ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF MAGNETIC RESONANCE (MR) IMAGING 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).

The performance of all magnetic resonance (MR) imaging systems must be evaluated upon installation and at least annually to ensure proper functioning within the manufacturer's specifications and accepted performance standards [1]. 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, adherence to this technical standard will encourage MR facilities to strive for, achieve, and maintain a high level of diagnostic image quality.

The goal is to establish performance standards to promote production of high-quality diagnostic MR images that are consistent with the clinical and safe use of MR imaging equipment and with the clinical objectives of examinations.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist or a Qualified MR Scientist must carry out acceptance testing and monitoring of MR imaging equipment.

A Qualified Medical Physicist or Qualified MR Scientist 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 or Qualified MR Scientist. 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 or Qualified MR Scientist should meet the ACR Practice Parameter for Continuing Medical Education (CME). [2]

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). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

Dedicated certification in Magnetic Resonance Imaging Physics by the ABMP is also appropriate for this technical standard.

A Qualified MR Scientist is an individual who has obtained a graduate degree in a physical science involving nuclear MR or MR imaging and has documented experience in a clinical MR setting. Additional guidance on the initial qualifications, as well as continuing experience and education for the Qualified Medical Physicist or MR Scientist, is available on the ACR MRI Accreditation webpage under comprehensive information [3].

The Qualified Medical Physicist or MR Scientist must be familiar with:

1. Principles of MR physics and MR technology.
2. Principles of MR safety for patients, personnel, and the public [4].
3. Principles of MR acceptance testing and quality assurance procedures [1].
4. The Food and Drug Administration (FDA) guidance for MR diagnostic devices [5,6].
5. ASTM F2503 standard for marking items for safety in the MR environment [7].
6. Laws and regulations pertaining to the equipment being monitored.
7. Standards of accrediting bodies pertaining to the equipment being tested.
8. The function, clinical uses, and performance specifications of the MR imaging equipment.
9. Calibration processes and limitations of the performance testing hardware, procedures, and algorithms [1,8,9].

The Qualified Medical Physicist or MR Scientist must have a working understanding of the clinical imaging protocols used on the scanner and methods of their optimization. This proficiency should be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

The Qualified Medical Physicist or MR Scientist is responsible for the test protocols, the test methods, and the acceptability criteria. The Qualified Medical Physicist or MR Scientist may be assisted by properly trained individuals in obtaining data in accordance with applicable regulations and relevant guidance where appropriate (eg, AAPM Medical Physics Practice Guidelines 3.b and 7.a [10,11]). A Qualified Medical Physicist or MR Scientist is responsible for determining whether the assisting individual is competent in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, the importance of the test results, and any other skills or knowledge needed to safely perform the work. The assisting individual must be under the direct supervision[1] of the Qualified Medical Physicist or MR Scientist during initial and annual surveys [12]. The Qualified Medical Physicist or MR Scientist is responsible for all surveys and must review, interpret, and approve all data as well as provide a signed report with conclusions and any recommended follow-up actions .

[1] For the purpose of this standard, direct supervision means that the Qualified Medical Physicist or MR Scientist must be present in the facility and immediately available to furnish assistance and direction throughout the performance of the survey. It does not mean that the Qualified Medical Physicist or MR Scientist must be present in the room where the procedure is performed.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

The monitoring of performance characteristics of MR equipment should be implemented as described below and in accordance with federal, state, and local regulations.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A. Acceptance Testing

Prior to initial MR imaging equipment performance evaluation, electrical safety, room conditions (eg, temperature and humidity), and digital image communication must be verified by appropriate personnel.

The initial MR imaging equipment performance evaluation should be performed by a Qualified Medical Physicist or MR Scientist. Time must be made available for the Qualified Medical Physicist or MR Scientist to perform the initial performance testing. Initial performance testing and establishment of the MR Safety program must be completed before clinical use.

MR Safety information from the MR system operator's manual should be located and reviewed prior to performance evaluation, both for the personal safety of the Qualified Medical Physicist or MR Scientist (and assistants, if applicable) and for establishment of the MR Safety program. The system-specific MR safety information from the operator's manual should be present and readily available to facility staff near the console of the MR system.

For MR systems capable of producing an A-weighted RMS sound pressure level higher than 99 dB(A), the Qualified Medical Physicist or MR Scientist should review the MR system operator's manual for the minimum rated hearing protection required to reduce sound pressure level below 99 dB(A), and provide recommendations to the MR Medical Director for selection of appropriate means of hearing protection for individuals in or near the MR system.

Initial MR imaging equipment performance evaluation must be conducted upon installation of the MR imaging scanner and after major upgrades. This evaluation should be more comprehensive than periodic evaluation and should be consistent with current MR imaging equipment performance acceptance evaluation practices [1,4]. The acceptance evaluation protocol should include a quantitative assessment of all coils. All new or replacement coils

should be evaluated prior to clinical use. Coil positioning, phantom positioning, data acquisition, and analysis protocols should be documented to enable reproducible measurements and trend assessments. Baseline values should be established for future MR imaging equipment performance evaluation and quality control.

The initial MR Safety program must be established under the oversight of the MR Medical Director and should be developed with the assistance of the Qualified Medical Physicist or MR Scientist. This program should include implementation of site access restrictions (MR Safety Zones), MR safety training of MR Personnel, as well as MR Safety screening of patients, personnel, and devices. The MR Safety program should be reviewed periodically for relevance, applicability, and continuous improvement.

Acceptance tests must include:

1. Compliance with relevant regulatory requirements
2. Compliance with special contractual terms
3. Evaluation of compliance with manufacturer's relevant imaging and safety performance specifications and inventory
4. Review of RF attenuation tests (eg, , radiofrequency [RF] shielding)
5. Evaluation of magnetic fringe fields (eg, static magnetic field shielding)
6. Baseline acquisition of tests performed during the annual performance evaluation

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

B. Performance Evaluation

The performance of each MR system must be evaluated at least annually. At a minimum this evaluation should include the following items or their equivalents:

1. Physical and mechanical system integrity inspection
2. Magnetic field homogeneity
3. Slice position accuracy and table positioning
4. Slice thickness accuracy [13]
5. Geometric accuracy (gradient calibration) [15]
6. High-contrast spatial resolution
7. Low-contrast resolution (detectability)
8. Performance evaluation for radiofrequency coils used clinically
    a. Coil physical visual inspection
    b. Transmitter gain/attenuator verification
    c. Image artifact assessment
    d. Image signal-to-noise ratio (SNR) [14,16,17]
    e. Image intensity uniformity (volume coils) [18]
    f. Percent signal ghosting (volume coils)
    g. Year-to-year variations of each of the above parameters should be tracked
9. Acquisition workstation monitor performance [19]
10. Evaluation of technologist quality control (QC) program and data
11. Review of service log
12. Assessment of the MR safety program [4]

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

C. QC Program

A continuous QC program must be implemented for all MR imaging systems. The program should be established with the assistance of a Qualified Medical Physicist or MR Scientist. The Qualified Medical Physicist or MR Scientist should verify the person(s) responsible for performing the tests and may recommend altering types of tests as well as frequency of testing based on the facility and MR imaging usage. The minimum number of tests and

testing frequency are specified in the ACR Magnetic Resonance Imaging Quality Control Manual [20]. At minimum, the QC program should include the following items or their equivalents:

1. Setup and table positioning accuracy
2. Center frequency
3. Transmitter gain or attenuation (RF calibration)
4. Geometric accuracy (gradient calibration)
5. High-contrast spatial resolution
6. Low-contrast detectability or SNR
7. Artifact evaluation
8. Visual checklist

For MR systems performing advanced MR techniques, a QC program relevant to the advanced imaging technique should be established [1,21]

The results of the QC program must be reviewed at least annually by the Qualified Medical Physicist. If any monitored QC parameter falls outside of the control limits, corrective action must be considered. A Qualified Medical Physicist or MR Scientist should be consulted regarding corrective actions for unresolved problems.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

D. Written Survey Reports and Follow-up Procedures

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

If appropriate, the Qualified Medical Physicist or MR Scientist 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 or MR Scientist 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. In some cases, it may be appropriate for the Qualified Medical Physicist to specify and/or perform additional measurements to confirm the status of the equipment.

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

IV. MR I SAFETY PROGRAM

The MR Medical Director should oversee the MR imaging safety program for employees, patients, and other individuals in the surrounding area [4]. The MR Medical Director should ensure that records concerning QC, safety, and protection are properly maintained and updated as specified in the MR imaging quality assurance (QA) procedures manual. The MR Medical Director should also ensure relevant safety information from the MR system operator's manual is available to any operator at the MR system console. A Qualified Medical Physicist or MR Scientist should review these records at least annually. Concurrent with MR system evaluation, the Qualified Medical Physicist or MR Scientist should verify MR safety information from the MR system operator's manual is present and readily available at the MR console.

To minimize risks in the MR environment to patients, health care professionals, and any others that may

encounter the fields of the MR scanner, each facility must establish, implement, and maintain current safety policies and procedures. Information regarding establishment of a quality MR Safety program can be found in the ACR Manual on MR Safety and the ACR Magnetic Resonance Imaging Quality Control Manual [4,20,]. To mitigate risk, MR safety information specific to the model of MR system is available in the MR system operator's manual, as required by IEC 60601-2-33 [8]. Information regarding the development of effective safety checklists can be found in the AAPM Medical Physics Practice Guideline 4.b: Development, implementation, use and maintenance of safety checklists [23].

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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

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