ACR-AAPM TECHNICAL STANDARD FOR MEDICAL PHYSICS PERFORMANCE MONITORING OF PET/MRI 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.

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.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

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

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."

II. QUALITY MANAGEMENT

A. Quality Management Team

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

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

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

II. QUALITY MANAGEMENT

B. Service Records

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

II. QUALITY MANAGEMENT

C. Records of Devices and Tools

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

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

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

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."

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 quality management team.

III. QUALITY ASSURANCE

B. Calibration of Measurement Devices/Tools

Measurement devices should be regularly calibrated or cross-referenced with calibrated devices to ensure the quality of their readings. 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." Equipment performance must be evaluated upon installation and monitored at least annually by a Qualified Medical Physicist to ensure proper functioning within the defined performance standards. Additional or more frequent performance monitoring may be necessary in certain situations (eg, after major equipment 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, estimated patient radiation dose, qualifications of personnel, and follow-up procedures.

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

IV. QUALITY CONTROL

A. Acceptance Testing

A Qualified Medical Physicist must conduct initial [...] equipment performance evaluation upon installation of the equipment and after major upgrades. This evaluation should be more comprehensive than periodic evaluation and should be completed before clinical use.

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

Acceptance testing and/or commissioning must include tests performed during the annual performance evaluation and, additionally, should include the following items [in both conventional and tomosynthesis modes if applicable]:

- 1. Test 1
 - 1. Test 1 item a if necessary
 - 2. Test 1 item b if necessary
- 2. Test 2

IV. QUALITY CONTROL

B. Equipment Performance Evaluation

The performance of each [...] system must be evaluated at least annually. At a minimum, this evaluation should include the following items [in both conventional and tomosynthesis modes if applicable]:

- 1. Checklist or Test 1
 - 1. More details as necessary

IV. QUALITY CONTROL

C. Continuous Quality Control

A continuous QC program must be implemented for all [...] systems with the assistance of a Qualified Medical Physicist. The Qualified Medical Physicist should determine the test frequency and tolerances (in conjunction with manufacturer specifications). At minimum, the QC program should include the following:

- 1. Checklist or Test 1
 - 1. More details as necessary
 - 2
- 2. Test or Item 2

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Qualified Medical Physicist

A Qualified Medical Physicist must carry out acceptance testing and performance evaluation of [...] systems.

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields of medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine (CCPM), the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education (CME)</u> [2].

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

The Qualified Medical Physicist is responsible for the test protocols, test methods, and acceptability criteria. The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining data in accordance with applicable regulations and relevant guidance (eg, AAPM medical physics practice guideline 7.a). 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 . These individuals must be properly trained and approved by the Qualified Medical Physicist such that they have knowledge about the techniques of performing tests, functions and limitations of the equipment and test instruments, reasons for the

tests, and the importance of the test results. The assisting individual shall be under the general supervision $\frac{1}{2}$ 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 [REF - AAPM 125-A].

¹ 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 must be available by phone to provide assistance and direction if 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

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 . As outlined in AAPM medical physics practice parameter 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 likely to be a valuable member of the quality management team and make the feasibility of a robust quality management program much easier.

VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775 web.pdf

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals in accordance with ALARA principles. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by applicable state, local, or other relevant regulatory agencies and accrediting bodies, as appropriate. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol, using body habitus or other customized method when such guidance is available.

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

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, 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 (https://www.acr.org/Advocacy-and-Economics/ACR-PositionStatements/Quality-Control-and-Improvement).

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Comments Reconciliation Committee

REFERENCES