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 care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

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

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

I. INTRODUCTION

Preoperative image-guided localization of breast abnormalities before surgical excision is typically performed for nonpalpable findings. Localization devices guide appropriate excision and provide a surgeon with the best means to ensure successful removal of the target tissue. Preoperative localization with image-guided wire placement remains a reliable and safe method for localization [1]; However, several recent advancements in nonwire localization (NWL) techniques minimize the limitations of wire localization and potentially improve patient care and clinical workflow [2, 3]. New technological approaches and devices are being developed and introduced,

continually expanding the variety of localization tools available.

II. INDICATIONS

Presurgical localization may be performed for patients with selected indications including, but not limited to:

1. Biopsy-proven cancer
2. Biopsy-proven metastatic lymphadenopathy
3. High-risk lesions diagnosed at core-needle 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:

1. Mammography Quality Standards Act Final Regulations [4]
2. ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures [5]
3. ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures [6]
4. ACR Practice Parameter for the Performance of a Diagnostic Breast Ultrasound Examination [7]
5. ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast [8]
6. ACR Practice Parameter for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedures [9]
7. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [10]

IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for a diagnostic breast ultrasound examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

V. SPECIFICATIONS OF THE PROCEDURE

Before localization, the radiologist should review all pertinent imaging examinations, clinical notes, and pathology reports to determine the extent of the target and method of localization, including imaging modality and approach. Review should determine whether biopsy markers, if deployed at the time of prior biopsy, are located in the appropriate position. In patients who have undergone neoadjuvant therapy, the original extent of disease and the visible residual disease are both important to consider. The localization may target a biopsy marker, biopsy site, and/or the spectrum of breast imaging abnormalities: mass, calcifications, asymmetry, architectural distortion, and enhancing findings. If there is known malignancy, it is necessary to understand the extent of malignancy and its location with respect to previously placed biopsy marker(s). More than one guidance device may be used to bracket the extent of disease [11, 12]. 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 [11].

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, modality in which the procedure is to be performed, and physician performing the procedure should be prepared in conformity with the principles of infection control.

V. SPECIFICATIONS OF THE PROCEDURE

A. Localization Techniques

1. Wire Localizations

Preoperative wire localization using mammography, tomosynthesis, sonography, or magnetic resonance imaging (MRI) guidance is optimally performed the day of surgery. The wire may be placed at the breast finding, adjacent to the biopsy marker (if it lies at the site of the lesion), or at the postbiopsy hematoma if the finding 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 finding on the overlying skin with the patient in the supine operative position and measuring the depth of the finding can assist the surgeon during excision.[13][< Limitations of wire localizations include the need for placement on the day of surgery, imprecision that results from variability in positioning by the radiologist, and inadvertent wire displacement (during patient transfer, postprocedure mammography, or surgical positioning) [14]. An important feature for some wire localization devices is the potential opportunity for repositioning or removal and reinsertion with another wire in the event of an improper localization. There are certain wires that have FDA approval for deployment under MRI guidance when necessary [15].

V. SPECIFICATIONS OF THE PROCEDURE

A. Localization Techniques

2. NWL Devices

Alternative forms of preoperative localization that do not use wire and mitigate wire localization limitations are now available and include radioactive seed, radiofrequency reflector, magnetic seed, and radiofrequency identification (RFID), among others [16]. These localization devices lack a component external to the breast after placement (as is present with the wire localization). The absence of an external component in NWL offers increased patient comfort and decreased risk of displacement or transection of the localizing device compared with wires [17]. 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 [18-22]. All forms of NWL typically have two components: a single-use sterilized device preloaded into a needle introducer and a console with a handheld probe for the detection of device deployment by the radiologist and for surgical guidance by the surgeon. The localizing device may be placed at the breast finding, adjacent to the biopsy marker (if it lies at the site of the lesion), or (dependent upon device used) 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), NWL may be subject to imprecise positioning during placement or deployment. An important limitation of NWL is that once deployed, they currently cannot be repositioned.

a. Radioactive seed localization (RSL)
   The radioactive seed placed for localization is currently composed of a titanium capsule containing iodine-125. The radioactive seed is inserted through a needle with sonographic,, mammographic, or tomosynthesis guidance. A handheld gamma probe is used intraoperatively to detect the seed, thus allowing the surgeon to choose the appropriate incision site. Because the iodine-125–labeled seed half-life is sufficiently long (59.4 days), preoperative RSL theoretically can be performed up to several weeks before surgery but is usually performed within a few days before surgery to minimize radiation exposure. Different facilities and vendors may have different maximum length of time a seed can stay inserted, depending on the source strength of their seeds.

   RSL programs require environmental safety processes and adherence to regulations for nuclear materials under the Nuclear Regulatory Commission or under Agreement States. A lost radioactive seed is a reportable medical event, and an established protocol is needed to manage the event. The possibility of a lost seed without the option of using a Geiger-Muller counter in the MRI scan room (Zone IV) generally prohibits direct RSL using MRI guidance. However, a protocol for seed placement in Zone III has been reported [23]. In addition, a migrated radioactive seed in the breast must be recovered [1, 14, 20, 24-27]. A

written directive, signed by an authorized user, may be required for each procedure by regulation. The information on the written directives may include the patient's name, the treatment site, the activity and type of radionuclide, the number of sources implanted, the total source strength, and the exposure time.

b. Radar reflector
Radar localization technology was introduced in 2014. This nonradioactive electromagnetic wave reflector is inserted via a needle under sonographic, mammographic, or tomosynthesis guidance. The reflector is passive until activated with infrared light from a 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/or visual indicators of the probe's proximity to the reflector. The reflector can be placed at any time before surgery. It has been approved by the FDA for long-term placement in the breast, providing the opportunity for placement before the initiation of neoadjuvant therapy. The reflector has little susceptibility artifact on MRI imaging, which is an advantage when compared to other NWL devices. Signal strength is directly related to reflector depth. Reflectors placed greater than 6 cm deep from the skin surface or within a postbiopsy hematoma may not produce a detectable signal to the skin [1, 27-29].

c. Magnetic seed
Magnetic seed localization technology was introduced in 2016. The localization device is currently 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 transiently magnetizes the seed. The seed is inserted via a needle under sonographic, mammographic, or tomosynthesis guidance. Some vendors provide a 14-gauge needle, which may require a skin incision. The console provides audible and visual indications of the probe's proximity to the seed. The seed can be placed any time before surgery. There is no restriction on the length of time the seed can remain in the breast, providing the opportunity for placement before the initiation of neoadjuvant therapy. Following deployment, the patient can have an MRI, albeit with significant artifact, which may limit local staging and extent of disease assessment as well as neoadjuvant tumor response assessment by MRI. Nonmagnetic surgical tools are required 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. Magnetic seeds are most effective placed at a depth of less than 4 cm; however, they can be detected at greater depths when palpation is combined with the handheld probe [1, 27, 30-34].

d. RFID tag
RFID technology was introduced in 2017. The RFID tag currently is made of a copper-wrapped ferrite rod and microprocessor within a glass casing enclosed within a polypropylene sheath to prevent migration [35]. The device absorbs, modifies, and re-emits a 134.2-kHz radiofrequency signal that is sent by the handheld reader device [35]. An integrated loop probe on the device has a 6-cm detection range and the disposable sterile surgical pencil-sized probe has a 3-cm detection range. The RFID tag is inserted via a 12-gauge needle under sonographic or mammographic guidance. Given the larger gauge of the insertion needle , a skin incision may be required. Removal of biopsy clip through the needle at time of localization has been reported [36]. Although RFID tags are approved for placement up to 30 days before surgery, the susceptibility artifact may interfere with determination of the extent of disease and follow-up MRI examinations if placed at the time of core biopsy [37].

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. A radiation detector (eg, a Geiger counter or a gamma probe) can be used to confirm the presence of a radioactive seed that was inserted using ultrasound alone. Confirmation with a radiation detector is usually

possible when more than one seed is placed, although it may not be able to distinguish two seeds close together [26]. 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 localization, communication with the surgeon for challenging cases can be helpful and may take the form of a telephone call, written comments, or annotation of the images.

Additional NWL options have also been described [16, 38, 39].

V. SPECIFICATIONS OF THE PROCEDURE

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 [40, 41]. This should occur while the patient is still in the operating room so that 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 [42]. If the finding contains microcalcifications, either extending from a mass or alone, specimen radiography is better to evaluate the adequacy of excision. When the 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. Assessment for clear margins on specimen radiograph may be improved with the addition of orthogonal or tomosynthesis views, although evidence is mixed [43-46]. Even though the tumor may not appear to extend to the margins of the resected specimen on the specimen radiograph, residual tumor may still be present in the breast. This may be particularly true for noncalcified ductal carcinoma in situ and infiltrating lobular carcinoma [47, 48]. When the radiologist reviews the specimen radiograph, any unexpected findings should be communicated to the surgeon.

V. SPECIFICATIONS OF THE PROCEDURE

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 may be performed [49],potentially sparing the patient from undergoing complete nodal dissection. In this procedure, a pathology-proven metastatic lymph node with biopsy marker may be localized. 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 [50].

Identifying and localizing a biopsy-proven clipped metastatic axillary node with imaging can be technically challenging following neoadjuvant therapy, particularly if the patient has had complete imaging response. Clipped axillary nodes are typically localized with ultrasound guidance, but alternative targeting options include tomosynthesis, mammography, CT, and intraoperative ultrasound [51, 52]. Additionally, there is increasing interest in localizing sampled axillary nodes with NWLs approved for long-term placement by placing the device within a biopsy-proven metastatic axillary node before initiating or early in the course of neoadjuvant therapy in order to facilitate accurate identification and localization for targeted axillary dissection [53, 54].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [55].

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 or axilla
6. Annotation of mammographic view (eg, craniocaudal, mediolateral oblique, 90° mediolateral)
7. Annotation of sonographic image: Anatomic location using clockface notation; a labeled diagram of the breast may be included, distance from the nipple to the lesion in centimeters, and transducer orientation
8. 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 or axilla
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 post-procedure mammogram documenting accurate localizing device placement, location, and number of devices 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. 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.

VII. 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).

VIII. EQUIPMENT

Equipment requirements are outlined in the following practice parameters:

1. ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures [5]
2. ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures [6]
3. ACR Practice Parameter for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedure [9]

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