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 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

This technical standard was developed collaboratively by individuals with recognized expertise in medical physics, representing the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

This technical standard provides guidance for the diagnostic medical physics performance monitoring of

stereotactic/tomosynthesis-guided breast biopsy systems.

The performance of all stereotactic/tomosynthesis-guided breast biopsy systems must 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 breast biopsy equipment and the clinical objectives of procedures.

II. QUALITY MANAGEMENT

Quality Management (QM) is, "an overall management system that includes establishing quality policies and quality objectives, and processes to achieve quality objectives through quality planning, quality assurance (QA), quality control (QC), and quality improvement." [1]

II. QUALITY MANAGEMENT

A. Quality Management Team

The quality management team is composed of individuals who are responsible for, and involved with, the technical aspects of clinical use of stereotactic/tomosynthesis-guided breast biopsy systems. In general, the supervising physician is responsible for the overall quality and safety of the clinical use of stereotactic/tomosynthesis-guided breast biopsy systems. The Qualified Medical Physicist has responsibility and oversight for equipment testing protocols, methods, and criteria for action. As such, the quality management team should be led or overseen by the supervising physician with support from the Qualified Medical Physicist on equipment issues. The quality management team should also include at least 1 technologist who routinely operates the stereotactic/tomosynthesis-guided breast biopsy system. Although different types of physicians (eg, radiologists and/or surgeons) may be involved in stereotactic/tomosynthesis-guided breast biopsy procedures, the participation of all physicians on a quality management team is likely unnecessary. At least 1 physician should participate on the quality management team so they may provide physician and end-user input to quality management processes.

The quality management team should be in communication at regular intervals (eg, quarterly, semiannually, or annually) to review issues, discuss upcoming activities, and perform general review of past QA and QC results. In addition, such correspondence provides an opportunity to discuss any necessary updates to the quality management components discussed later in this section.

The quality management team should be the group responsible for providing critical input on purchasing decisions for new or replacement equipment and the associated accessory hardware and software. A consistent quality management approach to hardware and software simplifies the requirements associated with the ongoing QA and QC measures.

II. QUALITY MANAGEMENT

B. Service Records

Equipment and relevant software calibrations should be performed as defined by the equipment manufacturer. Some manufacturers require calibrations to be performed by technologists or other clinical personnel, while other manufacturers describe calibrations as part of routine or corrective service. Similarly, some technical configurations may be required to be done by service engineers, especially at installation, while other configurations may be appropriately adjusted by technologists or medical physicists. For all equipment and relevant software, regular preventive maintenance and corrective service should be performed, documented, and records retained by a service engineer, following the maintenance schedule recommended by the manufacturer. Copies of all service records, including corrective actions, must be shared with, and retained by, the clinic providing patient care. The quality management team should, at minimum, have access to these records, and if sensible in the context of facility culture and operational practices, it may be best for the quality management team to keep and manage these records.

II. QUALITY MANAGEMENT

C. Records of Devices and Tools

Quality management of imaging and biopsy equipment requires accurate and complete installation records of the equipment. At a minimum, the quality management team should establish an asset management methodology to track location, manufacturer, model, date of manufacture, and unique identifier of all devices in their purview. The asset management system should serve as either the repository for, or link to, the permanent storage for quality performance records and reports.

In addition to the stereotactic/tomosynthesis-guided breast biopsy system itself, the quality management team should maintain accurate records of the tools used to perform QC tests. These records should include tool description or type, manufacturer, model, date of manufacture, and unique identifier. The calibration, calibration schedule, and/or intercomparison history and schedule of the applicable tools should be kept with these records to ensure regulatory and policy compliance.

The quality management team should include a review of the asset management system as part of its regular meetings. Individual members of the team should be assigned specific data points of interest to oversee. The more detailed and automated the asset management system, the easier the delineation of the data for the quality management team members.

II. QUALITY MANAGEMENT

D. Policies

Effective quality management requires a comprehensive set of policies and guidelines to address all aspects of breast biopsy system performance. This subsection lists those aspects that should be included in such documentation.

1. Equipment calibration targets
2. Expectations for installation or configurations
3. Summary of QA and QC frequencies
4. Reporting of QA and QC results
5. Review of applicable regulatory and accreditation requirements
6. Requirements for postservice
7. Personnel roles
8. User/operator responsibilities
9. Reporting structure for issues

III. QUALITY ASSURANCE

Quality assurance is,"a component of QM focused on providing confidence that quality requirements will be fulfilled; it includes all activities (planned, systematic, and practice-based activities) that demonstrate the level of quality achieved by the output of a process." [1]

A. Periodic Review of Settings/Protocols/Clinical Outputs

The Qualified Medical Physicist should review the routine QC results at least annually and report any findings or recommendations to the quality management team.

B. Calibration of Measurement Devices/Tools

Measurement devices should be regularly calibrated or cross-referenced with calibrated devices to ensure the quality of their readings. All measurement devices/tools must meet applicable regulatory requirements.

IV. QUALITY CONTROL

Quality Control is,"a component of QM focused on the fulfillment of quality requirements; it includes activities that impose specific quality on a process; and entails the evaluation of actual operating performance characteristics of a device or system, comparing it to desired goals, and acting on the difference; QC works on the input to a process to ensure that important elements or parameters specific to the process are correct." [1]

The Qualified Medical Physicist's monitoring of performance characteristics must comply with applicable federal, state, and local regulations. Equipment performance must be evaluated upon installation and monitored at least annually by a Qualified Medical Physicist to ensure proper functioning within the defined performance standards. Additional or more frequent performance monitoring may be necessary in certain situations (eg, after major equipment repairs). Although it is not possible to consider all variations of equipment performance to be monitored, adherence to this technical standard will help to optimize image quality and ensure the quality of equipment performance in clinical procedures. Key points to consider are performance characteristics to be monitored, estimated patient radiation dose, qualifications of personnel, and follow-up procedures.

A documented QC program with procedure manuals, records, and intervention results in either soft or hard copy should be maintained. The Qualified Medical Physicist should review these records at least annually.

The 1999 ACR Stereotactic Breast Biopsy Quality Control Manual and the 2018 ACR Digital Mammography Quality Control Manual may be used as guides in performing many of the tests outlined below [2, 3]. 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. If the stereotactic/tomosynthesis-guided breast biopsy system has contrast enhancement capabilities, facilities should follow manufacturer QC procedures for contrast enhancement applications.

The QC activities described in this section are broadly separated into three categories: acceptance testing and/or commissioning, annual equipment performance evaluation, and continuous QC.

IV. QUALITY CONTROL

A. Acceptance Testing

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

Before the initial equipment performance evaluation, electrical safety and interoperability (eg, DICOM transfer) must be verified by appropriate personnel.

Acceptance testing and/or commissioning must include tests performed during the annual equipment performance evaluation and, additionally, should include the following items:

1. Collimation assessment
2. Evaluation of compression thickness indicator accuracy
3. Evaluation of compression force
4. Tube potential (Kilovoltage peak) accuracy and reproducibility measurements
5. Beam quality assessment (eg, half-value layer measurement)
6. Ghost image evaluation *(optional)*

The evaluation of the technologist QC program is not required during acceptance testing but should be reviewed once QC has been performed and within 30 days of the first biopsy procedure.

Additional items that should be verified during the commissioning of new biopsy systems include:

1. Compliance with applicable local, state, 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. Radiation shielding, if structural shielding was recommended by the Qualified Medical Physicist
5. Completion of manufacturer calibrations and configurations

IV. QUALITY CONTROL

B. Annual Equipment Performance Evaluation

1. The performance of each stereotactic/tomosynthesis-guided breast biopsy system must be evaluated at least annually. At a minimum, this evaluation should include the following items and be performed in both stereotactic and tomosynthesis modes if applicable:

    i. Phantom image quality
    ii. Artifact evaluation
    iii. Spatial resolution assessment
    iv. DBT volume coverage (for equipment with tomosynthesis capabilities)
    v. Automatic exposure control system performance
    vi. Average glandular dose measurement
    vii. Stereotactic/tomosynthesis-guided system unit assembly assessment (ie, unit checklist)
    viii. Verification of localization accuracy
    ix. Acquisition workstation monitor performance assessment
    x. Evaluation of site's technologist QC program
    xi. Manufacturer's calibrations (if applicable)

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/tomosynthesis-guided 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, and shall adhere to applicable local, state, and federal regulatory requirements.

IV. QUALITY CONTROL

C. Continuous Quality Control

A continuous QC program must be implemented for all stereotactic/tomosynthesis-guided 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
4. Compression thickness indicator accuracy evaluation
5. Verification of compression force
6. Acquisition workstation monitor performance assessment
7. Manufacturer calibrations (*if applicable*)
8. Facility QC Review
9. Analysis of rejects and repeats (*optional*)
10. Receiving radiologist feedback regarding image quality (*optional*)

The results of the QC program must be reviewed at least annually by the Qualified Medical Physicist. If any 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 timeframe for implementation of corrective actions.

IV. QUALITY CONTROL

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 supervising 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.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist must carry out acceptance testing and performance evaluation of stereotactic/tomosynthesis-guided breast biopsy 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 (CCPM), the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [4].

The appropriate subfield of medical physics for this standard is Diagnostic Medical Physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

A. Qualified Medical Physicist

The Qualified Medical Physicist is responsible for the test protocols, test methods, and acceptability criteria. The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining data in accordance with applicable regulations and relevant guidance (eg, AAPM medical physics practice guideline 7.a [5]). Medical physics students, medical physics residents, and medical physicists-in-training may assist the Qualified Medical Physicist based on their training and at the discretion of the Qualified Medical Physicist [6]. These individuals must be properly trained and approved by the Qualified Medical Physicist such that they have knowledge about the techniques of performing tests, functions, and limitations of the equipment and test instruments, reasons for the tests, and the importance of the test results. The assisting individual shall be under the general supervision [7] of the Qualified Medical Physicist during all surveys. The Qualified Medical Physicist is responsible for all surveys and must review, interpret, and approve all data as well as provide a signed report with conclusions and recommendations [7].

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/tomosynthesis-guided 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.

B. Physician

For Physician qualifications related to stereotactic/tomosynthesis-guided breast biopsy systems, see the ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures [8].

C. Radiologic Technologist

For Technologist qualifications related to stereotactic/tomosynthesis-guided breast biopsy systems, see the ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures [8].

D. Service Engineer

Service Engineers who are involved with changes and/or upgrades to hardware or software that impacts the breast biopsy system should ensure that the Qualified Medical Physicist is notified of said changes before the initiation of changes and as soon as possible after completion.

VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers**,** 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 who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the ACR's Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). 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 periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, 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; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INEFCTION 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).

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*Practice parameters and technical standards that are collaborative with only radiation oncology societies (ACR Resolution 8, 2010) or are collaborative with the American Association of Physics in Medicine (ACR Resolution 54, 2015) are approved by the ACR Council Steering Committee (CSC) and the ACR Board of Chancellors (BOC) and will not go through the ACR Council. The effective date for these CSC/BOC documents is the first day of the month following a 60-day period that begins on the date the document was approved.

<u>Development Chronology for this Technical Standard</u>

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