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.

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ACR-AAPM TECHNICAL STANDARD FOR MEDICAL PHYSICS PERFORMANCE MONITORING OF SPECT-CT 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 care¹. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole purpose of this document is to assist practitioners in achieving this objective.

¹ <u>Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing</u>, _____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, <u>Stanley v. McCarver</u>, 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).

Combined single-photon emission computed tomography - computed tomography (SPECT-CT) systems are primarily designed to acquire sequential SPECT and CT datasets [1]. Some of these systems are capable of being used for diagnostic CT imaging alone, whereas others have CT capabilities that are intended solely for localization and attenuation correction. In either case, a SPECT-CT system combines two medical imaging technologies: x-ray CT for anatomical imaging and attenuation correction and SPECT for molecular imaging. These systems have both the advantages and the complexities of each subsystem while providing combined anatomic and functional information in the co-registered images.

All SPECT-CT imaging equipment must be tested upon installation and monitored at least annually by a Qualified Medical Physicist to ensure proper functioning within the manufacturer's specifications and 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 to optimize image quality and ensure the accuracy of quantitative results in clinical procedures. Key points to consider are performance characteristics to be monitored, estimated patient radiation dose, qualifications of personnel, and follow-up procedures.

The primary goal of SPECT-CT imaging is to produce highly accurate co-registered SPECT and CT images on the same platform. An equally important 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 [2]. The goal of this document is to establish performance standards for medical physics oversight of SPECT-CT imaging equipment.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist must carry out acceptance testing and performance monitoring of SPECT-CT 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 <u>ACR Practice Parameter for Continuing Medical Education (CME)</u>. (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [3]

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) with continuing medical education in CT physics.

OR

Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics) with continuing medical education in nuclear medical physics.

Certification by the American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation with continuing medical education in CT physics is also acceptable.

In any case, medical physicists who are board certified in an area limited to x-ray imaging or nuclear medicine imaging are expected to obtain additional training and directed experience according to the ACR technical standards and practice parameters before representing themselves as qualified to evaluate hybrid systems [4,5].

The continuing education must include at least 15 continuing education units (CEU) in the prior 36-month period; at least half of these units should be category 1. Continuing education must include credits in nuclear medicine and in CT physics.

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 the calibration processes and limitations of the instruments and techniques used for testing performance.

The Qualified Medical Physicist is responsible for:

- 1. The design of the overall program of performance monitoring (including the selection of specific methods for acceptance testing and quality control testing)
- 2. Documentation of program goals, policies, and procedures related to performance monitoring
- 3. Documentation of the results of all performance measurements
- 4. Review and approval of all measurements performed by other designated personnel

The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining data. 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 must review, interpret, and approve all data and must provide a signed report with conclusions.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A. Acceptance Testing

Initial performance testing must be performed on newly installed imaging equipment and on existing equipment that has undergone major repair (such as a gamma camera detector replacement) or movement (such as into a different room or different facility). This testing must be performed by a Qualified Medical Physicist and should be completed before clinical use. This testing should be more comprehensive than periodic performance testing and must be consistent with current acceptance testing practices. Electrical safety and digital image communication of the equipment must also be tested by appropriate personnel before initial acceptance testing.

Acceptance tests must include:

- 1. Compliance with local regulatory requirements
- 2. Compliance with special contractual terms
- 3. Compliance with manufacturer's specifications
- 4. Evaluation of shielding (eg, CT shielding, radioactive materials shielding)
- 5. Tests performed during the performance evaluation
- B. Performance Evaluation

The performance of each SPECT-CT unit, performance of displays used for image interpretation, and radiation dose assessment must be monitored at least annually by a Qualified Medical Physicist.

1. Characteristics to be monitored for SPECT

The performance evaluation of the SPECT subsystem should be based on the <u>ACR-AAPM Technical</u> <u>Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras</u> [6]. Similar manufacturer-specific performance measurements may be substituted. The performance evaluation typically includes the following:

Planar and SPECT image quality (as applicable to the design of the scanner)

- a. Intrinsic uniformity
- b. System uniformity with all commonly used collimators
- c. Intrinsic or system spatial resolution/linearity
- d. System sensitivity
 - i. Count rate per unit activity
 - ii. Interdetector variability
- e. Energy resolution
- f. Count rate performance
- g. Overall system performance for SPECT
 - i. Uniformity
 - ii. Contrast
 - iii. Spatial resolution
- h. System interlocks
- i. Safety evaluation
 - i. Mechanical
 - ii. Electrical
- 2. Characteristics to be monitored for CT

The performance evaluation of the CT components should be based on the <u>ACR-AAPM Technical</u> <u>Standard for Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment</u> [7]. The performance evaluation typically includes the following:

- a. Review of clinical protocols
- b. Scout prescription and alignment light accuracy
- c. Image thickness
- d. Table increment accuracy
- e. Radiation beam width
- f. Low contrast performance
- g. Spatial resolution
- h. CT number accuracy
- i. Artifact evaluation
- j. CT number uniformity
- k. Radiation output or dosimetry
- 1. Safety evaluation
 - i. Visual inspection, audible and visual signals, and posting requirements
 - ii. Scatter and stray radiation measurements
 - iii. Workload assessment, if workload and other related parameters have changed since acceptance testing
- m. Tests required by state and/or local regulations
- n. Other tests as described in AAPM Report 74 [8] and other publications [9,10]

There are CT components of hybrid systems that are not in conventional rotational CT systems, or they may incorporate a very low-power x-ray tube, a rotational cone beam system with a flat-panel x-ray detector, or a photon-counting gamma detector system. Consequently, some of the performance measurements identified in the technical standard may not apply to them. Similar manufacturer-specific performance measurements may be substituted.

3. Specific tests for SPECT-CT in combination

The performance of the combined system should be monitored at least annually by a Qualified Medical Physicist. This evaluation should include the following:

- a. Accuracy of co-registration of SPECT and CT images. To evaluate co-registration, specially designed phantoms are scanned on both SPECT and CT subsystems. The evaluation should also be performed after any major changes that might affect co-registration [2].
- b. Total system SPECT-CT performance should be evaluated by scanning a SPECT phantom, including CT following a typical clinical protocol. The protocol may include CT attenuation correction, scatter correction, and iterative reconstruction algorithms.
- c. Gray-level performance of SPECT-CT acquisition display monitors, and image processing monitors if applicable.
- 4. Evaluation of displays and viewing conditions used for image interpretation in which access is available
 - a. Display monitor luminance
 - b. Hardcopy printers, if used for primary interpretation
 - c. Viewing conditions, including illuminance and monitor cleanliness if used for primary clinical interpretation
- 5. Radiation output or dosimetry:
 - a. CT
 - i. The Qualified Medical Physicist should measure the CT dose indices (CTDI) or other established CT dose metrics. Refer to manufacturer dose measurement procedure for nonconventional CT.
 - ii. Review pediatric protocols to include age and weight considerations if pediatric patients are scanned with the system.
 - iii. Report CTDI_{vol} or other established CT dose metrics for representative examinations [11].
 - iv. CT dose levels should be compared to appropriate guidelines or recommendations when they are available. See the <u>ACR-AAPM-SPR Practice Parameter for Diagnostic Reference Levels and</u> <u>Achievable Doses in Medical X-Ray Imaging</u> [12]. The dose from low-dose CT protocols for attenuation correction and image registration may be one-third or lower than that of standard reference levels.
 - b. SPECT
 - i. The Qualified Medical Physicist should ensure that a table is available, listing radiopharmaceuticals and typical administered activities for all procedures commonly performed at the facility. Separate values for patient size and gender should be tabulated when applicable.
 - ii. The table should be reviewed by the Qualified Medical Physicist at least annually and updated when any of the following occur: 1) addition of new procedures and/or radiopharmaceuticals, 2) change in radiopharmaceutical dosage schedules, 3) change in route of administration, and 4) availability of more accurate dosimetric data.
- C. Quality Control Program

A continuous quality control (QC) program must be established by the Qualified Medical Physicist and implemented for all SPECT-CT units. The Qualified Medical Physicist should determine tolerances, the frequency of each test, and who should perform each test based on the facility and SPECT-CT usage. Appropriately trained on-site technologists must be identified to be responsible for conducting routine QC. The program should be consistent with the recommendations of the <u>ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals</u> [13] and the <u>ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment</u> [7,14]. In addition, it is recommended that the QC program includes:

- 1. Quarterly testing of the SPECT subsystem with a 3-D phantom for uniformity, resolution, and contrast
- 2. Other testing as recommended by the manufacturer

The Qualified Medical Physicist should periodically monitor the results of the QC program. If measured values of QC parameters fall outside the control limits, the Qualified Medical Physicist should initiate appropriate investigative or corrective actions. The Qualified Medical Physicist should be available to assist in recommending corrective actions for unresolved problems.

In addition, regular preventive maintenance should be performed and documented by an equipment service engineer following the recommendations of the equipment vendor.

D. Written Survey Reports and Follow-Up Procedures

The Qualified Medical Physicist must provide a 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 physician(s). Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

If appropriate, the Qualified Medical Physicist 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 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.

If use of the equipment would pose a danger to life or health or potentially result in erroneous clinical findings, the Qualified Medical Physicist in collaboration with the facility's Radiation 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. 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/Publ578_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 <u>Appropriateness Criteria</u>[®], 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 (<u>www.imagegently.org</u>) and Image Wisely[®] for adults (<u>www.imagewisely.org</u>) 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).

V. RADIATION SHIELDING CONSIDERATIONS

Special consideration must be given to radiation shielding requirements for SPECT-CT facility design. Shielding requirements should be evaluated by a Qualified Medical Physicist for all areas where radiopharmaceuticals or radioactive materials and wastes are prepared, used, or stored. An evaluation must be performed any time there is a change to the equipment in the room, a change of the physical layout of the immediate area, or when significant alterations to work processes occur.

The presence of the CT component may add additional shielding requirements not typically encountered in a nuclear imaging suite; therefore, special attention must be given to these requirements. A Qualified Medical Physicist should be consulted early in facility design planning stages so that shielding requirements can be determined and structural design issues resulting from the use of appropriate amounts of shielding can be assessed. The NCRP Report #147 [15] should be used as a reference in determining CT-specific shielding requirements.

A Qualified Medical Physicist should be consulted early in facility design planning stages so that shielding requirements can be determined and structural design issues, created from using the larger amounts of shielding, can be assessed.

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