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

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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[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 individuals with recognized expertise in medical physics, representing the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

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representing the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

The use of diagnostic ultrasound imaging is widespread throughout the hospital and outpatient environments. Where appropriate, it can be a safe and effective diagnostic imaging alternative compared to ionizing radiation imaging modalities. Studies have shown that degradation of the ultrasound transducer and its components can have an adverse effect on image quality and quantitative measurements [1]. The goal of this document is to establish a technical standard that will provide a consistent means for the evaluation of diagnostic ultrasound equipment. This document will outline— and in some cases specify— tasks, tests, and evaluations that should be performed to ensure optimal performance of the ultrasound equipment. Furthermore, this document will provide recommendations for identifying 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 patient clinical examinations as related 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 ultrasound 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].

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." [3]

II. QUALITY MANAGEMENT

A. Quality Management Team

The QM team defines the individuals who are responsible for, and involved with, the technical aspects of clinical use of ultrasound equipment. In general, the supervising physician is responsible for the overall quality and safety of the clinical operation of ultrasound equipment. The Qualified Medical Physicist has responsibility and oversight for equipment testing protocols, methods, and criteria for action. As such, the QM team should be led or overseen by the supervising physician with support from the Qualified Medical Physicist on equipment issues. The QM team should also include at least one sonographer who routinely operates the ultrasound equipment. While different types of physicians (e.g., radiologists, surgeons, etc.) may be involved in ultrasound procedures or imaging, the participation of all physicians on a QM team is likely unnecessary. At least one physician should participate on the QM team to provide physician and end-user input.

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

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

As described in *Qualifications and Responsibilities of Personnel*, the Qualified Medical Physicist may be assisted in the collection of data, subject to all applicable regulations and relevant guidance. The Qualified Medical Physicist and the QM team should define the required training and approval process for those individuals deemed

qualified for assisting under the general supervision of the Qualified Medical Physicist. This technical standard recommends that all annual testing be performed either by or under the general supervision [4] of the Qualified Medical Physicist, and all testing at more frequent intervals be performed under the oversight or direction of the Qualified Medical Physicist.

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 QM 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 QM team to keep and manage these records.

II. QUALITY MANAGEMENT

C. Records of Devices and Tools

QM of ultrasound imaging equipment requires accurate and complete installation records of the equipment. At a minimum, the QM team should establish an asset management methodology to track the location, manufacturer, model, date of manufacture and serial number 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 ultrasound equipment itself, the QM team should maintain accurate records of the phantom(s) and device(s) used to perform QC tests. These records should include the device description, manufacturer, model, date of manufacture and serial number. Additionally, the QM team should maintain records of the device calibration to ensure regulatory and policy compliance.

The QM team should review 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 QM team members.

II. QUALITY MANAGEMENT

D. Policies (as applicable)

Effective QM requires a comprehensive set of policies and guidelines to address all aspects of equipment performance. This subsection lists those aspects of ultrasound equipment that should be included in such documentation.

1. Acceptable equipment performance standards, ranges, and limits
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 and operator responsibilities

II. QUALITY MANAGEMENT

E. Reporting Structure for Findings

In the event of equipment malfunction or adverse findings during quality assessment, the following reporting and follow-up steps should occur:

1. A clear description of the malfunction or adverse finding should be documented and reported to the clinical manager. This should include the:
    a. Unit or part name and serial number
    b. Location of the unit or part
    c. Date of adverse findings
    d. Person responsible for repair or correction (e.g., service engineer, lead sonographer)
    e. Timeline for repair or correction (e.g., "within 30 days" or "before clinical use")
    f. Limitations to clinical use until repair or correction is complete
2. The clinical manager should schedule the service or correction. The service or correction should be documented.
3. A plan of action should be created to circumvent future failures or malfunctions.

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." [3]

III. QUALITY ASSURANCE

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 QM team.

III. QUALITY ASSURANCE

B. Calibration of Measurement Devices/Tools

Measurement devices should be regularly calibrated and cross-referenced with calibrated devices to ensure the quality of their readings. Tissue-mimicking ultrasound phantoms should undergo routine maintenance — such as weighing and rejuvenation — at manufacturer-recommended intervals to ensure long-term stability. Manufacturer-provided values for feature spacing, relative contrast, speed of sound, and attenuation coefficient in individual phantoms at the time of purchase or service can serve as reference standards for performance testing. The Qualified Medical Physicist should adhere to professional practice standards and 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." [3]

Equipment performance must be evaluated upon installation and should be 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 (e.g., after major equipment maintenance). 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, 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 QC activities described in this section are broadly separated into three categories: acceptance testing, annual

equipment performance evaluation and continuous QC.

IV. QUALITY CONTROL

A. Acceptance Testing

A Qualified Medical Physicist must conduct an initial performance evaluation upon installation ofequipment and after major upgrades. Acceptance testing should be more comprehensive than periodic evaluation and should be completed before clinical use. This includes new ultrasound systems 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. Testing should also be performed following major equipment repairs, after component replacements, following a major software upgrade, or when a unit is being 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.

Prior to the initial equipment performance evaluation, electrical safety and informatics connectivity (e.g., DICOM transfer) must be verified by appropriate personnel.

Acceptance testing must include tests performed during the equipment performance evaluation and should also include the following items:

1. Ultrasound units — Acceptance testing of a unit alone (i.e., without testing transducers) may be performed using a single transducer. These tests should include:
    a. Physical and mechanical inspection
        i. Brakes are operational
        ii. Wheels move freely
        iii. Monitor is movable and stable in set position
        iv. System is free of dust and debris
        v. Controls, knobs and sliders are in place, undamaged, and functional
        vi. Wires are covered and in good repair
    b. Transducer port inspections (image uniformity and artifact survey of each transducer port on the unit)
    c. Fidelity of ultrasound unit's electronic image display(s)

2. Ultrasound transducers – Acceptance tests should include a combination of the following tests:
    a. Physical and mechanical inspection
    b. Image uniformity and 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 also include evaluation of applicable usages, such as:
    a. Doppler sensitivity as a function of depth in attenuating media (e.g., 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 and 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 also include:
    a. Assessment of stiffness measurement accuracy as a function of depth in attenuating media

b. Contrast-detail assessment of elastography imaging performance

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.

IV. QUALITY CONTROL

B. Equipment Performance Evaluation

Ultrasound system equipment 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 [5-12]:

1. Physical and mechanical inspection
2. Image uniformity and artifact survey
3. System sensitivity
4. Fidelity of the ultrasound unit's electronic image display(s)
5. Evaluation of QC program (if applicable)

Tests may also include, but are not limited to, the following as applicable [10-12] (see Appendix A) [5-9]:

1. Geometric accuracy
2. Contrast resolution
3. 2D and 3D spatial resolution
4. Fidelity of the display device(s) used for primary interpretation
5. Doppler functionality (quantitative or qualitative evaluation)
6. 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 [5-10, 12-19]. If subjective methods are used, it is recommended that the images used to perform the tests be retained for comparison with subsequent test images.

A newer method with randomly placed spherical lesions is available that provides more rapid evaluation of system sensitivity, contrast resolution and spatial resolution. Use of these tests is recommended as available and verified [20]

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.The last sentence in the 3rd to last paragraph is not saving properly and should read: "Examples of tests may include the "paper clip test" [13] or tests that use transducer evaluation devices for testing electrical and acoustic characteristics of individual transducer elements .

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 [21].

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

IV. QUALITY CONTROL

C. Continuous Quality Control

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 units 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.

A continuous QC program must be implemented for all ultrasound 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 a minimum, the QC program should include the following tests to ensure consistent image quality, mechanical integrity of the system, and patient safety:

1. Physical and mechanical inspection
2. Image uniformity and artifact evaluation for each clinically used transducer
3. Fidelity of the ultrasound unit electronic image display(s) and printing devices [11, 21, 22][2]
4. All transducer ports on each unit should be tested using at least one transducer to ensure functionality

It is strongly recommended that the program include newer tests with randomly placed spherical lesions, as available; these provides much more rapid testing, combining evaluations of sensitivity, 3D resolution over the useable range and, in the future, geometric accuracy. Use of these tests is recommended as available and verified.

[2] Electronic image displays, both those on the ultrasound equipment and those used for primary interpretation (e.g., workstation displays), should be tested according to the recommendations in the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging and ACR–AAPM Technical Standard for Diagnostic Interpretation Displays, in terms of specific tests and testing frequency.

QUALITY CONTROL

Written Survey Reports and Follow-Up Procedures

All performance evaluation test results including, but not limited to, acceptance tests, annual equipment performance evaluations 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. The facility should retain service reports as verification that the issue(s) was appropriately resolved. 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.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Qualified Medical Physicist

A Qualified Medical Physicist is the most appropriate person to perform or supervise acceptance testing and performance evaluation of ultrasound equipment.

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) [23].

The appropriate subfield of medical physics for this technical standard is Diagnostic Medical Physics. See the ACR policy on Physics for medical physics certifications categories that are also acceptable. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

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 (e.g,, AAPM Medical Physics Practice Guideline 7.a [24]). 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 [25]. These individuals must be properly trained and approved by the Qualified Medical Physicist such that they have knowledge about the techniques needed to perform tests, the functions and limitations of the equipment and test instruments, the reasons for the tests, and the importance of the test results. The assisting individual shall be under the general supervision[3] [4] 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 [4].

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 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 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 actions to be taken when test results show failures or quality issues with the system.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.

[3] For the purposes of this standard, general supervision means all procedures are performed under a Qualified

Medical Physicist's overall direction and control. The Qualified Medical Physicist's presence is not required during the procedure, but they must be available by phone to provide assistance and direction as needed. The training of the personnel who perform the procedure and the maintenance of the necessary equipment and supplies are the responsibility of the Qualified Medical Physicist.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Physician

For Physician qualifications related to diagnostic ultrasound equipment, see the ACR–SPR–SRU Practice Parameter for the Performance and Interpretation of Diagnostic Ultrasound Examinations [26].

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

C. Medical Physicist Assistant

A Medical Physicist Assistant is an individual who has the necessary didactic education and practical medical physics knowledge to work under the supervision and responsibility of a Qualified Medical Physicist [24, 27]. As outlined in AAPM Medical Physics Practice Guideline 7.a, a Medical Physicist Assistant is an individual who is not a Qualified Medical Physicist but extends to a Qualified Medical Physicist through a formal chain of authority. The Medical Physicist Assistant is a valuable member of the QM team and makes a robust QM program more feasible.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

D. Information Technology (IT) Professional

The imaging IT professional should be qualified to assess and provide problem-solving input, initiate repair, and coordinate system-wide maintenance programs to assure sustainable high image quality and system function.

The responsibilities and experience for an IT professional include:

1. Maintenance of the network for all informatics systems
2. Assisting with establishing networks and informatics systems for collecting and analyzing QC data
3. Assisting with automated QC processes
4. Assisting with training of personnel involved with IT operations
5. Troubleshooting and service support

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

E. Diagnostic Medical Sonographer

For Diagnostic Medical Sonographer qualifications related to diagnostic ultrasound equipment, see the ACR–SPR–SRU Practice Parameter for the Performance and Interpretation of Diagnostic Ultrasound Examinations [26].

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Roles and Responsibilities

To understand the roles and responsibilities of equipment monitoring, the types of monitoring to be performed must be delineated. General acceptance testing, annual performance evaluations and routine QC testing are considered the minimum acceptable standard. Acceptance testing is performed at installation and after major repairs or upgrades 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 performed more frequently, with some tests performed weekly, monthly, or on a semiannual time frame.

The Qualified Medical Physicist should participate in establishing a routine QC program, help to implement the routine QC, and should oversee the 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. It is strongly recommended that acceptance testing and annual performance evaluations be 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.

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*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.

Development Chronology for this Technical Standard
1999 (Resolution 18)
Revised 2004 (Resolution 17c)
Amended 2006 (Resolution 16g)
Revised 2009 (Resolution 9)
Revised 2011 (Resolution 3)
Revised 2016 (CSC/BOC)
Revised 2021 (CSC/BOC)
Amended 2022 (Resolution 41f)
Amended 2023 (Resolution 2c)
Revised 2026 (CSC/BOC)

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. However, water or clinical patient images can be used to qualitatively evaluate uniformity and identify artifacts.

3. Geometric accuracy – tests often involve use of the unit 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 propagation speed closely matching 1,540 m/s is recommended for determining absolute performance. Automated analysis of the position in the image volume of known targets via image registration should soon be available.

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) for targets as a function of position in the field of view, have both been reported.

5. Spatial resolution – this should be measured in the axial, lateral, and elevational directions, or a combination thereof as in the randomly-placed spherical lesion phantom and its automated analysis [20, 28]. 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 [5]. The use of a phantom with a sound propagation speed closely matching 1,540 m/s is recommended for determining absolute performance.

6. Dynamic Range and Contrast Calibration – 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 unit electronic image display(s) – when used for diagnostic purposes, the electronic displays on the unit and any modality workstations should be considered as primary diagnostic devices. This would not necessarily be the case for units 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. Consistency between exported image look-up table and calibration of display device(s) used for primary interpretation of images acquired on a given unit should be ensured [28].

8. Fidelity of 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 [28].

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 [5].