ACR-AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF RADIOGRAPHIC 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 lowa Society of Anesthesiologists v. lowa Board of Nursing, 831 N.W.2d 826 (lowa 2013) lowa 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 the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

The performance of all radiographic equipment, whether a stand-alone system or part of a hybrid radiographic/fluoroscopic system, must be evaluated upon installation and should be monitored at least annually. The goal of this document is to establish standards for the performance of radiographic X-ray equipment to maintain the highest-quality diagnostic image at the lowest reasonable radiation dose consistent with the intended use of the equipment and the requirements of the clinical examination. Additional or more frequent evaluation may be necessary after repairs that might change the imaging performance of the equipment or the radiation exposure to patients or personnel. Adherence to this technical standard will assist in optimizing image quality and patient radiation dose.

In the context of this document, "designated use(s)" means specific clinical use(s) of an individual X-ray system designated by the facility (eg, chest radiography, upper gastrointestinal with small-bowel follow-through). The facility's designated use should be within the stated intended use by the manufacturer as provided in their accompanying documents [1]. This technical standard does not apply to dental or mammographic units.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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 (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)

A qualified medical physicist must be responsible for acceptance testing, routine performance and evaluation, and the technical aspects of radiographic procedures. Those responsibilities should be clearly defined (see Section III).

Understanding the relationship between image quality and patient radiation dose is essential for proper performance evaluation of equipment. The qualified medical physicist must be familiar with the principles of imaging physics and radiation protection; the current guidelines of the National Council on Radiation Protection and Measurements (NCRP); federal and local laws and regulations pertaining to the performance of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments used for testing performance.

The qualified medical physicist is responsible for developing the test methods and setting appropriate acceptability criteria. The qualified medical physicist may be assisted by other properly trained individuals in obtaining test data for performance evaluation. These individuals must be properly trained and approved by the qualified medical physicist in the test methods, function and limitations of the imaging equipment and test instruments, reasons for the tests, and importance of the test results. The tests must be performed by or under appropriate supervision of the qualified medical physicist according to local regulatory requirements and/or facility policies and procedures. The Qualified Medical Physicist is responsible for and must review, interpret, and approve all data and provide a signed report [3].

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A qualified medical physicist's monitoring of performance characteristics must comply with appropriate federal,

state, and local regulations.

A. Acceptance Testing

Prior to acceptance testing, electrical safety and digital image communication must be verified by appropriate personnel.

Acceptance testing of imaging equipment must be performed before clinical use. The evaluation should include all tests performed during the periodic performance evaluation and must verify:

- 1. Compliance with regulatory requirements
- 2. Compliance with contractual terms
- 3. Agreement with applicable manufacturer's specifications

Thorough testing of the radiographic imaging chain during acceptance testing provides information necessary for clinical use and establishes baseline measurements for future quality control (QC) checks. A critical issue is the development and/or validation of imaging acquisition protocols and consideration of image processing. This task should be carried out at the time of equipment acceptance testing by a multidisciplinary team composed of 1) the qualified medical physicist, 2) the interpreting physician(s), 3) the radiologic technologists, 4) the manufacturer's representative, 5) the service engineer, if one is available, and 6) an information technology specialist.

A table that lists the recommended parameters to be evaluated during acceptance testing for radiographic equipment is presented in Appendix A. The parameters are written in general terms, with additional guidance provided as applicable. The qualified medical physicist responsible for acceptance testing may modify the table and the extent of the measurements depending on the designated use(s) of the radiographic equipment. Measurement methods and criteria are given in multiple reports [1,4-7].

B. Performance Evaluation

After acceptance testing, the performance of each radiographic system should be evaluated at least annually or upon replacement/repair of a major component or upon change of designated use that may affect the image quality or the patient or staff radiation dose. Equipment performance and usage may necessitate increased periodic testing. The table in Appendix A lists the recommended parameters to be evaluated during annual performance evaluation for radiographic equipment. For further information on computed radiography (CR) and digital radiography (DR) systems please see the ACR-AAPM-SIIM-SPR Practice Parameter for Digital Radiography [8].

C. Quality Control Program

A continuous QC program must be implemented for all radiographic units. The QC program should be established by the facility with the assistance of the qualified medical physicist and should include, but not be limited to, the QC tests listed in Appendix A. The facility should identify the person(s) responsible for performing the tests, and the qualified medical physicist may choose to modify the frequency of testing based on the system's complexity, usage, and performance. The qualified medical physicist should periodically review and approve the QC program data.

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 responsible physician(s), and, if appropriate, to the professional(s) in charge of obtaining or providing necessary service to the equipment. If authorized and within their scope, the qualified medical physicist should initiate any required service. Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

If use of the equipment would pose an undue risk to patients or staff, the qualified medical physicist must

immediately communicate this risk to appropriate medical staff or the facility's radiation safety officer (RSO) to either prevent or limit its use until the equipment hazard is addressed.

¹ Equipment cannot be used for clinical purposes without the FDA mandated installation report being completed (<u>Assembler's Guide to Diagnostic X-Ray Equipment Form FDA 2579</u>).

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).

Routine imaging protocols must be evaluated for appropriate image quality. Radiation dose levels must be compared with appropriate guidelines [9]. The qualified medical physicist should assist facilities in understanding and developing policies and procedures to evaluate risks to patients, personnel, and physicians from radiographic studies. The qualified medical physicist may assist the RSO in evaluating the radiation risks to occupationally exposed individuals as well as members of the public who may be affected by the radiographic equipment, which can include radiation shielding calculations, scatter surveys, and integrity evaluations.

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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.

<u>Development Chronology for this Technical Standard</u>

1992 (Resolution 11)

Amended 1994 (Resolution 13)

Revised 1997 (Resolution 17)

Revised 2001 (Resolution 18)

Revised 2006 (Resolution 29, 16g, 17)

Amended 2009 (Resolution 11)

Revised 2011 (Resolution 4)

New 2016 (CSC/BOC) – previously part of the joint Rad-Fluoro document

Revised 2021 (CSC/BOC)

Amended 2022 (Resolution 41f)

Amended 2023 (Resolution 2c, 2d)

APPENDIX A

Radiographic Equipment Performance Evaluation

The recommended parameters to be evaluated by the Qualified Medical Physicist (as applicable) are listed below, with designations for acceptance testing, performance evaluation, and quality control.

Parameter	Acceptance Testing	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
Mechanical and system safety evaluation	Υ	Υ	Υ	eg, All mechanical parts move smoothly, without obstructions. Unit is mechanically stable, image receptor properly fits into holder assembly. All electrical wiring is secured as designed and undamaged. All system protective coverings are

Parameter	Acceptance Testing	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
				intact. *Emergency power switches
Functionality of all system indicators, and interlocks	Υ	Υ	Υ	eg, SID indicator accuracy, x-ray tube detents, visual and audible signal during image acquisition, room x-ray warning signs are operational
Radiation protection equipment	Υ	Υ	Υ	eg, as applicable, operator is appropriately shielded or has access to appropriate shields, appropriate patient shields are available
Acquisition display monitor(s) performance	Y– quantitative and visual assessment	Y – quantitative and visual assessment	Y– visual assessment	eg, uniformity, L _{min} , and L _{max}
**Appropriateness of adult protocols	Y – for most common uses	Y – for most common uses	N	See <u>radiologyinfo.org</u> and the ACR Appropriateness Criteria [®] [9]
**Appropriateness of pediatric protocols	Y – for all designated uses	Y – for most common uses	N	See ACR Appropriateness Criteria® and www.imagegently.org [9]
Grid(s) properly focused without apparent gridlines in the image	Y	N	N	
Accuracy of the displayed radiation field size	Υ	Υ	N	
Radiation beam centering and light field congruence	Υ	Υ	N	

Parameter	Acceptance Testing	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
Positive Beam Limitation (PBL) functionality	Y	Y	N	
X-ray field and image receptor alignment	Y	Y	N	
Air kerma or exposure (radiation output)	Y	Υ	N	eg, mGy/mAs @ 100cm from the focal spot at a given kVp
Accuracy of the displayed radiation metrics	Υ	Υ	N	eg, Dose Area Product (DAP)/Air kerma Area Product (P _{KA}) [10] Image receptor exposure index (EI)
Exposure reproducibility	Υ	Υ	N	
Tube potential (kVp) accuracy and reproducibility	Υ	Y	N	
Linearity of exposure versus mA or mAs	Υ	Υ	N	
Timer accuracy	Y	Υ	N	
Minimum beam quality (half-value layer)	Υ	Υ	N	
Radiographic patient entrance exposure for a "typical" adult patient and a "typical" pediatric patient if applicable	Υ	Υ	N	At a minimum chest abdomen and lumbar spine [9]
Automatic exposure control (AEC)	Υ	Υ	N	eg, backup timer, sensor verification and balance, reproducibility, thickness tracking
Image quality: system high contrast spatial resolution	Y	Y	N	Use appropriate test tools or phantom and

Revised 2021 (CSC/BOC) Parameter	'	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
				software
Image quality: system low contrast resolution	Υ	Y		Use appropriate test tools or phantom and software
Image quality: flat-field artifact evaluation	Y	Y	Υ	
Repeat analysis	N	Y	Υ	QMP review at performance evaluation, if available
Vendor recommended QC (if applicable)	Y	Υ	Y	eg, detector calibrations

^{*}When testing the emergency off switch, it is recommended a service engineer be present.

^{**}Protocols should be evaluated prior to clinical patient imaging. Commissioning of X-ray equipment for clinical use may be subject to local or state regulations.