ACR-AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF COMPUTED TOMOGRAPHY (CT) 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.

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

The performance of all computed tomography (CT) equipment used for diagnostic imaging, whether it is part of a hybrid system (eg, positron emission tomography [PET/CT] or single-photon emission computed tomography [SPECT/CT]) or is a stand-alone system, must be evaluated upon installation to verify that it complies with manufacturer specifications and federal and local regulations and must be monitored periodically, the frequency depending on the complexity and intended use of the equipment (excludes dental and interventional cone beam CT).

Monitoring should be done at least annually, or more often if required by state or local regulatory agencies, by a Qualified Medical Physicist to ensure that the equipment is functioning properly and the patients do not receive unnecessary radiation dose. Additional or more frequent monitoring may be necessary after repair or service (see section III.B.2) that might change the performance of the equipment, the image quality, or the radiation exposure to patients or personnel.

Although it is not possible to consider all possible variations of equipment performance to be monitored, adherence to this technical standard will assist in optimizing image quality and patient radiation dose [1-5]. Key points to consider are performance characteristics to be monitored, patient radiation dose, qualifications of personnel, and follow-up procedures.

The goals are 1) to produce optimal-quality diagnostic images using a dose consistent with the clinical use of the equipment and the information requirement of the examination and 2) to evaluate system performance and adherence to manufacturer performance standards or regulatory requirements at acceptance or as part of periodic constancy testing.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist must carry out acceptance testing and monitoring of CT equipment.

A Qualified Medical Physicist is an individual who is competent to practice independently in 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 in 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, 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>. [6]

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)

A Qualified Medical Physicist must be responsible for acceptance testing, routine performance evaluation, and providing support and consultation regarding the optimization of dose and image quality on the equipment. Understanding the relationship between image quality and patient radiation dose is essential for proper medical physics support.

The Qualified Medical Physicist must be familiar with:

- 1. Principles of imaging physics and of radiation protection.
- 2. The guidelines and recommendations of widely recognized authoritative bodies (such as the AAPM and the

National Council on Radiation Protection and Measurements [NCRP]).

- 3. Laws and regulations pertaining to the equipment being tested.
- 4. Standards of accrediting bodies pertaining to the equipment being tested.
- 5. The function, clinical uses, and performance specifications of the imaging equipment.
- 6. Calibration processes and limitations of the instruments used for testing performance.

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 where appropriate (eg, AAPM medical physics practice guideline 7.a [7]). These individuals must be properly trained and approved by the Qualified Medical Physicist such that they have knowledge about the techniques of performing tests, function and limitations of the imaging equipment and test instruments, reasons for the tests, and the importance of the test results. The assisting individual must be under the direct supervision [8] of the Qualified Medical Physicist during initial and annual 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 [9].

² For the purpose of this standard, direct supervision means that the Qualified Medical Physicist must be present and immediately available to furnish assistance and direction throughout the performance of the survey. It does not mean that the Qualified Medical Physicist must be present in the room where the procedure is performed.

III. PERFORMANCE CHARACTERISITICS TO BE MONITORED

The monitoring of performance characteristics of CT equipment [1,5,10,11] must be implemented as described below and in accordance with federal, state, and local regulations.

III. PERFORMANCE CHARACTERISITICS TO BE MONITORED

A. Acceptance Testing

Prior to initial physics testing, electrical safety, room conditions (eg, temperature and humidity), and digital image communication must be verified by appropriate personnel.

Initial performance testing of imaging equipment must be performed by a Qualified Medical Physicist and must be completed before clinical use. Time must be made available for the Qualified Medical Physicist to perform the initial performance testing.

Acceptance tests must include:

- 1. Compliance with local regulatory requirements
- 2. Compliance with special contractual terms
- 3. Evaluation of compliance with manufacturer's specifications as relevant
- 4. Evaluation of room radiation shielding, if not performed and documented previously
- 5. Tests performed during the annual performance evaluation

III. PERFORMANCE CHARACTERISITICS TO BE MONITORED

B. Performance Evaluation

- 1. Equipment performance and patient dosimetry must be evaluated for each CT system at least annually. This evaluation, at a minimum, must include the following as applicable to the design of the CT scanner and be completed using clinically relevant protocols:
 - a. Alignment light accuracy
 - b. Image localization from scanned projection radiograph (localization image)
 - c. Table travel accuracy
 - d. Radiation beam width

- e. Image quality
 - i. High-contrast (spatial) resolution
 - ii. Low-contrast detectability
 - iii. Image uniformity
 - iv. Noise
 - v. Artifact evaluation
 - vi. CT number accuracy
 - vii. Acquisition workstation display quality
- f. Radiation output or dosimetry [10,12]
 - i. Measurement and comparison to baseline of radiation output of the CT scanner (CTDIvol, CTDI100, CTDI_{free, air}, or Equilibrium Dose-Pitch Product [measured in phantom or in air]) at all available tube potentials. For some scanners, it may be appropriate to include output measurements for clinically relevant filter/scan field of view (SFOV) selections using at least one tube potential.
 - ii. Comparison of calculated values to scanner-reported values. These comparisons should include both 16-cm and 32-cm dosimetry phantoms or measurements in air, as appropriate for the CT system and for use with the indicated protocols and must comply with tolerances identified in manufacturer accompanying documents as well as requirements of relevant accrediting bodies and/or local regulations.
- g. Safety evaluation
 - i. Inquire whether workload and other related parameters have significantly changed since acceptance testing. If so, a review of shielding adequacy may be necessary.
- h. Visual inspection
 - i. Audible/visual signals
 - ii. Posting requirements
 - iii. Dose reporting requirements
 - iv. Validation of DICOM communication setup and transmission of RDSRs when available [13]
- i. Other tests as required by relevant regulatory and accrediting bodies (such as geometric accuracy)

Operational performance evaluation and clinical optimization of CT systems may warrant further characterization of certain advanced features, such as tube current modulation, scanner-assisted tube potential selection, iterative or deep learning-based reconstruction configuration/settings, multi-energy CT acquisition configurations, and multi-energy CT image reconstruction and postprocessing options. Furthermore, more objective measures of image quality, such as task transfer function (TTF), slice sensitivity profiles, and noise power spectrum, can be made with freely available software. Such measurements better quantify scanner acquisition and reconstruction performance and provide valuable insights when tracked over time. These quantitative metrics also facilitate cross-scanner and cross-protocol comparisons. Suggested testing procedures that could be used to evaluate these features have been described in AAPM Report 233 [14] and other publications. Their incorporation into routine performance evaluation is at the discretion of the Qualified Medical Physicist.

2. Monitoring required after replacement or repair of a major component

If a major component is replaced or repaired, a Qualified Medical Physicist must, in a timely manner, evaluate the need for performance testing of the CT 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. Major repairs that must involve participation or oversight by the Qualified Medical Physicist include X-ray tube replacement, high voltage generator replacement, detector assembly replacement, and tube current/tube potential (mA/kV) modulation modification. Software upgrades can affect scanner performance and dose, and therefore, the Qualified Medical Physicist should communicate with the manufacturer to determine potential impact and test accordingly.

III. PERFORMANCE CHARACTERISITICS TO BE MONITORED

C. QUALITY CONTROL PROGRAM

A continuous quality control (QC) program must be established for all CT systems with the assistance of a Qualified Medical Physicist. The Qualified Medical Physicist must determine tolerances in conjunction with manufacturer specifications, and the frequency of each test based on the facility and CT usage. An on-site radiologic technologist should be identified to be responsible for conducting routine QC.

The QC program should minimally include the following:

- 1. Water CT number accuracy
- 2. Noise (CT number standard deviation)
- 3. Artifact evaluation for axial mode for head and body scan FOVs as practical
- 4. Display device performance
 - a. Acquisition workstation
 - b. Hard-copy display unit(s), if used for patient images
- 5. Visual checklist

The results of the QC program must be reviewed at least annually by the Qualified Medical Physicist. If measured values of QC parameters fall outside the established tolerances, the QC technologist should consult with the Qualified Medical Physicist. The Qualified Medical Physicist should recommend or, when appropriate, initiate investigative or corrective actions. A Qualified Medical Physicist should be available to assist in prescribing corrective actions for unresolved problems.

III. PERFORMANCE CHARACTERISITICS TO BE MONITORED

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) 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 must 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. In some cases, it may be appropriate for the Qualified Medical Physicist to make specific 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, 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.

III. PERFORMANCE CHARACTERISITICS TO BE MONITORED

E. Protocol Review and Quality Assurance

The Qualified Medical Physicist must review a selection of the most commonly used protocols during the annual equipment performance evaluation. These should include head and abdomen protocols for adult and pediatric patients as applicable to the facility's practice. In addition, facility protocols for screening procedures and potentially high-dose procedures (eg, brain perfusion) should be reviewed [15-17]. The review should take into account key technical and clinical elements associated with image quality and patient dose. These should include, but are not limited to [2,18-20]:

- Tube voltage and filtration as applicable (eg, Sn filter)
- Tube current (mA or mAs as appropriate)

- · Rotation time
- Detector configuration
- Pitch (if scan mode is helical)
- Appropriate FOV for acquisition and reconstruction
- Reconstructed image thickness
- Appropriate use of automated settings, such as tube current modulation and tube voltage and filtration selection
- Other image reconstruction parameters, such as reconstruction kernels for filtered backprojection and advanced image reconstruction algorithm settings
- Appropriateness of CTDI_{vol} DLP, SSDE, or other relevant dose indices as compared to established reference values

The Qualified Medical Physicist must be involved with reviewing clinical protocols and keeping them current, in coordination with the interpreting physician(s), the imaging technologist(s), and other member(s) of the care team as needed.

The Qualified Medical Physicist should periodically audit occurrences when patient radiation dose indices fall outside facility-established ranges or when clinical image quality does not meet facility standards. In addition, the Qualified Medical Physicist should be consulted during the development of quality improvement actions.

IV. 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

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.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

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).

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Writing Committee - members represent their societies in the initial and final revision of this technical standard

<u>ACR</u> <u>AAPM</u>

Gregory J. Anthony, PhD, Co-Chair Frank Dong, PhD

Douglas E Pfeiffer, MS, FACR, Co-Chair Zhihua Qi, PhD

Maxwell R. Amurao, PhD, MBA Mark P. Supanich, PhD

Marthony Robins, PhD, BS

Committee on Practice Parameters and Technical Standards – Medical Physics

(ACR Committee responsible for sponsoring the draft through the process)

Mary Ann Keenan, DMP, Chair Samuel A. Einstein, PhD

Maxwell R. Amurao, PhD, MBA Per H. Halvorsen, MS, FACR

Katherine P Andriole, PhD Ralph P. Lieto, MS, FACR

Eric Arthur Berns, Ph.D, FACR Osama Mawlawi, PhD, FACR

Priscilla F. Butler, MS, FACR Tariq A. Mian, PhD, FACR

Diana E. Carver, PhD Douglas E. Pfeiffer, MS, FACR

Heidi A. Edmonson, PhD Ashley Erin Rubinstein, PhD

Mahadevappa Mahesh, MS, PhD, FACR, Chair, Commission on Medical Physics

David B. Larson, MD, MBA, Chair, Commission on Quality and Safety

Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

William F. Sensakovic, PhD, Chair Paul A. Larson, MD, FACR

K. Elizabeth Hawk, MD, MS, PhD, Co-Chair Shuai Leng, PhD

Mahadevappa Mahesh, MS, PhD, FACR

Gregory Anthony, PhD Rebecca Milman, PhD

Timothy J. Blackburn, PhD Mary S. Newell, MD, FACR

Timothy A. Crummy, MD, FACR Jessica L. Nute, PhD

Frank Dong, PhD Douglas E. Pfeiffer, MS, FACR

Mary Ellen Jafari, MS, FACR Zhihua Qi, PhD

David W. Jordan, PhD Marthony Robins, PhD, BS

Mary Ann Keenan, DMP Naimuddin Shaikh, PhD

Robert J Kobistek, MS Mark P. Supanich, PhD

Amy L. Kotsenas, MD, FACR James Tomlinson, MS, FACR

Janaki Krishnamoorthy, PhD David L. Vassy Jr., MS, FACR

David B. Larson, MD, MBA Roland Wong, ScM

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*As of May 2015, all practice parameters and technical standards that are collaborative with only the American Association 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.

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