

ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF FLUOROSCOPIC EQUIPMENT

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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 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 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 *Iowa 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 the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

Fluoroscopy is a technique that provides real-time x-ray imaging that is especially useful for guiding a variety of diagnostic and interventional procedures. Equipment may consist of conventional fluoroscopic units mainly used in diagnostic radiology departments; bi-plane or C-arm systems used for cardiac, neurological, and vascular interventions; and mobile C-arm and mini C-arm machines mostly used in surgery and orthopedics. Some of the

new fluoroscopic systems have 3-D and 4-D reconstruction capabilities. Equipment operating outside radiology departments, such as surgery, cardiology, urology, orthopedics, obstetrics and gynecology, gastroenterology, physiatry and pain management clinics [1], are subject to the same performance evaluation criteria. Fluoroscopic units used in the diagnosis and follow-up of patients who have undergone radiation therapy are also considered in this standard. Equipment used in radiation therapy rooms for image-guided radiation therapy (IGRT) that have a fluoroscopy component or fluoroscopes used for radiation therapy treatment planning are not considered in this standard. Performance standards for these types of systems are addressed in [ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of Image-Guided Radiation Therapy \(IGRT\)](#) [2].

The performance of all fluoroscopic equipment, whether a stand-alone system or part of a hybrid radiographic/fluoroscopic system, must be evaluated upon installation and monitored at least annually by a qualified medical physicist. The goal is to establish and maintain performance standards that will result in the highest-quality diagnostic image at the lowest reasonable radiation dose consistent with the designated use of the equipment and the information requirement of the 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, cardiac catheterization, neurointerventions, orthopedic surgeries, etc). The facility should ensure that the designated use of the equipment matches the intended use or indications for use found in the manufacturer/vendor-supplied user manual or on the FDA website [3].

II. QUALIFICATIONS AND RESPONSIBILITIES OF A QUALIFIED MEDICAL PHYSICIST

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 [ACR Practice Parameter for Continuing Medical Education \(CME\)](#). [4]

The appropriate subfield of medical physics for this technical 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 fluoroscopic procedures. Those responsibilities should be clearly defined (see Section III).

Understanding of the relationship between image quality and patient radiation dose is essential for the 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) and the International Commission on Radiological Protection; federal and local laws and regulations pertaining to the performance of the equipment being tested; current requirements of accrediting organizations, such as The Joint Commission; 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 the test protocols, the test methods, and the acceptability criteria. The qualified medical physicist may be assisted by other properly trained individuals in obtaining test data for performance monitoring. These individuals must be properly trained and approved by the qualified medical physicist in the techniques of performing the 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 tests will 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 [5].

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

The qualified medical physicist's monitoring of performance characteristics must comply with all appropriate 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 use². The evaluation should include all of the tests performed during the periodic performance evaluation and must verify the following:

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

Thorough testing of the fluoroscopic imaging chain during acceptance testing provides information necessary for clinical use and establishes baseline measurements for future quality control (QC) checks [6-8]. A critical issue, especially in interventional radiology and pediatric fluoroscopy, is the development and/or validation of patient imaging protocols, a task that should be carried out at the time of equipment acceptance testing by a multidisciplinary team composed of the 1) qualified medical physicist, 2) the manufacturer/vendor's representative, 3) the user physician(s) performing the fluoroscopic procedures, 4) the radiologic technologists, and 5) the service engineer, if one is available. If the images are going to be part of a PACS, an information technology specialist may also be part of this multidisciplinary team.

Fluoroscopic systems may be used to image pediatric patients in addition to adult patients. The qualified medical physicist should ensure that fluoroscopes that may image pediatric patients are as carefully configured for the smallest pediatric patient to be examined as they are for small- to large-sized adult patients [9].

A table listing the recommended parameters to be evaluated during acceptance testing for fluoroscopic 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 select an appropriate subset of parameters to be assessed or modify the extent of the measurements depending on the designated use(s) of the fluoroscopic equipment. Measurement methods and criteria are given in multiple reports [10-19]. Digital image communication and the storage of dose indices should also be verified [18].

B. Performance Evaluation

After acceptance testing, the performance of each fluoroscopic system must be evaluated at least annually and upon change of designated use or replacement/repair of a major component that may affect the image quality, patient radiation dose, or personnel (staff) irradiation. A periodic review of clinical data should be performed to assess the appropriateness of protocols and to help determine the most clinically relevant modes to test during performance evaluations. These evaluations should include all modes of operation including fluoroscopy, digital acquisition, and volumetric imaging.

The table in Appendix A also lists the recommended parameters to be assessed during performance evaluation for fluoroscopic equipment. The qualified medical physicist may repeat some of the evaluations performed at acceptance testing as part of the periodic performance evaluation.

C. Quality Control Program

A continuous QC program should be implemented for all fluoroscopic systems. The program should be established with the assistance of the qualified medical physicist and should identify the individual or job role responsible for performing the tests. 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. The QC program should include, but

not be limited to, the QC tests listed in Appendix A.

A regular review of radiation dose indices and a comparison with guidelines is recommended as part of a comprehensive QC program [20].

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 appropriate, the qualified medical physicist should initiate the 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 to either prevent or limit its use until the equipment hazard is addressed.

² Equipment cannot be used for clinical purposes without the FDA mandated installation report being completed ([Assembler's Guide to Diagnostic X-Ray Equipment Form FDA 2579](#)).

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 [ACR's Appropriateness Criteria](#)[®], 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).

All applicable sections of the [ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](#) [21] must be implemented. The qualified medical physicist should assist facilities in understanding and developing policies and procedures to evaluate risks to patients, personnel, and physicians from studies and interventions requiring prolonged radiation exposure [12]. The qualified medical physicist may assist the radiation safety officer in evaluating the radiation risks to occupationally exposed individuals as well as members of the public who may be affected by the fluoroscopic equipment, which can include radiation shielding calculations, scatter surveys, and radiation shielding integrity evaluation.

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Writing Committee – members represent their societies in the initial and final revision of this practice parameter

Comments Reconciliation Committee

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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.

Development Chronology for this Technical Standard

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