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

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

2020 (CSC/BOC)

ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF STEREOTACTIC / TOMOSYNTHESIS-GUIDED BREAST BIOPSY SYSTEMS

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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, 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 the practice parameters 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 the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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 these practice parameters 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 these practice parameters is to assist practitioners in achieving this objective.

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

I. INTRODUCTION

This technical standard was developed collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

The proposed technical standard is aimed at providing guidance for the diagnostic medical physics performance monitoring of stereotactic/tomosynthesis-guided systems. For screen-film or computed radiography (CR) systems, please see the current [Stereotactic Breast Biopsy Quality Control Manual](#).

The performance of all stereotactic/tomosynthesis-guided system units should be evaluated upon installation and at least annually to ensure proper function and optimal image quality. Additional or more frequent performance monitoring may be necessary in certain situations (eg, after major equipment repairs or upgrades). Although it is not possible to consider all possible variations of equipment to be monitored, the goal is to establish performance monitoring standards to promote the production of high-quality breast images consistent with the clinical use of stereotactic/tomosynthesis-guided system equipment and the clinical objectives of procedures.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist must carry out acceptance testing and performance evaluation of breast biopsy guidance systems.

A Qualified Medical Physicist is an individual who is competent to practice independently 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).

A Qualified Medical Physicist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [1]. (ACR Resolution 16g adopted in 2006 – revised in 2012, Resolution 42)

The appropriate subfield of medical physics for this standard is Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, or Diagnostic Imaging Physics).

Initial qualifications, as well as continuing experience and education for the Qualified Medical Physicist, is provided in the current document “Stereotactic Breast Biopsy Accreditation Program Requirements,” which can be found at <https://www.acraccreditation.org/modalities/stereotactic-breast-biopsy>.

The Qualified Medical Physicist must be familiar with:

1. Principles of imaging physics and radiation protection
2. Regulations pertaining to the performance of the equipment being monitored
3. The function, clinical uses, and performance specifications of the stereotactic breast biopsy equipment
4. Calibration processes and limitations of the performance testing hardware, procedures, and algorithms

These proficiencies should be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

The Qualified Medical Physicist’s monitoring of performance characteristics must comply with appropriate federal, state, and local regulations. The 2018 ACR Digital Mammography Quality Control Manual may be used as a guide in performing many of the tests outlined below [2]. If an add-on biopsy device is used on a 2-D or digital breast tomosynthesis (DBT) full-field digital mammography system, the 2-D or DBT results obtained following the 2018

ACR Digital Mammography QC Manual or the manufacturer's QC manual may be used to fulfill applicable tests in the sections below.

A. Acceptance Testing

A Qualified Medical Physicist must conduct initial stereotactic/tomosynthesis-guided system equipment performance evaluation upon installation of the equipment and after major upgrades. This evaluation should be more comprehensive than periodic evaluation and should be completed before clinical use.

Prior to the initial equipment performance evaluation, electrical safety and digital image communication must be verified by appropriate personnel.

Acceptance tests must include tests performed during the annual performance evaluation and, additionally, should include the following items in both conventional and tomosynthesis modes if applicable:

1. Compliance with applicable local and federal regulatory requirements
2. Compliance with all terms and line items of the purchase agreement or contract (*if the documentation is available to the Qualified Medical Physicist*)
3. Compliance with manufacturer's relevant imaging and safety performance specifications
4. Evaluation of radiation shielding
5. Verify that manufacturer calibrations have been completed
6. Compression thickness indicator accuracy evaluation
7. Evaluation of compression force
8. Tube potential (kVp) accuracy and reproducibility measurements
9. Beam quality assessment (eg, half-value layer measurement)
10. Collimation assessment
11. Ghost image evaluation (*optional*)

The evaluation of the technologist quality control (QC) program is not required during acceptance testing.

B. Performance Evaluation

1. The performance of each stereotactic/tomosynthesis-guided system must be evaluated at least annually. At a minimum, this evaluation should include the following items in both conventional and tomosynthesis modes if applicable:
 - a. Stereotactic/tomosynthesis-guided system unit assembly assessment (ie, unit checklist)
 - b. Image quality and artifact evaluation
 - c. Assessment of receptor uniformity
 - d. Spatial resolution assessment
 - e. Automatic exposure control (AEC) system
 - f. Average glandular dose measurement
 - g. Verification of localization accuracy
 - h. Acquisition workstation monitor performance assessment
 - i. Evaluation of site's technologist quality control (QC) program
 - j. Verify that there are policies in place for the quality, safety, infection control, and patient education programs
 - k. Additionally, for breast biopsy equipment with tomosynthesis capabilities, the performance evaluation should include tomosynthesis volume coverage.
2. Monitoring required after replacement or repair of a major component

If a major component is replaced or repaired, a Qualified Medical Physicist should evaluate the need for performance testing of the stereotactic breast biopsy system. The scope and timeline of the evaluation

should be determined by the Qualified Medical Physicist based on the type of component that was replaced or repaired.

C. QC Program

A continuous QC program must be implemented for all stereotactic breast biopsy systems with the assistance of a Qualified Medical Physicist. The Qualified Medical Physicist should determine the test frequency and tolerances (in conjunction with manufacturer specifications). At minimum, the QC program should include the following:

1. Verification of localization accuracy
2. Image quality and artifact evaluation
3. Completion of the visual checklist (see Appendix)
4. Compression thickness indicator accuracy evaluation
5. Verification of compression force
6. Acquisition workstation monitor performance assessment
7. Zero alignment test (*if required by manufacturer*)
8. Additional manufacturer-required tests and calibrations (*if applicable*)
9. Analysis of rejects and repeats (*optional*)
10. Receiving radiologist feedback regarding image quality (*optional*)

The results of the QC program must be monitored at least annually by the Qualified Medical Physicist. If any monitored QC parameter falls outside of the control limits, corrective action should be taken. A Qualified Medical Physicist should be consulted regarding corrective actions for unresolved problems. The Qualified Medical Physicist should establish a time-frame for implementation of corrective actions.

D. Written Survey Reports and Follow-Up Procedures

The Qualified Medical Physicist must provide a written report of the findings of acceptance testing and a performance evaluation to the professional(s) in charge of obtaining or providing necessary service to the equipment and, if appropriate, to the responsible physician(s). Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

If appropriate, the Qualified Medical Physicist should notify the facility to initiate the required service. The facility must complete corrective actions in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports from competent service personnel as verification that the issue(s) were appropriately resolved. The reports may be reviewed by a Qualified Medical Physicist to confirm that the equipment is performing in a safe and acceptable fashion after the required service is performed or as required by federal, state, or local regulations.

If use of the equipment would pose a danger to life or health or potentially result in erroneous clinical findings, the Qualified Medical Physicist in collaboration with the facility's Radiation Safety Officer and interpreting physician must take immediate action to either prevent equipment use or to indicate in writing what limited studies can be performed safely using the equipment until the hazard is addressed.

IV. 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.

Nationally developed guidelines, such as the ACR's [Appropriateness Criteria](#)[®], 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[®] for children (www.imagegently.org) and Image Wisely[®] for adults (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)

A documented quality control program with procedure manuals, records, and intervention results in either soft or hard copy should be maintained for stereotactic-guided breast interventions [3]. The Qualified Medical Physicist should review these records at least annually.

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Collaborative Committee – members represent their societies in the initial and final revision of this technical standard

ACR

William R. Geiser, MS, Chair
Samuel A. Einstein, PhD
Tyler S. Fisher, MS
Phoebe Freer, MD
Mary Ellen Jafari, MS

AAPM

Aaron Fenster, PhD
Katie W. Hulme, MS
Ingrid S. Reiser, PhD
Raja Subramaniam, PhD

Committee on Practice Parameters and Technical Standards – Medical Physics
(ACR Committee responsible for sponsoring the draft through the process)

Maxwell R. Amurao, PhD, MBA, Chair
Mary Ann Keenan, DMP, Vice Chair
Priscilla F. Butler, MS, FACR
Heidi A. Edmonson, PhD
Samuel A. Einstein, PhD
Per H. Halvorsen, MS, FACR

Ralph P. Lieto, MS, FACR
Lijun Ma, PhD, FAAPM
Tariq A. Mian, PhD, FACR
Anshuman Panda, PhD
Douglas E. Pfeiffer, MS, FACR
Premavathy Rassiah, PhD

Committee on Practice Parameters and Technical Standards – Medical Physics
(ACR Committee responsible for sponsoring the draft through the process)

Loretta M. Johnson, PhD

Thomas G. Ruckdeschel, MS

Mahadevappa Mahesh, MS, PhD, FACR, Chair, Commission on Medical Physics
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Ralph P. Lieto, MS, FACR, Chair

Lauren Golding, MD

Maxwell R. Amurao, PhD, MBA

Jacqueline Anne Bello, MD, FACR

Eric A. Berns, PhD, FACR

Caridad Borrás, DSc, FACR

Priscilla F. Butler, MS, FACR

Richard Duszak Jr., MD, FACR

Samuel A. Einstein, PhD

Aaron Fenster, PhD

Tyler S. Fisher, MS

Phoebe Freer, MD

William R. Geiser, MS

Kathie W. Hulme, MS

Mitchell M. Goodsitt, PHD

Mary Ellen Jafari, MS

Mary Ann Keenan, DMP

Amy L. Kotsenas, MD, FACR

Stephanie M. Leon, PhD

Mahadevappa Mahesh, MS, PhD, FACR

Mary S. Newell, MD, FACR

Douglas E. Pfeiffer, MS, FACR

Vincent Plagnol, MS

Ingrid S. Reiser, PhD

Raja Subramaniam, PhD

Roland Wong, ScM

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2. Berns EA, Pfeiffer DE, Butler PF, et al. *Digital Mammography Quality Control Manual*. Reston, VA: American College of Radiology; 2018.
3. American College of Radiology. ACR practice parameter for the performance of stereotactic-guided breast interventional procedures. 2016.

APPENDIX A

VISUAL CHECKLIST

The visual checklist may include the following items:

1. X-ray tube locks and detents working properly?
2. Is the table immobilized when the patient is in compression?
3. Is there adequate lighting?
4. Do all moving parts move smoothly?
5. Do all foot switches operate properly?
6. Is the biopsy device properly immobilized to prevent recoil?
7. Are the needle guides free from excessive wobble?
8. Are all paddles free from cracks, sharp edges, and other hazards?
9. Is the operator shielded from radiation during the procedure?
10. Is the patient visible to the operator during the procedure?
11. Are technique charts posted?
12. Are cleaning supplies and disinfectants available and used after every patient?
13. Has all blood been cleaned from the equipment?
14. Other tests as recommended by the manufacturer

*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.

As of May 2015, all practice parameters and technical standards that are collaborative with *only* the American Association Physics in Medicine are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 54, 2015). The effective date is displayed below

Development Chronology for this Technical Standard

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