The American College of Radiology, with more than 30,000 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.

Revised 2016 (CSC/BOC)*

ACR–AAPM TECHNICAL STANDARD FOR MEDICAL NUCLEAR PHYSICS PERFORMANCE MONITORING OF PET IMAGING 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. 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).

The primary goal of PET imaging is to produce quantifiably accurate images representing the biodistribution of an administered radiopharmaceutical. An additional goal is to produce images with the lowest reasonable radiation dose consistent with the clinical use of the equipment and the information requirements of the examination.

All positron emission tomography (PET) imaging equipment should be tested on installation and monitored at least annually by a Qualified Medical Physicist to ensure that it is functioning within the manufacturer’s specifications and meets accepted 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 optimize image quality and ensure the accuracy of quantitative results in clinical procedures. Key points to consider are qualifications of personnel, system performance characteristics, patient radiation dose, quantification accuracy, radiation shielding, and follow-up procedures.

The goal of this document is to provide technical standards for medical physics oversight of stand-alone PET imaging equipment. For guidance on PET/CT Equipment, please see the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment [1].

II. QUALIFICATIONS AND RESPONSIBILITIES OF A QUALIFIED MEDICAL PHYSICIST

A Qualified Medical Physicist must carry out acceptance testing and have oversight in monitoring of PET 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 Physics 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) [2]

The appropriate subfield of medical physics for this technical standard is Nuclear Medical Physics. (including medical physics certification categories of Radiological Physics, Medical Nuclear Physics and Nuclear Medicine Physics).

Certification by the American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation is also acceptable.

The Qualified Medical Physicist must be familiar with the principles of imaging physics and radiation protection; the guidelines of the National Council on Radiation Protection and Measurements (NCRP); laws and regulations pertaining to the use of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments and techniques used for testing performance.

The Qualified Medical Physicist may be assisted by properly trained individuals (eg, nuclear medicine technologists, medical physics assistants or residents) in obtaining data [3]. These individuals must be approved by the Qualified Medical Physicist in the techniques of performing tests, the function and limitations of the
imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The Qualified Medical Physicist is responsible for and should be present during initial and annual surveys and must review, interpret, and approve all data and must provide a signed report of the conclusions.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A. Acceptance Testing

Initial performance testing of imaging equipment must be performed upon installation and should be completed before clinical use. This testing should be more comprehensive than periodic performance testing and should be consistent with current acceptance testing practices [4-8].

B. Performance Evaluation

The Qualified Medical Physicist must design a quality assurance (QA) program that includes regular testing procedures to insure proper operation on a daily basis. The PET testing procedures must follow the manufacturer’s prescribed schedule and must include, at a minimum, daily quality control (QC) tests as well as quarterly scanner testing to evaluate scanner calibration, uniformity, resolution, and contrast. The QA program must be reviewed at least annually by the Qualified Medical Physicist who must be onsite at least annually.

The following characteristics should be evaluated on at least an annual basis as applicable to the design of the scanner [8,9]:

1. Spatial resolution
2. Count rate performance (count rate versus activity), including count loss correction
3. Sensitivity (cps/MBq/mL)
4. Image uniformity
5. Image quality
6. Accuracy of attenuation and scatter correction, and SUV measurement
7. Safety evaluation
   a. Mechanical
   b. Electrical

Information on typical organ doses from radiopharmaceuticals should be available for all procedures. This information must be reviewed by the Qualified Medical Physicist at least annually and updated when any of the following occur: addition of new procedures and/or pharmaceuticals, changes in dosage schedules, change in route of administration and availability of more accurate dosimetry data [9-17].

If a major component is replaced or repaired, a Qualified Medical Physicist should, in a timely manner, evaluate the need for performance testing of the PET scanner. The scope of the evaluation should be determined by the Qualified Medical Physicist based on the type of component that was replaced or repaired.

C. Quality Control Program

A QC program must be established for the PET system with the assistance of a Qualified Medical Physicist consistent with the recommendations of the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [18]. The Qualified Medical Physicist should determine tolerances, the frequency of each test and who should perform each test based on the facility and PET usage. An on-site technologist should be identified to be responsible for conducting routine QC.

The QA program and the results of the QC tests must be monitored annually by the Qualified Medical Physicist. If measured values of QC parameters fall outside the control limits, the Qualified Medical Physicist should initiate appropriate investigative or corrective actions. A Qualified Medical Physicist should be available to assist in prescribing corrective actions for unresolved problems.
D. Written Survey Reports and Follow-Up Procedures

The Qualified Medical Physicist or other qualified individual must report the findings to the physician(s), to the responsible professional(s) in charge of obtaining or providing necessary service to the equipment and, in the case of the consulting physicist(s), to the representative of the hiring party. If appropriate, the Qualified Medical Physicist should initiate the required service. Action should be taken immediately by direct verbal communication if there is imminent danger to patients or staff using the equipment due to unsafe conditions. Written survey reports must be provided in a timely manner consistent with the importance of any adverse findings. The Qualified Medical Physicist should confirm that the unit is performing in a safe and acceptable fashion as soon as possible after the required service is performed.

IV. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.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 and that they are adhered to in accordance with ALARA. 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 state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriate N ess Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

A table of organ doses must be prepared for all procedures that involve administration of radiopharmaceuticals to patients. The table must specify the dosage schedule used at the facility. All organs that receive significant doses should be included. Separate values for patient size should be tabulated where applicable. The table must be reviewed at least annually and updated when any of the following occur: addition of new procedures and/or pharmaceuticals, changes in dosage schedules, change in route of administration, and availability of more accurate dosimetry data.
V. RADIATION SHIELDING CONSIDERATIONS

Special care must be exercised regarding radiation shielding requirements for PET facility design. Appropriate shielding must be provided for patient injection/uptake rooms, PET imaging suites, and any other areas where PET radiopharmaceuticals are prepared, used, or stored. Due to the high energy of annihilation radiation used in PET, the amount of shielding materials needed to protect adjacent areas is typically much larger than that for conventional CT scanners or other diagnostic imaging modalities. A medical physicist should be consulted early in facility design planning stages so that shielding requirements can be determined and structural design issues arising from the need for large amounts of shielding can be assessed. The American Association of Physicists in Medicine Task Group #108 report “PET and PET-CT Shielding Requirements”[19] should be used as a reference in determining PET shielding requirements.

ACKNOWLEDGEMENTS

This parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (http://www.acr.org/guidelines) by the Committee on Practice Parameters and Technical Standards – Medical Physics of the ACR Commission on Medical Physics in collaboration with the AAPM.

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REFERENCES


*Practice parameters and 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 standards published before 1999, the effective date was January 1 following the year in which the parameter or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Standard
2001 (Resolution 20)
Revised 2006 (Resolution 28, 16g, 17)
Amended 2009 (Resolution 11)
Revised 2011 (Resolution 2)
Revised 2016 (CSC/BOC)