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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 2013 (Resolution 35)\*

## **ACR–SIR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF IMAGE-GUIDED PERCUTANEOUS NEEDLE BIOPSY (PNB)**

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

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

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

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<sup>1</sup> Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, \_\_\_ N.W.2d \_\_\_ (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

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology.

Image-guided percutaneous needle biopsy (PNB) is an established, effective procedure for selected patients with suspected pathology. Extensive experience documents its safety and efficacy. The patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians [1-3]. This practice parameter outlines the principles for performing PNB.

For information on breast biopsy, see the [ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures](#) or the [ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures](#).

## II. DEFINITION

PNB is defined as percutaneous placement of needles into a suspected abnormal lesion or organ for the purpose of obtaining tissue, cells, or fluid for diagnosis. Following specimen procurement, the needles are removed.

For purposes of this practice parameter, successful image-guided PNB is defined as the procurement of sufficient material to establish a pathologic diagnosis or to guide appropriate patient management. At times nondiagnostic materials may be obtained; at the discretion of the referring clinician and interventional radiologist, repeat biopsy can be considered.

## III. INDICATIONS AND CONTRAINDICATIONS

A. Indications for PNB include, but are not limited to:

1. To establish the benign or malignant nature of a lesion.
2. To obtain material for microbiologic analysis in patients with known or suspected infections.
3. To stage patients with known or suspected malignancy when local spread or distant metastasis is suspected.
4. To determine the nature and extent of certain diffuse parenchymal diseases (e.g., hepatic cirrhosis, renal transplant rejection, glomerulonephritis).
5. To obtain tissue for biomarker, protein, or genotype analysis to subsequently guide therapy.
6. To determine the primary cell of origin in a patient with metastatic disease and an unknown primary tumor.

B. There are no absolute contraindications. However, there are relative contraindications and, as for all patients considered for this procedure, the relative risks of the procedure should be weighed carefully. These relative contraindications should be addressed and corrected or controlled before the procedure, when feasible. The relative contraindications for PNB include:

1. Significant coagulopathy that cannot be adequately corrected.
2. Severely compromised cardiopulmonary function or hemodynamic instability.

3. Lack of a safe pathway to the lesion.
4. Inability of the patient to cooperate with, or to be positioned for, the procedure.
5. Patient refusal of biopsy.

For the pregnant or potentially pregnant patient, see the [ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#).

#### **IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

##### **A. Physician**

Image-based diagnosis and treatment planning require integrating the preprocedural imaging findings within the context of the patient’s history and physical findings. Therefore, the physician must be clinically informed and understand the specific questions to be answered and goals to be accomplished by PNB prior to the procedure in order to plan and perform it safely and effectively.

The physician performing PNB must have knowledge of the benefits, alternatives, and risks of the procedure. The physician must have an understanding of imaging anatomy, imaging equipment, radiation safety considerations, and physiologic monitoring equipment, and have access to adequate supplies and personnel to perform the procedure safely and manage potentially related complications.

PNB procedures must be performed by a physician who has the following qualifications. The physician’s experience in PNB is best documented by use of a formal case log submitted by the applicant.

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of PNB procedures to demonstrate competency as attested by the supervising physician(s).  
or
2. Completion of a residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and has performed (with supervision) a sufficient number of PNB procedures to demonstrate competency as attested by the supervising physician(s).  
or
3. Physicians whose residency or fellowship training did not include the above may still be considered qualified to perform PNB provided that the following can be demonstrated:

The physician must have at least 2 years of image-guided procedural experience during which the physician was supervised, and during which the physician performed and interpreted at least 35 image-guided percutaneous biopsy procedures, 25 of them as primary operator, with outcomes within the quality improvement thresholds of this practice parameter.

and

4. Physicians meeting any of the qualifications in 1, 2, and 3 above also must have written substantiation that they are familiar with all of the following:
  - a. Indications and contraindications for the procedure.
  - b. Preprocedural and intra-procedural assessment, monitoring, and management of the patient and potential complications.
  - c. Where applicable, pharmacology of moderate sedation medications and recognition and treatment of adverse reactions and complications.

- d. Imaging systems that may be used for guidance during percutaneous procedures and determining which imaging modality would be optimal for a specific PNB procedure in terms of both safety and effectiveness.
- e. Where applicable, principles of radiation protection, the hazards of radiation, and radiation monitoring requirements.
- f. Where applicable, pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
- g. Percutaneous needle introduction techniques.
- h. Technical aspects of performing the procedure, including the use of various biopsy devices.
- i. Anatomy, physiology, and pathophysiology of the structures being considered for PNB.

The written substantiation should come from the chief of interventional radiology, the director or chief of body imaging or ultrasound, or the chair of the radiology department of the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional director or chair who solicits the additional input.

#### Maintenance of Competence

Physicians must perform a sufficient number of procedures to maintain their skills, with acceptable success and complication rates as laid out in this practice parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates.

#### Continuing Medical Education

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

#### B. Qualified Medical Physicist

A Qualified Medical Physicist should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging equipment, both upon installation and routinely on an annual basis. Medical physicists assuming these responsibilities should meet the following qualifications:

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The Qualified Medical Physicist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised 2012, Resolution 42)

The appropriate subfield of medical physics for this practice parameter is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

#### C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under

radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” [4] and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

#### D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position<sup>2</sup> the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The technologist should provide assistance to the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. If intravenous contrast material is to be administered, qualifications for technologists performing intravenous injection should be in compliance with current ACR policy statements<sup>3</sup> and existing operating procedures or manuals at the facility. The technologist should also perform regular quality control testing of the equipment under supervision of the physicist.

Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the image-guided percutaneous procedure.

#### E. Diagnostic Medical Sonographer

The sonographer, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The sonographer should be able to prepare and position the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The sonographer should provide assistance to the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. The sonographer should also perform regular quality control testing of the equipment under supervision of the physicist.

Diagnostic medical sonographers involved in PNB should have documented training and experience in assisting with these procedures. When possible, they should be certified by the ARRT or by the American Registry for Diagnostic Medical Sonography (ARDMS). When applicable, they should have an unrestricted state license.

#### F. Computed Tomography Technologist

For biopsies performed using computed tomography (CT), the CT technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The CT technologist should provide assistance to the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. The CT technologist should also perform regular quality control testing of the equipment under supervision of the physicist.

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<sup>2</sup>The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available\*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

\*For the purposes of this parameter, “personally and immediately available” is defined in manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

<sup>3</sup>See the [ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media](#).

CT technologists should be certified by the ARRT or have an unrestricted state license with documented training and experience in CT.

#### G. Other Ancillary Personnel

Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform specific interventional fluoroscopic or other image-guided procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state, and federal regulations. Individuals should be credentialed for specific fluoroscopic and other image-guided interventional procedures and should have received formal training in radiation management and/or application of other imaging modalities as appropriate.

#### H. Nursing Services

Nursing services, when deemed appropriate by the performing physician, are an integral part of the team for preprocedural, intraprocedural, and postprocedural patient management and education and are recommended in monitoring the patient during the procedure.

#### I. Nonphysician Practitioner

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team but should not perform PNBs independent of supervision by physicians with training, experience and privileges to perform the relevant procedures. See the [ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management](#).

### V. SPECIFICATIONS AND PERFORMANCE OF THE PROCEDURE

#### A. Imaging Equipment and Facilities

1. The minimum requirements for facilities in which PNB is performed include:
  - a. When fluoroscopic guidance is used, a high-resolution unit with adequate shielding and collimation is desirable. Ability to perform complex angle (e.g., anteroposterior, lateral, or oblique) fluoroscopy views is often necessary to ensure proper needle placement. Overhead fluoroscopic tube suites are less desirable because of increased radiation exposure to personnel during this procedure.
  - b. When appropriate, availability of ultrasound is desirable. Proper transducer frequency is required to direct and monitor needle placement.
  - c. At times, CT and/or CT fluoroscopy equipment may be necessary to better demonstrate anatomy, particularly in:
    - i. Patients with lesions that are difficult to visualize or access with other modalities, or are in unusual or precarious locations.
    - ii. Planning the optimal route of biopsy to avoid, when possible, transgression of vital structures.
    - iii. Patients with unusual anatomy.
  - d. The facility should provide an area within the institution appropriate for patient preparation and for observation after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit as outlined in the Patient Care Section below. There should be immediate access to emergency resuscitation equipment. Personnel and equipment to diagnose and treat acute complications should also be available.
  - e. For patients undergoing thoracic procedures, appropriate equipment for decompression of a tension pneumothorax should be available.
  - f. Access to laboratory facilities with expertise in cytopathology, microbiology, and chemistry should be available. (These resources need not be located in the biopsy facility.)

## 2. Performance guidelines

When using fluoroscopy for PNB, a facility should meet or exceed the following imaging practices:

- a. Fluoroscopic times for both X-ray and CT guidance should be kept to a minimum. The operator will use only as much fluoroscopy as is necessary to complete the biopsy, consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines. One method to minimize fluoroscopic time is to use units with “last image hold” capability [5].
- b. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal, eye) should be used for the operating radiologist, for the patient, and for any other personnel who might be affected.
- c. On units where dose reduction pulsed fluoroscopy is available, its use is recommended.
- d. For CT guided biopsies, lowering the mAs and/or increasing slice thickness can substantially reduce radiation dose without compromising the procedure.

### B. Physiologic Monitoring and Resuscitation Equipment

1. Appropriate equipment should be present to allow for monitoring the patient’s heart rate, cardiac rhythm, and blood pressure. For facilities using moderate sedation, a pulse oximeter should be available. (See the [ACR–SIR Practice Parameter for Sedation/Analgesia.](#))
2. There should be ready access to emergency resuscitation equipment and drugs, to include the following: a defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-valve-mask apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular dysrhythmias should also be readily available. Resuscitation equipment should be monitored and checked on a routine basis in compliance with institutional policies.
3. Any procedure performed using MRI guidance must have MRI safety compatible emergency resuscitation equipment available.
4. Appropriate emergency equipment and medications must be immediately available to treat procedural complications or adverse reactions associated with administered medications. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and/or sizes in the patient population.

### C. Acute Care Support

Although complications of PNB only rarely require urgent surgery, some of these procedures should be performed in an environment where surgical intervention can be instituted promptly. Ideally, this would be a facility with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding center, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

### D. Patient Care

The requested examination should be specific to body site and side, if appropriate.

#### 1. Preprocedural care

- a. The physician performing the procedure must have knowledge of the following:
  - i. Clinically significant history, including indications for the procedure and any related preprocedure imaging.

- ii. Clinically significant physical examination findings, including an awareness of clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics or other measures.
- iii. Possible alternative methods, such as other imaging modalities, serologic analysis, or surgery, to obtain the desired diagnostic information or therapeutic result.
- b. Informed consent must be in compliance with all state laws and should comply with the [ACR–SIR Practice Parameter on Informed Consent for Image-Guided Procedures](#).

## 2. Procedural care

- a. Adherence to the Joint Commission’s current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings, including bedside procedures.  
The organization should have processes and systems in place for reconciling differences in staff responses during the “time out.”
- b. During the use of fluoroscopy, the physician should use exposure factors consistent with the ALARA radiation safety guidelines.
- c. Nursing personnel, technologists, and those directly involved in the patient’s care during PNB should have protocols for use in standardizing care. These should include, but are not limited to:
  - i. Equipment needed for the procedure and its commonly related complications.
  - ii. Patient monitoring.
- d. Protocols should be reviewed and updated periodically.

## 3. Postprocedural care

- a. Orders for postprocedure patient care should include frequency of obtaining vital signs and discharge instructions. Discharge instructions should include contact information about an appropriate resource that the patient or his or her representative can call to ask questions or express concerns about the development of complications or other issues.
- b. Specific anatomic considerations
  - i. Thoracic cavity: pulmonary and appropriate imaging assessment for the presence of pneumothorax.
  - ii. Peritoneal and other solid organ biopsies: appropriate imaging and/or laboratory studies to evaluate for acute complications when indicated.

## E. Specifics of the Procedure

1. All image-guided PNB procedures are performed for specific indications, and they should be tailored accordingly.
2. The physician should be aware of the various types of aspiration and core cutting needles that are available.
3. The physician should be aware of the diagnostic possibilities and request the appropriate laboratory studies.
4. Prior consultation with pathology may be useful in selected cases.
5. The postinterventional procedure note should include the names of the operator and assistant, specifics about the procedure, complications if any, medication or drugs used, condition of the patient, and disposition. Notification of the referring physician is highly recommended if significant complications occurred.

## VI. DOCUMENTATION

Reporting should be in accordance with the [ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#).

## VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)

[http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578\\_web-57265295.pdf](http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf)

Nationally developed guidelines, such as the ACR’s [Appropriateness Criteria](#)<sup>®</sup>, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently<sup>®</sup> for children ([www.imagegently.org](http://www.imagegently.org)) and Image Wisely<sup>®</sup> for adults ([www.imagewisely.org](http://www.imagewisely.org)) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

## 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 *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>).

Equipment performance monitoring should be in accordance with the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiological and Fluoroscopic Equipment](#).

## IX. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these practice parameters, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure (e.g., major complications). Individual complications may also be associated with complication-specific thresholds.

When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a departmental review should be performed to determine causes and to implement changes, if necessary. For example, if the incidence of bleeding is one measure of the quality of image-guided PNB, then values in excess of the defined threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Each department is urged to alter the threshold to higher or lower values as needed to meet its own quality improvement program needs.

#### A. Success Rates and Thresholds

Many variables will affect the eventual success of a PNB procedure. These include the number of samples obtained, the size of the target abnormality, the organ system in which biopsy is performed, the availability of an on-site cytopathologist [6], the experience of the institution's pathology staff, the imaging equipment available, and the skill of the operating physician.

Table 1 lists the success rates and suggested thresholds for PNB.

<b>Table 1 Success Rates of PNB [7-29]</b>			
<b>PNB Site</b>	<b>Reported Range of Success (%)</b>	<b>Pooled Mean Success (%)</b>	<b>Suggested QI Threshold (%)</b>
Thoracic/pulmonary [7-15]	77-96	89	75
Musculoskeletal [16-23]	76-93	82	70
Other Sites [24-29]	70-90	89	75
Overall	70-90	85	75
Note: – QI = quality improvement.			

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

The range of successful biopsies may vary depending on the mix of organ systems, the size and location of lesions, and the overall condition of patients who are sampled. A nondiagnostic specimen means is one in which the tissue sample is inadequate for pathologic determination of whether the specimen is benign, malignant, or representative of the organ being biopsied.

#### B. Complication Rates and Thresholds

Complications can be stratified on the basis of outcome. Major complications result in admission to the hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (see Appendix A). The complication rates and thresholds presented refer to major complications, unless otherwise noted. Indicator thresholds may be used to assess the efficacy of quality improvement programs.

The complications of percutaneous biopsies are divided into 2 types: generic and organ-specific. Generic refers to complications that are common to all biopsies. The major generic complications include bleeding, infection, perforation, and unintended organ or nerve injury [31]. Clinically significant bleeding is infrequent, although relative bleeding risks increase with increasing needle size, use of cutting needles, and vascularity of the organ or lesion biopsied (i.e., renal and liver biopsies, hypervascular lesions) [8,32]. Infection as a result of biopsy is also rare. Injury may occur to the target organ or to a nearby organ that is traversed by the needle. Injuries of this type require further interventions in fewer than 2% of patients [33-35]. How a given complication is managed

clinically is a major predictor of the clinical outcome of a given patient and should be included in the oversight of complications of percutaneous biopsies.

Organ-specific complications are those that are only associated or most commonly associated with biopsy of a specific organ. For example, pneumothorax is most commonly associated with lung biopsy but can occur during vertebral, rib, liver, spleen, adrenal, kidney, and breast biopsies or aspirations. Other complications may occur, but rarely require therapy. These include hematuria after renal or prostate biopsy and hemoptysis after lung biopsy. Perforation may be considered organ-specific.

The following table (Table 2) lists the reported rates of given complications and suggested thresholds that should prompt a review when exceeded. In addition, there are certain complications that are almost always associated with a single organ [36]. Very rare complications, such as hypertensive crisis after adrenal biopsy, pancreatitis, and tumor seeding of the needle tract [37,38] are not given thresholds. Each major incident should be investigated as appropriate.

<b>Major Complication</b>	<b>Complication Rates (%)</b>	<b>Suggested QI Threshold (%)</b>
Bleeding requiring transfusion or intervention		
Solid organ*		
Kidney [39,41-55]		
Large caliber needle (>18 gauge)	2.7-6.6	10
Small caliber needle (≤18 gauge)	0.5-2.8	5
Liver [36,45,56-64]	0.3-3.3	5
Spleen [65-69]	0-8.3	10
Other [28,34]	0.1-3	6
Tract seeding [34,38,40,70-78]†	0.3.4	5
Pneumothorax requiring chest tube for Nonpulmonary/mediastinal biopsy	0.5	1
Note: - QI = quality improvement. *Data based on studies involving at least 200 patients. †Most of the literature is related to needle tract seeding after percutaneous biopsy of hepatocellular carcinoma. Data based on studies involving at least 100 patients.		

**From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].**

Lung and pleural biopsy: There are special considerations for classifying major versus minor complications requiring chest tube management after lung biopsy resulting in the development of a pneumothorax. Special note is also made that there are lung biopsies during which planned placement of a chest tube is accepted for the successful completion of the procedure. Placement of a chest tube in these settings therefore should not be considered a complication. [9,35,79-86]

**Table 3**  
**Complication Rates and Suggested Thresholds for Transthoracic PNB**  
**[8,9,79-81,83,87-97]**

<b>Complication</b>	<b>Complication Rate (%)</b>	<b>Suggested QI Threshold (%)*</b>
<b>Major</b>		
Hemoptysis requiring hospitalization or specific therapy transthoracic biopsy [80,81]	0.5	2
Thoracostomy tube placement requiring prolonged admission, catheter exchange, or pleurodesis [87,88]	1-2	3
<b>Complication</b>	<b>Complication Rate (%)</b>	<b>Suggested QI Threshold (%)*</b>
<b>Major</b>		
Air embolism [81,89]	0.06-0.07	<0.1
<b>Minor</b>		
Pneumothorax [8,9,79,83,90-97]	12-45	45
Thoracostomy tube placement [8,9,79,87,90-97]	2-15	20
Note – QI = quality improvement *Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Exceeding a suggested QI threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication.		

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a larger volume than most individual practitioners are likely to treat. Generally the complication-specific thresholds should be set higher than the complication-specific reported rates listed above. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient series (e.g., early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program.

In Table 4 below, the suggested threshold value is supported by the weight of literature evidence and panel consensus.

<b>Table 4</b> <b>Overall Complication Threshold</b>	
<b>Overall Procedure</b>	<b>Suggested QI Threshold (%)*</b>
All major complications resulting from image-guided PNB*	2
*The threshold for overall major complications should be used when the individual practice performs a broad spectrum of biopsies and no particular biopsy site or type dominates the experience. This threshold is based on the premise that uncomplicated thoracostomy tube placement for management of pneumothorax is considered a minor complication.	

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

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## Appendix A

### Society of Interventional Radiology Standards of Practice Committee Classification of Complications by Outcome

#### Minor Complications

- A. No therapy, no consequence.
- B. Nominal therapy, no consequence; includes overnight admission for observation only.

#### Major Complications

- C. Require therapy, minor hospitalization (<48 hours).
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
- E. Permanent adverse sequelae.
- F. Death.

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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.

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