color as the cleaning solution.

VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Adequate documentation is essential for high quality in patient care. There should be a permanent record of the US examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. The initials of the operator should be accessible on the images or electronically on the PACS. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the US examination should be included in the patient’s
medical record. Retention of the US examination images should be based on clinical need and relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [40].

1. SIS

Measurement of the endometrium should be done in the sagittal plane by measuring each layer of the endometrium separately and then adding the results together to obtain the endometrium thickness. One should document whether the layers are uniform and symmetric or if there is asymmetry or irregularities present. Measurement of endometrial polyps and fibroids should be made in three orthogonal planes. When addressing fibroids, a comment about the subjective depth of projection into the endometrial cavity, as a percentage of the overall size of the fibroid, is helpful in determining treatment options.

2. HyCoSy

Images should be obtained in the transverse plane, ideally visualizing both uterine cornua simultaneously. Documentation should include flow of contrast through the interstitial portion of the tube, the ampullary portion of the tube, and out the fimbriated end of the tube. Documentation should include any change in the amount of cul-de-sac fluid during the HyCoSy. Flow of contrast may not be seen in all tubal segments because of overlying bowel loops or acoustic shadows from bowel contents. If brisk flow is seen through at least one tubal segment, without associated tubal dilatation, the tube is considered patent. The lack of flow into and through the tube should be documented.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [32].

Sonohysterography HyCoSy is usually conducted with a high-frequency transvaginal endovaginal transducer. In cases of an enlarged uterus, additional transabdominal images during infusion may be required to fully evaluate the endometrium. The transducer should be adjusted to operate at the highest clinically appropriate frequency under the ALARA ("as low as reasonably achievable") principle.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:

Vaginal transducers should be covered by a protective sheath prior to insertion. Coupling gel should be used. Following the examination, the sheath should be disposed of and the transducer cleaned with a high-level disinfectant. The type of solution and amount of time for cleaning should follow manufacturer and infectious disease control recommendations.

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,
NOT FOR PUBLICATION, QUOTATION, CITATION


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 – Ultrasound of the ACR Commission on Ultrasound in collaboration with the AIUM, the ACOG, and the SRU.

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PRACTICE PARAMETER 8 Sonohysterography/HyCoSy
2020 Resolution No. 4
References


*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

2002 (Resolution 28)
Amended 2006 (Resolution 35)
Revised 2007 (Resolution 26)
Revised 2011 (Resolution 6)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 37)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 5

BE IT RESOLVED, that the American College of Radiology adopt the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of Scrotal Ultrasound Examinations

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

Revised 2015 (Resolution 35) *

ACR–AIUM–SPR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF SCROTAL ULTRASOUND EXAMINATIONS

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. 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. 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 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.

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.
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.

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the Society of Radiologists in Ultrasound (SRU), and the Society for Pediatric Radiology (SPR). Recommendations for Qualifications and Responsibilities of Personnel, physician requirements Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the four organizations and are addressed by each separately.

These practice parameters are intended to assist practitioners performing ultrasound studies of the scrotum. In some cases, additional and/or specialized examinations may be necessary. Although it is not possible to detect every abnormality, adherence to the following practice parameters will maximize the probability of detecting most of the abnormalities that occur in the scrotum.

II. INDICATIONS

Indications for scrotal ultrasound include, but are not limited to [1,2], the following:

1. Evaluation of scrotal pain, including, but not limited to, testicular trauma, ischemia/torsion, postsurgical and infectious or inflammatory scrotal disease [3-10]
2. Evaluation of a palpable inguinal, intrascrotal, or testicular mass [1,2,11-13]
3. Evaluation of scrotal asymmetry, swelling, or enlargement [1,2,14-16]
4. Evaluation of potential intrascrotal hernia [17]
5. Detection/evaluation of varicoceles [18]
7. Follow-up of prior indeterminate scrotal ultrasound findings [19]
8. Localization of nonpalpable testes [20,21]
9. Evaluation of inguinal testes [22]
10. Detection of an occult primary tumor in patients with metastatic germ cell tumor [23] or unexplained retroperitoneal adenopathy
11. Follow-up of patients with prior primary testicular neoplasms, leukemia, or lymphoma [24]
12. Evaluation of an abnormality noted on other imaging studies (including, but not limited to, computed tomography [CT], magnetic resonance imaging [MRI] and positron emission tomography [PET])

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document. ACR language is as follows:
IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document. ACR language is as follows:

The written or electronic request for scrotal ultrasound 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)

V. SPECIFICATIONS OF THE EXAMINATION

The presence of two testes should be documented either on a single transverse, coronal, or coronal oblique image. Also, a cine loop survey scan, taken in both longitudinal and transverse projections, can be obtained and stored with the rest of the study. The testes should be evaluated in at least two planes, longitudinal and transverse. Transverse images should be obtained in the superior, mid, and inferior portions of the testes. Longitudinal views should be obtained centrally as well as medially and laterally. In cases of acute swelling or pain, some authors suggest that the asymptomatic side should be evaluated first and the symptomatic side afterward with the same/similar grayscale and Doppler settings [8]. Each testis should be evaluated in its entirety. The size, echogenicity, and blood flow of each testis and the epididymis should be compared with the contralateral side. Comparison of the testes is best accomplished with a side-by-side transverse image. If a palpable abnormality is the indication for the sonogram, this area should be directly imaged [1,2]. In the event that a testis is not identified within the scrotum, the ipsilateral inguinal canal and inguinal rings should be scanned. The pelvis and the retroperitoneum may also be scanned to look for testicular ectopia [21].

Relevant extratesticular structures should be evaluated. The head, body, and tail of the epididymis should be evaluated when technically feasible. The spermatic cord and the supratesticular area should be evaluated if there is suspicion for testicular torsion [9,10,27]. The scrotal wall, including the overlying skin, should be evaluated. Additional techniques, such as the Valsalva maneuver or upright positioning, can be used as needed. Any abnormality should be documented. In pediatric patients, testicular volumes could be provided using the Lambert formula length (L) × width (W) × height (H) × 0.71) or ellipsoid formula (L × W × H × 0.52) [28].

Doppler sonography (spectral and color/power Doppler imaging) should be used as necessary in examinations of the scrotum and is required in the setting of acute scrotal pain and evaluation of varicocele. If used, color and/or power Doppler sonography should include at least one side-by-side image comparing both testes. Identical Doppler settings should be used to evaluate symmetry of flow between the testes. Low-flow detection settings should be used, if necessary, to document testicular blood flow.
VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [29].

VII. EQUIPMENT SPECIFICATIONS

Scrotal studies should be conducted with a real-time scanner, preferably using a 7–12 MHz or higher linear array transducer. A curvilinear or vector transducer or linear transducer with lower frequencies may be needed if the scrotum is enlarged, recognizing that there is a trade-off between spatial resolution and beam penetration. The highest possible Doppler frequencies (typically in the 5.0–10 MHz range) providing optimal resolution and flow detection should be utilized. The Doppler frequency may differ from imaging frequency. Stand-off pads can be used, if necessary, to improve imaging.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:

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).

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [30].

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 – Ultrasound of the ACR Commission on Ultrasound and by the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the AIUM, the SPR, and the SRU.
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REFERENCES


OLD REFERENCES


*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 Guideline

1993 (Resolution 5)
Revised 1997 (Resolution 30)
Revised 2001 (Resolution 38)
Revised 2006 (Resolution 42, 35)
Revised 2010 (Resolution 33)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 35)
RESOLUTION NO. 6

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SRU Practice Parameter for the Performance of Ultrasound Evaluation of the Prostate (and Surrounding Structures)

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

Revised 2015 (Resolution 34) *

ACR–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND EVALUATION OF THE PROSTATE (AND SURROUNDING STRUCTURES)

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

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.
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.

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician qualifications, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the three organizations and are addressed by each separately.

Ultrasound examination of the prostate and surrounding structures is used in the diagnosis of prostate cancer, benign prostatic enlargement, prostatitis, prostatic abscess, congenital anomalies, ejaculatory dysfunction, and male infertility as well as for the treatment of prostate cancer, abscess, and benign prostatic enlargement [1]. Ultrasound-guided biopsy of the prostate is useful for evaluating those patients who have abnormal digital rectal examinations or an abnormal serum prostatic-specific antigen (PSA) level, azoospermia, a low ejaculatory volume, and those in whom tissue diagnosis is needed for further management.

Ultrasound findings may be used to guide a targeted or systematic biopsy of the prostate or guide a targeted biopsy approach, which is performed to supplement the standard systematic biopsy protocol in order to improve the positive cancer yield of prostate biopsy [2,3]. However, current Conventional ultrasound techniques using grayscale Doppler, color Doppler, and power Doppler imaging elastography, and contrast-enhanced ultrasound are not sufficient to confirm or exclude the presence of prostate cancer and they should not be used to preclude the performance of prostate biopsy [4-6]. Although newer techniques using elastography and contrast-enhanced ultrasound may provide superior detection of prostate cancer, these techniques are not sufficiently established to be included as standard of care at this time.

These practice parameters are intended to assist practitioners performing an ultrasound examination of the prostate. Ultrasound of the prostate and surrounding structures should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure should be used to gain the necessary diagnostic information. In some cases, an additional and/or specialized examination may be necessary. Although it is not possible to detect every abnormality, following this practice parameter will maximize the detection of abnormalities of the prostate.

II. INDICATIONS

Indications for prostate ultrasound include, but are not limited to, the following:

1. Guidance for biopsy in the presence of an abnormal digital rectal examination or elevated PSA [7] or a suspicious prostatic lesion detected on MR. This includes use of transrectal ultrasound (TRUS) biopsy as part of the TRUS/MRI fusion technique [6]
2. Assessment of prostate volume prior to medical, surgical, or radiation therapy [8,9] and to calculate PSA density [10]
5. Assessment of congenital anomalies [13]
6. Infertility including azoospermia and a low ejaculatory volume
7. Hematospermia
8. Evaluation for suspected recurrence in the prostatectomy bed in patients who have undergone prostatectomy
9. Ejaculatory dysfunction or painful ejaculation

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document. ACR language is as follows:

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [14].

IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document. ACR language is as follows:

The written or electronic request for ultrasound evaluation of the prostate 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)

V. SPECIFICATIONS OF THE EXAMINATION

The following practice parameters describe the examination of the prostate and surrounding structures.

A. Prostate

The transrectal approach to ultrasound of the prostate is the method of choice because the resulting image quality is superior to transabdominal or transperineal examinations. In patients for whom the transrectal approach is not possible, a transperineal ultrasound examination may be used to direct a biopsy procedure [15]. A transabdominal approach can be useful to obtain an estimate of prostate size in some settings.

The prostate should be imaged in its entirety in at least two orthogonal planes, sagittal and axial or longitudinal and coronal, from the apex to the base of the gland. An estimated volume is determined from measurements in three orthogonal planes (volume = length × height × width × 0.52) [16,17]. The volume of the prostate may be correlated with the PSA level. Alternatively, prostate volume can be calculated using prostate planimetry, which allows greater accuracy by accommodating individual variations in prostate shape [18].
The gland should be evaluated for focal mass, echogenicity, symmetry, and continuity of margins. Color and power Doppler sonography may be helpful in detecting areas of increased vascularity that can be used to select potential sites for biopsy [19]. A cine loop survey scan, taken in both longitudinal and transverse projections, can be obtained and stored with the rest of the study. The periprostatic fat and neurovascular bundle should be evaluated for symmetry and echogenicity. Demonstration of any interruption in the normal fat plane along the anterior perirectal space may be particularly important to aid characterization of malignant lesions in the prostate and for evaluation of periprostatic spread of cancer. The course of the prostatic urethra should be documented when possible, and asymmetry between left and right periurethral tissues as well as any effect on the base of the bladder should be noted.

B. Seminal Vesicles, Vasa Deferentia, and Perirectal Space

The seminal vesicles should be evaluated for size, shape, position, symmetry, and echogenicity from their insertion into the prostate via the ejaculatory ducts to their cranial and lateral extents. Particular attention should be given to the normal tapering of the seminal vesicle as it joins the prostate. In patients being evaluated for infertility, the vasa deferentia must be evaluated. The presence and size of seminal vesicle, ejaculatory, Müllerian, or utricle cysts or evidence of seminal vesicle or ejaculatory duct obstruction should be noted. Inclusion of the anterior perirectal space, in particular the region that abuts the prostate and perirectal tissues, is important.

VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [20].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. The prostate should be measured in three planes. Any focal abnormality should also be measured. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [21].

A. Equipment

Endorectal ultrasound of the prostate should be conducted with a transrectal (also termed endorectal) transducer using the highest clinically appropriate frequency (usually 6 MHz or higher), realizing that there is a trade-off between resolution and beam penetration. Both side-fire and end-fire transducers may be used. A lower-frequency transducer may be necessary for transabdominal and transperineal examinations, which may be performed with curvilinear or sector transducers.
Ultrasound-guided prostate biopsy can be performed with side-fire probe, or end-fire probe, or biplanar or triplanar transducer configuration, acknowledging that transducer selection may vary with specific anatomic considerations [22].

B. Care of the Equipment

The transrectal probe, after ultrasound gel application, must be covered by a disposable sheath prior to its insertion. Additional gel should be applied after covering the probe with a disposable sheath to aid in comfort with probe insertion and optimizing transducer to target interface. Following the examination and disposal of the sheath, the probe must be disinfected. The method of disinfection may vary by manufacturer recommendations and institutional practices. It is optimal to use a high-level disinfection protocol. Disposable accessory items used during the study must be discarded after each examination. Reusable accessory items should be processed or sterilized according to appropriate guidelines and procedures.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:

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).

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 – Ultrasound of the ACR Commission on Ultrasound, in collaboration with the AIUM and the SRU.

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*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
1992 (Resolution 10)
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Amended 2006 (Resolution 35)
Revised 2010 (Resolution 32)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 34)
ACR–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF DIAGNOSTIC AND SCREENING ULTRASOUND OF THE ABDOMINAL AORTA IN ADULTS

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. 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.

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.
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.

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician requirements, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the three organizations and are addressed by each separately.

These practice parameters are intended to assist in the performance and interpretation of the dedicated sonographic examination of the abdominal aorta. The examination may be performed as a diagnostic or screening study [1-3]. Although it is not possible to detect every abnormality, following this practice parameter will maximize the detection of abnormalities of the abdominal aorta.

II. INDICATIONS/CONTRAINDICATIONS

Indications for ultrasound of the abdominal aorta include, but are not limited to, the following:

A. Diagnostic Evaluation for Abdominal Aortic Aneurysm (AAA).

1. Palpable or pulsatile abdominal mass or abdominal bruit
2. Unexplained lower back pain, flank pain, or abdominal pain
3. Follow-up of a previously demonstrated AAA

Recommendations for rescanning patients are as follows [4]:

a. For AAA size 3.0-3.9 cm: follow-up ultrasound every three years
b. For AAA size 4.0-4.9 cm: follow-up annually
c. For AAA size 5.0-5.4 cm: follow-up every 6 months

4. Follow-up of patients with an abdominal aortic and/or post-AAA repair, particularly post-endovascular aortic aneurysm repair (EVAR) iliac endoluminal stent graft

B. Screening Evaluation for Abdominal Aortic Aneurysm

1. Men age 65 or older who have ever smoked
2. Women age 65 or older with cardiovascular risk factors
3. Patients Individuals age 50 or older with a family history of aortic and/or peripheral vascular aneurysmal disease
4. Patients Individuals with a personal history of peripheral vascular aneurysmal disease
5. **Individuals with other risk factors for AAA** Groups with additional risk include patients with a history of smoking, hypertension, or certain connective tissue diseases (e.g., Marfan syndrome).

There are no absolute contraindications to ultrasound of the aorta. If aortic rupture or dissection is clinically suspected, ultrasound is usually not the examination of choice.

### III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Each organization will address this section in its document. ACR language is as follows:

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [5].

### IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization addresses this requirement individually. ACR language is as follows:

The written or electronic request for ultrasound of the abdominal aorta 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)

### V. SPECIFICATIONS OF THE EXAMINATION

A. Diagnostic Examination

The examination includes the following, when feasible:

1. **Abdominal aorta**
   a. Longitudinal images (along the long axis of the vessel)
      i. Proximal (below diaphragm, near the celiac artery)
      ii. Mid (near the level of the renal arteries)
      iii. Distal (**above through** the iliac bifurcation)
   b. Transverse images (perpendicular to the long axis of the vessel)
      i. Proximal (below diaphragm, near the celiac artery)
      ii. Mid (near the level of the renal arteries)
      iii. Distal (**above through** the iliac bifurcation)
c. Measurements

i. Measurements of the proximal, mid, and distal aorta should be obtained using predominantly the long axis view to measure the AP dimension. Transverse or coronal views should also be obtained to measure the width. Measurements are taken at the greatest diameter of the aorta, from outer edge to outer edge. The aorta should be imaged in the plane that is parallel to the long axis of the lumen (for measurement of the anteroposterior [AP] dimension) and perpendicular to the long axis of the lumen (for measurement of the transverse dimension). The aorta may also be scanned using a lateral or coronal approach if it cannot be visualized from an anterior transducer approach. The measurements obtained via these scan planes are equivalent to transverse measurements.

ii. If an AAA is present, the maximal size and location of the aneurysm should be documented and recorded. The relationship of the dilated segment to the renal arteries and to the aortic bifurcation should be determined if possible.

iii. At a minimum, the largest measurement should be recorded and reported. A measurement of the length of the aneurysm is optional, not necessary.

iv. If an AAA is present, the shape of the aneurysm should be documented either as fusiform, eccentric, or saccular. Documentation should include representative images, which enable the radiologist to characterize the shape of the aneurysm.

2. Common iliac arteries

a. Longitudinal images of the proximal right and left common iliac arteries (along the long axis of the vessel)

b. Transverse images (perpendicular to the long axis of the vessel) of the proximal common iliac arteries, just below the bifurcation

c. Measurement of the widest visualized portion of each common iliac artery, from outer edge to outer edge

Color Doppler imaging and/or spectral Doppler with waveform analysis of the aorta and iliac arteries may be helpful to demonstrate patency and the presence of intraluminal thrombus.

After EVAR endoluminal graft placement, color (or power) and spectral Doppler are required to document the presence or absence of endoleaks. Contrast-enhanced ultrasound (CEUS) may be helpful for identification of endoleaks. Note: This would be an off-label use of CEUS based upon current FDA approval status [6].

Interobserver measurements of an aortic aneurysm can vary by as much as 5 mm. Visual comparison with prior studies is recommended to ensure measurements are obtained at similar locations and to assess for interval change in aneurysm size. Consistent measurements of aneurysm diameter are recommended following endograft repair to check for interval enlargement in sac size [7]. Excessive transducer pressure should be avoided when measuring aortic size.

B. Screening Examination for Abdominal Aortic Aneurysm AAA

1. Abdominal aorta

a. Longitudinal images (along the long axis of the vessel)

i. Proximal (below diaphragm, near the celiac artery)

ii. Mid (near the level of the renal arteries)

iii. Distal (above the iliac bifurcation)

b. Transverse images (perpendicular to the long axis of the vessel)

i. Proximal (below diaphragm, near the celiac artery)

ii. Mid (near the level of the renal arteries)
iii. Distal (above the iliac bifurcation)
e. Measurements

AP measurements of the aorta sufficient to determine if an aortic aneurysm exists according to the criteria in Section C1 below V. A. above should be obtained. If an aneurysm is present, its greatest dimension should be reported. However, if no aneurysm is identified, the largest diameter of the abdominal aorta should be reported.

C. Interpretation of the Screening Examination Should Include at Least 3 Categories

1. Positive: Infrarenal abdominal aortic aneurysm AAA greater than or equal to 3 cm in diameter or greater than or equal to 1.5 times the diameter of the more proximal infrarenal aorta [8]. The latter definition is particularly important in women and small adults [9].
2. Negative: No infrarenal AAA
3. Indeterminate: Aneurysmal status not defined because of nonvisualization or partial visualization of the infrarenal abdominal aorta and/or iliac bifurcation.
4. The report should also state whether or not the suprarenal aorta was seen and, if seen, should reflect whether or not it is normal. The report should also state whether dilation of the aorta above the celiac artery is noted. For the area above the celiac artery, an aneurysm may be reported if the diameter is greater than 3.9 cm for males or 3.1 cm for females.

VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [10].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.


VII. EQUIPMENT SPECIFICATIONS

Abdominal aortic ultrasound should be performed with real-time scanners with transducers that allow for appropriate penetration and resolution, depending on the patient’s body habitus. Diagnostic information should be optimized while keeping total ultrasound exposure as low as reasonably achievable.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:
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).

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2020 Resolution No. 7

NOT FOR PUBLICATION, CITATION, OR QUOTATION

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REFERENCES


OLD REFERENCES


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

- 2005 (Resolution 32)
- Amended 2006 (Resolution 35)
- Revised 2010 (Resolution 34)
- Amended 2014 (Resolution 39)
- Revised 2015 (Resolution 32)
RESOLUTION NO. 8

Non-Physician Radiology Providers (NPRP) – Definitions

WHEREAS, the 2018 ACR Task Force on Non-physician Providers (NPPs) in Radiology (“the Task Force”) cited inconsistencies and ambiguity in ACR policies and practice parameters regarding the use of the various terms for NPPs and called for clarity in existing and future ACR policies and practice parameters; and

WHEREAS, ACR existing policies and practice parameters, including “Section II Professional and Public Policy Statements” of the ACR’s Digest of Council Actions, refer to various types of NPPs who work in radiology departments and with radiologists, using many different terms, including Nurse Practitioners (NP), Physician Assistants (PA), Registered Radiologist Assistants (RRA), Radiologist Assistants (RA), Radiology Practitioner Assistants (RPA), allied health professionals, ancillary personnel, and radiologist extenders; and

WHEREAS, the education and training requirements, licensing, credentialing, and roles and responsibilities differ among various types of NPPs (e.g. NPs, PAs, RRAs, …) on radiologist-led teams; and

WHEREAS, Radiology physicians (e.g. diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians) possess the knowledge and leadership skills that are needed to provide the highest level of care to patients; and

WHEREAS, the concept of physician-led team-based care is supported by the American Medical Association and patients and considered an important component of achieving the quadruple aim of providing better patient experience, better population health, lower overall costs and improved professional satisfaction; and

WHEREAS, the Task Force concluded that current ACR policies and practice parameters concerning scope of practice and roles of NPs and PAs do not necessarily distinguish NPs and PAs from RRAs; and

WHEREAS, some current ACR policies and practice parameters regarding scope of practice and roles of NPPs are written to apply broadly to all NPPs, rather than
specific/individual types of NPPs (e.g. NPs vs. PAs vs. RRAs) and that this approach can be confusing, result in unintended consequences, and disenfranchise one or more type of NPP relative to another; and

WHEREAS,

the ACR NPP Task Force called for all existing and future ACR policies and practice parameters concerning scope of practice and roles of NPPs to be modified and written, whenever possible and appropriate, such that each policy or practice parameter explicitly address individual type(s) of NPP (e.g. NP, PA, and RRA), rather than addressing all NPPs similarly or generically; therefore,

BE IT RESOLVED,

that for the purposes of ACR policy the term “Non-Physician Radiology Provider (NPRP)” will be defined as “all Non-Physician Providers (e.g. RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a Radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term “NPRP” does not include radiology, CT, US, NM, MRI technologists, radiation therapists, who have specific training for radiology related tasks (e.g. acquisition or images, operation of imaging and therapeutic equipment) that are not typically performed by Radiologists; and

BE IT FURTHER RESOLVED,

that the term 'Radiologist-led team' is defined as a team supervised by a radiologist (i.e. diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients; and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters will be reviewed, modified and written to incorporate the term “Non-Physician Radiology Provider” (NPRP); and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters concerning NPRPs or NPRP-issues will be reviewed, modified, and written as necessary to address the intention of the policy and practice parameter by referring separately and specifically to each particular NPRP (e.g. NP, PA, RRA, and any other specific NPRP impacted by the policy or practice parameter); and
BE IT FURTHER RESOLVED,

that any existing and future ACR policies and practice parameters concerning NPRP or NPRP-issues that are intended to apply broadly and generically to all NPRPs should explicitly state this intention; and

BE IT FURTHER RESOLVED,

that these ACR policy and practice parameter reviews and language modifications would ideally be accomplished prior to the 2021 ACR annual meeting and will be completed no later than the 2022 ACR annual meeting.

Sponsored by: Council Steering Committee
Fiscal Note

Non-Physician Radiology Providers (NPRP) – Definitions

To support the resolution for Non-Physician Radiology Providers (NPRP) – Definitions, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
RESOLUTION NO. 9

Roles of Non-Physician Radiology Providers (NPRP) – Policies, Parameters and Legislation/Regulations

WHEREAS,

the 2018 ACR Task Force on Non-physician Providers (NPPs) in Radiology (“the NPP Task Force”) reported that “there is little if any guidance in ACR policy related to scope of practice of Nurse Practitioners (NPs) and Physician Assistants (PAs) within radiology practices”; and

WHEREAS,

the NPP Task Force reported that ACR’s policies regarding NPPs do not clearly state that performance of diagnostic interpretations is outside of the scope of practice of many NPPs (e.g. NPs, PAs); and

WHEREAS,

the 2018 ACR Human Resources Task Force report stated that greater than 50% of radiology practices in the United States employ or will hire NPPs to enhance services; and

WHEREAS,

some NPPs are generally expected to pursue scopes of practice to the level of independent practitioners; and

WHEREAS,

NPPs, other than RRAs, can be supervised by any physician and perform and interpret imaging procedures as determined by individual state regulation; and

WHEREAS,

no training program curricula of NPPs (except RRAs) specifically include imaging procedures, vocabulary, radiation safety, protocols, appropriateness; and

WHEREAS,

the American Medical Association (AMA) has specific policy [H-160.949] to actively oppose legislation allowing non-physician groups to engage in the practice of medicine without physician (MD, DO, MBBS) training or appropriate physician supervision; the AMA encourages state medical societies to oppose legislation allowing non-physician groups to practice medicine without physician oversight; the AMA, through legislative and regulatory efforts, vigorously supports and advocates for the requirement of appropriate physician supervision of non-physician clinical staff in all areas of medicine; and
WHEREAS,

the ACR strongly supports the statement that Radiologists (e.g. diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians) are the best trained and most expert in the use of imaging and image-guided, diagnostic and therapeutic, non-invasive and minimally-invasive exams, and the therapeutic use of radiation; and

WHEREAS,

all NPPs have significantly less training than Radiologists in the comprehensive understanding of anatomy, physiology, pathophysiology, physics of various forms of medical imaging (e.g. x-ray, ultrasound, MRI, etc.), imaging artifacts, visualization of additional significant findings not associated with the original indication, and the knowledge to discern when and when not to perform a procedure for a patient; and

WHEREAS,

independent, non-supervised performance and interpretation of diagnostic and therapeutic non-invasive and invasive medical imaging procedures could put the patient population at significant additional risk; and

WHEREAS,

for the purposes of this resolution, the term “Non-Physician Radiology Provider (NPRP)” is used in accordance with the definition established by an accompanying 2020 Resolution (see Resolution 8):

“all Non-Physician Providers (e.g. RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a Radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians)”; therefore,

BE IT RESOLVED,

that the ACR continue to oppose any legislation or regulation permitting NPPs (e.g. NPs, PAs, RRAs, ...) to provide interpretations (preliminary, final, or otherwise) of diagnostic imaging examinations; and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters concerning NPRPs will be reviewed, modified, and written such that the intention of the policy and practice parameter reflects that NPRPs (including but not limited to NPs, PAs, and RRAs) will not perform interpretations (preliminary, final, or otherwise) of any radiological examination. NPRPs may identify imaging findings or observations and communicate those only to the supervising radiologist. Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond the scope of practice and is not
the intended role of an NPRP. Interpretations are distinguished from observations in that interpretations involve synthesizing imaging findings in the context of clinical histories, physical examination findings, laboratory testing, and/or comparison with prior or other imaging studies in a manner that leads to clinical impressions or conclusions, specific diagnoses and/or differential diagnoses; and

**BE IT FURTHER RESOLVED,**

that existing and future ACR policies and practice parameters concerning NPRPs will be reviewed, modified, and written such that the intention of the policy and practice parameter reflects that NPRPs working in a radiology setting (e.g. diagnostic, interventional, or neurointerventional radiology; nuclear medicine; or radiation oncology setting) assisting with or participating in minimally-invasive procedures must operate under the supervision of a Radiologist and as part of a Radiologist-led team; and

**BE IT FURTHER RESOLVED,**

that the ACR continue to oppose any legislation or regulation permitting the independent practice of NPRPs (e.g. NPs, PAs, RRAs, ...) in radiology; and

**BE IT FURTHER RESOLVED,**

that the ACR will:

1. assist medical and radiology societies and specialty organizations that seek to enact legislation that would define the valued role of mid-level and other health care professionals within a physician- and radiologist-led team-based model structured to efficiently deliver optimal quality patient care and to assure patient safety; and

2. actively support the concept of radiologist-led radiology teams and oppose radiology teams that are not radiologist-led;

**BE IT FURTHER RESOLVED,**

that these ACR policy and practice parameter reviews and language modifications would ideally be accomplished prior to the 2021 ACR annual meeting and will be completed no later than the 2022 ACR annual meeting.

Sponsored by: Council Steering Committee
To support the resolution for Roles of Non-Physician Radiology Providers (NPRP) – Policies, Parameters and Legislation/Regulations, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
RESOLUTION NO. 10

Interim Support Position for RRA Legislation and Regulation

WHEREAS,

the American College of Radiology (ACR) Council adopted its original RRA policy (ACR RRA policy) in 2003 and renewed it in 2013; and

WHEREAS,

the ACR RRA policy was amended in 2008 to require Board of Chancellors (BOC) and Council Steering Committee (CSC) review and approval of Intersocietal Commission of the Radiologist Assistant (ICRA) recommended changes to the roles and responsibilities of the RRA; and

WHEREAS,

the ACR has worked with and supported non-radiologist societies [eg. American Registry of Radiologic Technologists’ (ARRT), American Society of Radiologic Technologists (ASRT)] to co-promote the Medicare Access to Radiology Care Act (MARCA) legislation as well as federal- and state-level regulations to support the role of registered radiologist assistants (RRAs) in clinical care, the development of the RRA as a profession, and appropriate payment for work rendered by RRAs; and

WHEREAS,

the ARRT’s current Entry-Level Clinical Activities (ELCA) document (which describes entry-level clinical activities potentially performed by RRAs under radiologist oversight) explicitly includes clinical activities that substantially broaden the scope of practice of RRAs beyond those cited and approved in current ACR RRA policies; and

WHEREAS,

the current ELCA was not submitted to the BOC and CSC for formal review. Thus, the modifications to the ARRT ECLA documents that broaden the scope of practice of RRAs have not been approved (as required per 2008 ACR RRA Policy); and

WHEREAS,

the next scheduled update of the ARRT ELCA is not until 2023 and communication from the ARRT leadership suggests that the earliest that the current ECLA could potentially be significantly revised is 2022; therefore

BE IT RESOLVED,

that the ACR supports its RRA policies as approved by Council in 2003 (and renewed in 2013), 2006, and 2008; and
BE IT FURTHER RESOLVED, that ACR will study updating the 2003 RRA policy to contemporary practice (2020) at or before its scheduled 10-year renewal in 2023; and

BE IT FURTHER RESOLVED, that any current, past, or future RRA ELCA document that has not followed the approval process outlined in 2003, 2008, and other ACR RRA policies is not ACR policy; and

BE IT FURTHER RESOLVED, that the ACR will work with the ARRT, ASRT, and other RRA stakeholders to align both the ELCA document and the processes for modification and approval of future RRA scope of practice changes with ACR policy; and

BE IT FURTHER RESOLVED, that until the BOC and CSC review and approve ELCA and RRA scope of practice documents consistent with existing ACR policy, the ACR shall suspend all activities to promote, sponsor, or otherwise support MARCA and other legislation and regulations on the national, state, and local levels that would in any way expand or modify RRA clinical activities beyond those explicitly cited in ACR policy.

Sponsored by: Council Steering Committee
Fiscal Note

Interim Support Position for RRA Legislation and Regulation

To support the resolution Interim Support Position for RRA Legislation and Regulation, the ACR would incur the following estimated costs:

Costs:

De minimis (<$10,000)
RESOLUTION NO. 11

Update to Existing ACR Policies on Radiologist Assistants

WHEREAS,

the ACR has existing Registered Radiologist Assistant (RRA) policies originally approved in 2003, 2006, 2008; and

WHEREAS,

the ACR’s RRA policies were written by different authors, for different ACR Councils, spanning a period of many years; and

WHEREAS,

in 2018 a late resolution named “Updating ACR Policy on Non-MD or Non-DO Healthcare Personnel in Radiology” was submitted as a late resolution and subsequently withdrawn in response to the Council Speaker calling for review of existing ACR policies regarding non-physicians working in radiology; and

WHEREAS,

in 2018 ACR leadership formed a Task Force to report to the CSC and Council about non-physician providers (NPP) working in radiology and related ACR NPP policies; and

WHEREAS,

the ACR Council Speaker, in 2018, formed an NPP Work Group to consider and implement the NPP Task Force’s recommendations; and

WHEREAS,

the NPP Work Group recommended to CSC that existing 2003, 2006, and 2008 ACR RRA policies should be updated to reflect contemporary (2020) radiology practice and use consistent language among all ACR RRA policies; therefore,

BE IT RESOLVED,

that the Council of the American College of Radiology adopt the revised ACR Statement on Radiologist Assistant Roles and Responsibilities in lieu of the ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities, currently Appendix H, adopted in 2003 as Resolution 2; and

BE IT FURTHER RESOLVED,

that the ACR will work with ASRT to get approval for the revised statement so that it may be accepted as a new ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities; and
BE IT FURTHER RESOLVED,
that the ACR Council of the American College of Radiology adopt the revised policy *Registered Radiologist Assistant Inclusion in Practice Parameters* in lieu of the policy originally adopted in 2006 and renewed in 2016 as Resolution 1-c; and

BE IT FURTHER RESOLVED,
that the Council of the American College of Radiology adopt the revised policy *Developing a Process for Updating the Roles and Responsibilities of the Radiologist Assistant* in lieu of the policy originally adopted in 2008 as Resolution 39.

Sponsored by: Council Steering Committee
Fiscal Note

Update to Existing ACR Policies on Radiologist Assistants

To support the resolution, Update to Existing ACR Policies on Radiologist Assistants, the ACR would incur the following estimated costs:

Costs:
- De minimis (< $10,000)
ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities

The American College of Radiology adopted a statement on Radiologist Assistant – Roles and Responsibilities; 2003 (Res. 2).

A Registered Radiologist Assistant (RRA) is an advanced-level radiologic technologist who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the diagnostic imaging environment. The RRA is an ARRT-certified radiographer who has successfully completed an advanced academic program encompassing a nationally recognized RRA curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and assist the radiologist with selected exams, as described below and subject to state law:

- Obtaining consent for and injecting agents that facilitate and/or enable contrast agents administered as part of radiology procedures diagnostic imaging
- Obtaining clinical history from patients or the medical record
- Performing pre-procedure and post-procedure evaluation of patients undergoing invasive procedures
- Assisting radiologists with invasive procedures
- Performing fluoroscopy for non-invasive procedures with the under radiologist providing direct supervision of the service
- Monitoring and tailoring selected exams under radiologist direct supervision [e.g. IVU, CT Urogram, GI studies, VCUG, and retrograde urethograms, and preparation and colonic insufflation for CT Colonography.]
- Communicating the reports of radiologist’s findings to the referring physician or an appropriate representative with appropriate documentation
- Providing naso-enteric and oro-enteric feeding tube placement in uncomplicated patients. Attempt placement of fluoro-guided naso- or oro-enteric feeding tubes in patients whom the supervising radiologist has determined are appropriate for RRA involvement and under radiologist supervision as part of a radiologist-led team.
- Performing selected peripheral venous diagnostic procedures

The RRA will should not perform interpretations (preliminary, final or otherwise) of any radiological examination, nor will he or she transmit his or her observations other than to the supervising radiologist. The RRA may make initial observations of diagnostic images and forward communicate them to the supervising radiologist. The RRA may identify imaging findings or observations and communicate those only to the supervising radiologist (i.e. make ‘observations’). Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond scope of practice and is not the intended role of an RRA. Interpretations are distinguished from observations in that interpretations involve synthesizing imaging findings in the context of clinical histories, physical examination findings, laboratory testing, and/or comparison with prior or other imaging studies in a manner that leads to clinical impressions or conclusions, specific diagnoses, differential diagnoses, and/or medical decision-making.

At the supervising radiologist’s direction, the RRA may communicate the radiologist’s findings and interpretation to the referring physician or an appropriate representative, consistent with the ACR policies on Communication of Diagnostic Imaging Findings

Documentation of any RRA’s observations/findings on a diagnostic imaging examination as required by the institution, statute, or regulatory body, should describe the RRA’s role and clearly state that the RRA
did not interpret the imaging examination (preliminary, final, or otherwise). Documentation of any RRA's participation in a procedure should (1) describe the RRA's role in the procedure, (2) clearly state that the RRA did not perform the procedure independently, and (3) include the name of the supervising radiologist.

The education of the RRA should be granted through nationally recognized accredited academic programs that lead to certification through the ARRT. Advisory committees to such programs should include representation of radiologists.

The RRA should actively participate in a facility quality assurance program.

Any formal national, state, or facility certification and/or credentialing of RRA competency should include the representation of radiologists. Any facility RRA credentialing process should involve radiologists.

The ACR believes that the advent of the RRA working under the supervision of a radiologist and part of a radiologist-led team, with defined responsibilities as described herein, will enhance the performance of radiological procedures and patient care and also provide a professionally satisfying career pathway for radiologic technologists.

The Centers for Medicare and Medicaid Services (CMS) direct supervision requirement states that the "physician is required on site and immediately available."
ee. Registered Radiologist Assistant (RRA) Inclusion in Practice Parameters

The American College of Radiology will insert the following language describing the role of the RRA into the appropriate Practice Parameters of the various radiologic examinations in which an RRA might participate:

Registered Radiologist Assistant (RRA)

An RRA is an advanced level radiographer who is certified and registered as a “Registered Radiologist Assistant” by the American Registry of Radiologic Technologists (ARRT) after successful completion of an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) RRA curriculum and a radiologist-directed clinical preceptorship.

Under radiologist supervision, the RRA 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” subject to state law. The RRA transmits to the supervising radiologist those observations that have a bearing on diagnosis. Performance of diagnostic interpretations (preliminary, final, or otherwise) remains outside the scope of practice of the RRA. 

adopted 2006, 2016 (Res. 1-c).

RRAs performing invasive or non-invasive procedures should function under radiologist supervision and as part of radiologist-led teams.
SECTION II

12. DEVELOPING A PROCESS FOR UPDATING THE ROLES AND RESPONSIBILITIES OF
THE RADIOLOGIST ASSISTANT (RRA)

The American College of Radiology will continue to require that the tasks performed by the RRA are under radiologist supervision and that they should be well-defined and documented; within the criteria and standards defined in the “ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities;” and that the RRA will not independently interpret imaging studies (preliminary, final, or otherwise). The RRA may identify imaging findings or observations and communicate those only to the supervising radiologist. Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond scope of practice and is not the intended role of an RRA. Interpretations are distinguished from observations in that interpretations involve synthesizing imaging findings in the context of clinical histories, physical examination findings, laboratory testing, and/or comparison with prior or other imaging studies in a manner that leads to clinical impressions or conclusions, specific diagnoses, differential diagnoses, and/or medical decision-making.

The ACR will create a process to participate in enabling the expeditious ongoing review of the roles and responsibilities of the RRA and ensure communication of recommendations to the ACR Board of Chancellors and Council Steering Committee. This process will incorporate an expert panel, including a member(s) of the from an ACR Commission such as on Quality and Safety, Human Resources, or equivalent to review and make initial recommendations for any changes in the roles and responsibilities of the RRA over time.

The ACR representatives to the Intersocietal Commission on the Radiologist Assistant (ICRA) will present for review and recommendation to the ACR Council Steering Committee and ACR Board of Chancellors only any changes recommended by the expert panel and agreed to by all members of ICRA. Only approval of the ICRA recommendations by the CSC and BOC will be sufficient to permit implementation of changes in the roles and responsibilities of the RRA; adopted 2008 (Res. 39).