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

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

I. INTRODUCTION

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

All ultrasound equipment must be evaluated upon installation (acceptance testing) and routinely thereafter to ensure that it is functioning properly. Acceptance testing and performance evaluations should be performed or supervised by a Qualified Medical Physicist. In addition, regular preventive maintenance should be performed and documented by a qualified equipment service engineer following the recommendations of the equipment vendor. 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. Key points to consider are performance characteristics to be monitored, qualifications of personnel, and follow-up procedures.

The goal of this document is to establish a technical standard that will allow production of the highest quality diagnostic images consistent with the clinical use of the equipment and the information requirement of the examination.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist should carry out acceptance testing and monitoring 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, or by the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [1]

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

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.

Properly trained individuals may assist the Qualified Medical Physicist in the overall program design and documentation, and in obtaining test data for performance monitoring, as well as other aspects of the program. These individuals should be 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, measurement methods, the reasons for the tests, and the importance of the test results. The Qualified Medical Physicist should periodically review and approve all performance measurements and actions taken to address any specific problems detected by the testing. If it is not possible for a Qualified Medical Physicist to perform the tasks designated for a Qualified Medical Physicist, these tasks may be performed by other appropriately trained personnel with experience. These individuals must be approved by the physician(s) directing the clinical ultrasound practice.

Program documentation must include:

1. Program goals, policies, and responsible personnel
2. Testing procedures, equipment, frequencies, and performance criteria
3. Results of all performance measurements
4. Actions taken to address any specific problems detected by the testing

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A. Acceptance Testing

The performance of all ultrasound imaging equipment must be evaluated at the time it is acquired. This includes purchases of new scanners and/or transducers, as well as replacement equipment obtained under warranty or service contract. Acceptance testing should be done following equipment repair, and may also be warranted following major equipment upgrade. Equipment pulled from storage should also undergo acceptance testing. These tests should provide complete performance baselines for comparison with future test 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. Image uniformity/artifact survey (each transducer port on the scanner should be tested)
    c. Geometric accuracy
    d. System sensitivity
    e. Spatial resolution
    f. Contrast resolution
    g. Fidelity of ultrasound scanner electronic image display(s)

    For those systems with tissue harmonic imaging capabilities, at minimum, tests d, e, and f above should be tested using the most clinically used mode.

    For those systems with spectral Doppler and color-flow imaging capabilities, strain imaging and shear wave elastography, evaluations of these capabilities should be performed [2,4].

2. Ultrasound transducers – Acceptance tests should include:
    a. Physical and mechanical inspection
    b. Image uniformity/artifact survey
    c. Geometric accuracy
    d. System sensitivity
    e. Spatial resolution
    f. Contrast resolution

All tests done as part of the quality control (QC) program must be included in acceptance testing.

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 [2-9]:

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

They may also include, but not be limited to, the following tests (as applicable) [7-9] (see Appendix A) [2-6]:

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)

All tests done 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 [2-7,9-12]. 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 approaches to performance measurement not requiring ultrasound images of phantoms have been reported, eg, the "paper-clip test" [10] and use of transducer evaluation devices which test the electrical and acoustic characteristics of each individual transducer array element [11]. These approaches may be used for evaluating some performance characteristics if they are appropriately described in the overall program documentation. The topic of display device performance assessment is discussed in the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging [13].

C. Quality Control Program

A continuous QC program is essential to assure the proper functioning of all ultrasound equipment. Routine QC is typically performed by appropriately trained sonographers or equipment service engineers. Transducers are a weak link in the ultrasound imaging chain since they are easy to drop, their cables may be easily kinked and stressed, and the active elements are relatively fragile.

All scanners and all transducers in routine clinical use must be tested during each QC evaluation. It is recommended that the QC Program be performed at least semiannually.

These tests must include:

1. Physical and mechanical inspection
2. Image uniformity and artifact survey
3. Fidelity of the ultrasound scanner electronic image display(s)

All transducer ports on each scanner should be tested using at least 1 transducer.

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 [13]. Test methods for hard-copy display equipment are described in Siegel et al [14] and Goodsitt et al [8].

D. Written Survey Reports and Follow-Up Procedures

If test results fall outside of the acceptable limits, corrective action must be taken. The surveyor should include an appropriate time-frame for corrective action. Corrective actions are typically accomplished by an equipment 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. After a problem has been addressed, acceptance testing should be performed to assure adequate resolution of the problem, and these test results should be documented.

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

IV. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (http://www.acr.org/guidelines).

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Appendix A

1. Physical and mechanical inspection – this assures 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.

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 2D cylindrical targets and 3D spherical targets. The use of larger 2D targets emphasizes contrast resolution performance, while 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 gray scale response, presence of pixel defects, and overall image quality. These evaluations are typically performed using specialize test pattern images, and may also involve the use of photometric equipment.

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 gray scale response, presence of pixel defects, and overall image quality. These evaluations are

typically performed using specialize 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 [2].

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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