ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF REAL TIME ULTRASOUND EQUIPMENT

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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

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

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 revised collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Ultrasound imaging is a useful and safe method for diagnostic imaging. The use of diagnostic ultrasound imaging is widespread throughout the hospital and outpatient environments. Studies have shown that degradation of the transducer and its components can have an adverse effect on image quality and measurement information [1].

Ensuring continued efficacy of this modality requires focused attention toward ensuring high-quality information. The goal of this document is to establish a technical standard that will safeguard the production of diagnostic information of consistent quality. Quality should be consistent with the capabilities and clinical use of the equipment. This document will outline—and in some cases specify—tasks, tests, and evaluations that should be performed to ensure this intended outcome. Furthermore, this document will provide recommendations for appropriate individual(s) to perform the testing. Although it is not possible to consider all possible variations of equipment performance to be monitored, adherence to this technical standard will maximize image quality, system performance, and safety. This document will not address the operational performance, skills, or qualifications of the individual(s) performing the patient clinical examinations as it pertains to quality images. Additional documents on Practice Parameters and Technical Standards are available on the ACR website.

The scope of this technical standard is limited to ultrasonic systems used for diagnostic imaging and therapeutic guidance, including those with Doppler and elastography capabilities. Therapeutic ultrasound systems (such as high-intensity-focused ultrasound systems) as well as intravascular and nondirectional Doppler systems are beyond the scope of this technical standard. Ultrasound systems used for specialized tasks, such as radiation dosimetry calculations may require additional quality management beyond that described in this document [2].

The qualified medical physicist must be familiar with the principles of ultrasound safety and bioeffects; regulations pertaining to the performance of the equipment being tested; the physics, function, clinical uses, and performance specifications of the imaging equipment; methods and equipment used for testing performance; and analysis and interpretation of test results.

The qualified medical physicist (as described above) may utilize the assistance of properly trained individuals for program design and documentation in obtaining test data for performance monitoring and with other aspects of the quality control (QC) program. A properly trained individual is one who is trained and approved by the qualified medical physicist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the measurement methods, the reasons for the tests, and the importance and specifications of the test results. To ensure the efficacy of the individual's training, the qualified medical physicist should periodically review and approve all performance measurements, as well as recommend the actions to be taken when test results show failures or quality issues with the system. (appropriately trained personnel with documented experience.) This training and documentation should be provided by a qualified medical physicist. If training by a qualified medical physicist is not possible, training can be achieved through the ultrasound equipment manufacturer or through an appropriate course.

For the purposes of this technical standard, a qualified service engineer is an individual trained to evaluate the specific manufactured components, characteristics, and functionality of the ultrasound system(s) they are responsible for servicing. The qualified service engineer should be able to repair nonfunctioning components or provide replacement components for the system(s) when failures occur.

Roles and Responsibilities

To understand the roles and responsibilities of equipment monitoring, we must delineate the types of monitoring to be performed. General acceptance testing, annual performance evaluations, and routine QC testing are considered the minimally acceptable tests to be performed. Acceptance testing is performed at installation to ensure the unit and its components meet contractual specifications for general performance quality. Annual performance evaluations are performed once per calendar year and typically incorporate testing similar to acceptance testing, including a thorough interrogation of the system and its components. Routine QC is typically performed on a more frequent schedule, with some tests performed weekly, monthly, or in a semiannual time frame.

The qualified medical physicist should participate in establishing a routine QC program, helping to implement the routine QC, and should oversee evaluation of equipment after repairs and upgrades that affect the performance of the unit or its components.

All ultrasound equipment must be evaluated upon installation (acceptance testing) to ensure that it is functioning properly. Resource permitting, best practice would include acceptance testing and annual performance evaluations performed or supervised by a qualified medical physicist.

Regular preventive maintenance should be performed and documented by a qualified equipment service engineer. Preventive maintenance and service should follow the manufacturer's recommendations.

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 Physicists 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). [3]
The appropriate subfield of medical physics for this technical standard is diagnostic medical physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

A. Acceptance Testing

The performance of all ultrasound imaging equipment must be evaluated at the time it is acquired. This includes new ultrasound system acquisitions as well as components of the system, such as new or replacement transducers. Evaluations should be performed even when the system is covered under warranty or a service contract. Acceptance testing should also be performed following major equipment repairs, after component replacements, following a major software upgrade, or when a unit is begin reintroduced for clinical use after dormancy, as defined by the institution. Thorough acceptance testing should provide complete performance baselines for comparison with future testing results.

1. Ultrasound scanners – Acceptance testing of a scanner alone (ie, without testing transducers) may be performed using a single transducer. These tests should include:
    a. Physical and mechanical inspection
    b. Transducer port inspections (image uniformity/artifact survey of each transducer port on the scanner) Geometric accuracy (2-D and 3-D, if applicable)
    c. System sensitivity
    d. Spatial resolution (axial, lateral, and elevational)
    e. Contrast resolution
    f. Fidelity of ultrasound scanner electronic image display(s)
2. Ultrasound transducers – Acceptance tests should include:
    a. Physical and mechanical inspection
    b. Image uniformity/artifact survey
    c. Geometric accuracy (2-D and 3-D, if applicable)
    d. System sensitivity
    e. Spatial resolution (axial, lateral, and elevational)
    f. Contrast resolution
    g. Dead zone (near field) assessment
3. For systems with Doppler capabilities, if appropriate testing equipment is available, acceptance tests should include (in addition to any applicable imaging tests):
    a. Doppler sensitivity as a function of depth in attenuating media (eg, determination of the lowest detectable flow)
    b. Verification of velocity measurement accuracy over a clinical range, including pathologies such as stenosis
    c. Verification of correct directional discrimination
    d. Accuracy of angle correction
    e. Assessment of gate/sample volume registration
    f. Verification of volume flow measurement accuracy, if applicable
4. For systems with elastography capabilities, if appropriate testing equipment is available, acceptance tests should include (in addition to any applicable imaging tests):
    a. Assessment of stiffness measurement accuracy as a function of depth in attenuating media
    b. Contrast-detail assessment of elastography imaging performance
    c. All tests performed as part of the QC program must be included in acceptance testing. Ideally, a sampling of clinical protocols should be reviewed with a special focus on advanced techniques (such as contrast-enhanced ultrasound, shear-wave elastography, and 3-D ultrasound) to optimize image quality while reducing risks due to thermal and mechanical effects.

B. Performance Evaluation

Ultrasound system performance evaluations must be performed at least annually, in addition to routine QC as described below.

The following performance evaluation tests must be performed at least annually on all machines and transducers [4-11]:

Physical and mechanical inspectionImage uniformity and artifact survey
Fidelity of the ultrasound scanner electronic image display(s)
Evaluation of QC program (if applicable)

Tests may also include, but not be limited to, the following as applicable [9-11] (see Appendix A) [4-8]:

1. System sensitivity
2. Geometric accuracy
3. Contrast resolution
4. Spatial resolution
5. Fidelity of the display device(s) used for primary interpretation
6. Doppler functionality (quantitative or qualitative evaluation)
7. Elastography functionality (quantitative or qualitative evaluation)

All tests performed as part of the routine QC program must also be performed as part of this performance evaluation.

Either subjective visual methods or objective computer-based approaches may be used to make these measurements [4-9,11-18]. If subjective methods are used, it is recommended that the images used to perform the tests be retained for comparison with subsequent test images.

Image-based performance measurements must be made using an ultrasound phantom. Acceptable phantoms are available from a variety of commercial vendors. Appropriate custom phantoms may also be fabricated by experienced personnel. Other nonphantom evaluation methods can be used to supplement performance evaluations, but these supplemental tests cannot replace required tests. Examples of nonphantom tests may include the "paper-clip test" [12] or tests that use transducer evaluation devices for testing electrical and acoustic characteristics of individual transducer elements [13].

These approaches may be used if they are appropriately described in the overall program documentation. For a specific discussion of display device performance assessment, please consult the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging [19].

Reproducibility of results is critical in evaluating the performance of ultrasonic equipment, and care should be taken to utilize identical protocols, phantoms, and other variables that were previously used for testing.

C. Quality Control Program

A continuous QC program is essential to ensure proper functioning of all ultrasound equipment. Routine QC is typically performed by appropriately trained sonographers or a qualified service engineer. Routine QC describes tests that are be performed
weekly, monthly, or semiannually.

All scanners and all transducers in routine clinical use must be tested during each QC evaluation. Transducers are a weak link in the ultrasound imaging chain because they are easy to drop, their cables easily kink and become stressed, and the active elements are relatively fragile.

1. Physical and mechanical inspection
2. Image uniformity and artifact evaluation
3. Fidelity of the ultrasound scanner electronic image display(s) [10,19,20][2]
4. All transducer ports on each scanner should be tested using at least 1 transducer to ensure functionality.

D. Written Survey Reports and Follow-Up Procedures

All performance evaluation test results including, but not limited to, acceptance tests, annual, and routine

QC tests must be documented. Documentation must be accessible by each facility and results should be reviewed by the qualified medical physicist, as recommended in Section A.

If test results fall outside of the acceptable limits, corrective action must be taken. The qualified medical physicist should include an appropriate time frame for corrective action. Corrective actions are typically accomplished by a qualified service engineer. Appropriate action and notification must occur immediately if there is imminent danger to patients or staff using the equipment due to unsafe conditions. A transducer should be removed from service if the qualified medical physicist finds it to be unsafe, have the potential for poor diagnostic evaluations, or have poor image guidance. Ultimately, the lead interpreting physician, or their designated representative, must be consulted to determine its continued use. After a problem has been addressed, an evaluation should be performed to verify adequate resolution of the problem and to establish new baseline performance metrics. These test results should be documented, maintained, and reviewed as described above.

Results of the acceptance and QC program testing must be reported to the physician(s) directing the clinical ultrasound practice and, if necessary, to the responsible professional(s) in charge of scheduling necessary service of the equipment. In the case of consulting personnel, results should be reported to the representative of the hiring party. This communication should be provided in a timely manner consistent with the importance of any adverse findings.

[2] Electronic image displays, both those on the ultrasound equipment and those used for primary interpretation (eg, workstation displays), should be tested according to the recommendations in the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging, in terms of specific tests and testing frequency. Test methods for hard-copy display equipment are described in Siegel et al and Goodsitt et al.

IV. PERFORMANCE CHARACTERISTICS TO BE MONITORED

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 & 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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Appendix A

1. Physical and mechanical inspection – this ensures the mechanical integrity of the equipment, and the safety of patient and operator.

2. Image uniformity/artifact survey – this test aims to identify the presence of artifacts, often axial or lateral streaks in scans of uniform sections of a phantom. The use of "in-air" images (ie, images acquired without the use of gel or phantom) may also be useful in detecting superficial artifacts. Testing as part of the continuous QC program is typically nonquantitative and less rigorous than other testing. The continuous QC program may use water or clinical patient images to qualitatively evaluate uniformity and identify artifacts.

3. Geometric accuracy – tests often involve use of the scanner calipers to measure known distances between phantom test targets in the axial and lateral directions, although other tests of geometric accuracy have been described. The use of a phantom with a sound speed closely matching 1,540 m/s is recommended for determining absolute performance.

4. System sensitivity – visual determination of the maximum depth of visualization of speckle patterns or phantom targets, and quantitative measurements of signal-to-noise ratio (SNR), have both been reported.

5. Spatial resolution – this should be measured in the axial, lateral, and elevational directions. Various approaches have been described for making axial and lateral resolution measurements, including visual interpretation of groups of phantom pin/fiber targets and measurement of pin target dimensions. Similarly, various approaches for making elevational resolution measurements have been discussed, one requiring a special phantom and one compatible with multipurpose phantoms [4]. The use of a phantom with a sound speed closely matching 1,540 m/s is recommended for determining absolute performance.

6. Contrast resolution – the use of both anechoic and low contrast echogenic targets has been suggested, as has the use of 2-D cylindrical targets and 3-D spherical targets. The use of larger 2-D targets emphasizes contrast resolution performance, whereas the use of small targets also tests spatial resolution capabilities.

7. Fidelity of ultrasound scanner electronic image display(s) – when used for diagnostic purposes, the electronic displays on the scanner and any modality workstations should be considered as primary diagnostic devices. This would not necessarily be the case for scanners used exclusively as an aid to guide procedures. Display characteristics that are evaluated may include grayscale response, presence of pixel defects, and overall image quality. These evaluations are typically performed using specialized test pattern images and may also involve the use of photometric equipment. Testing as part of the continuous QC program is typically nonquantitative and less rigorous than other testing.

8. Display device(s) used for primary interpretation – these primary diagnostic displays may be electronic soft-copy displays on a workstation or hard-copy films. Display characteristics that are evaluated may include grayscale response, presence of pixel defects, and overall image quality. These evaluations are typically performed using specialized test pattern images and may also involve the use of photometric equipment.

9. Qualitative evaluations of Doppler functionality – for spectral Doppler mode, the tests include positioning of the Doppler sampling volume, specification of Doppler angle, Doppler spectral display, directionality of flow, and lack of velocity signal where no flow is present. For color flow imaging mode, the tests include color map and flow direction and color signal superimposition on the grayscale image. As these are visual, qualitative tests, the use of a phantom is not required [4].

*As of May 2015, all practice parameters and technical standards that are collaborative with only the American Association of 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 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>

1999 (Resolution 18)
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Revised 2009 (Resolution 9)
Revised 2011 (Resolution 3)
Revised 2016 (CSC/BOC)
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