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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 DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF FLUOROSCOPIC 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 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 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, mobile C-arm and mini C-arm machines mostly used in surgery and orthopedics. Some of the new fluoroscopic systems have 3-dimensional (3D) and 4-dimensional (4D) reconstruction capabilities. Equipment operating outside radiology departments such as surgery, urology, orthopedics, obstetrics and gynecology, gastroenterology, psychiatry and pain management clinics [1] is subject to the same performance evaluation criteria. Fluoroscopic units used in the diagnosis and follow up of radiotherapy patients are also considered in this standard. Equipment used in radiotherapy rooms for image-guided radiotherapy (IGRT) that have a fluoroscopy component or fluoroscopes used for radiotherapy treatment planning are not. Performance standards for this type of systems have been 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 it is part of a hybrid system (radiographic/fluoroscopic) or is a stand-alone system – must be evaluated upon installation to check that it complies with manufacturer specifications and federal and local regulations and must be monitored periodically, the frequency depending on the complexity of the equipment and the potential impact of the clinical procedure. Performance evaluation should be done at least annually by a Qualified Medical Physicist to ensure that the equipment is functioning properly and that patients are not exposed to unnecessary doses of radiation. Additional or more frequent evaluations may be necessary after repairs that might change the imaging performance of the equipment 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 both image quality and patient radiation doses.

The goal is to establish and maintain performance standards which will result in diagnostic or interventional studies with the appropriate quality diagnostic image at the lowest reasonable radiation dose consistent with the designated use of the equipment and the information requirement of the examination.

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, neuro-interventions, uterine fibroid embolization, etc). The facility designated use should be included in the supplier’s intended use list for that individual system.

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, 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) [3]

The appropriate subfield of medical physics for this technical standard is Diagnostic Medical Physics. (Previous medical physics certification including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

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 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 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 the general supervision of the Qualified Medical Physicist, who is responsible for and must review, interpret, and approve all data and provide a signed report.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

The Qualified Medical Physicist's monitoring of performance characteristics must comply with appropriate federal, state and local regulations.

A. Acceptance Testing

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

Initial physics testing of imaging equipment should be performed upon installation and before clinical use and must be performed no later than 30 days after first use ², and should include all of the tests performed during the periodic performance evaluation. Acceptance tests must verify:

Compliance with local regulatory requirements

1. Compliance with special contractual terms
2. Compliance with manufacturer's specifications

Thorough testing of the fluoroscopic imaging chain during acceptance testing provides information necessary for clinical use and establishes base-line measurements for future quality control (QC) checks [4-6]. 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 Qualified Medical Physicist, the manufacturer's representative, the imaging physician(s) who is (are) going to be doing the fluoroscopic procedures, the radiologic technologists and the local service engineer, if one is available. If the images are going to be part of a picture archiving and communication system (PACS), an information technology specialist may also be part of the imaging acquisition protocols.

Fluoroscopic systems may be used to image pediatric patients in addition to adult patients. The Qualified Medical Physicist should ensure that fluoroscopes which may image patients less than 12 years of age are as carefully configured for the smallest pediatric patient that will be examined as they are for small to large sized adult patients [7].

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](#)).

A table which lists 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 modify the table and the extent of the measurements depending on the designated use(s) of the fluoroscopic equipment. Measurement methods and criteria are given in [8-13].

B. Performance Evaluation

After acceptance testing, the performance of each fluoroscopic system must be evaluated periodically, at least annually, upon replacement/repair of a major component, or upon change of designated use that may affect the image quality, patient radiation dose, or personnel (staff) irradiation. This evaluation should include all modes of operations including fluoroscopy, 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 must be implemented for all fluoroscopic systems. The program should be established with the assistance of the Qualified Medical Physicist. The Qualified Medical Physicist should identify the person responsible for performing the tests and 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.

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 a danger to patients or staff, the Qualified Medical Physicist in collaboration with the facility's radiation safety officer must take immediate action to either prevent its use, or to indicate in writing what limited studies can be performed safely until the equipment 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/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR's [Appropriateness Criteria](#)[®], should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation

dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

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).

Patient radiation dose rates must be estimated for fluoroscopic equipment at least annually. Tables of patient radiation dose rates for representative examinations should be prepared and supplied to the facility and must comply with any applicable regulations. These tables must be prepared using measured radiation output data and imaging techniques provided by the facility. These results must be compared with appropriate guidelines [14]. All applicable sections of the [ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](#) [15] 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 [10]. 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 calculation and evaluation.

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APPENDIX A

Fluoroscopic 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 QC.

Parameter	Acceptance Testing	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
Visual equipment checklists	Y	Y	Y	
Integrity of unit assembly	Y	Y	Y	
Operation of alerts and interlocks	Y	Y	Y	
Other radiation safety functions	Y	Y	N	
Appropriateness of protocols (fluoroscopic and acquisition)	Y – for all designated uses	Y – for selected uses	Y – for most common uses	
Pediatric protocols and equipment configurations	Y –for all designated pediatric uses	Y – for selected pediatric uses	Y – for most common pediatric use	
Isocenter location	Y	N	N	
Radiation field size measurement	Y	Y	N	
Acquisition display monitor(s) performance	Y	Y	Y	
Collimation and radiation beam alignment	Y	Y	N	
Tube potential (kVp) accuracy and reproducibility	Y	Y	N	
Minimum beam quality (half-value layer)	Y – for all designated uses	Y – for selected uses	N	
Automatic dose rate control performance	Y	N	N	
Image quality: system high contrast resolution	Y	Y	N	Use appropriate test tools or phantom and software
Image quality: system low contrast sensitivity	Y	Y	N	Use appropriate test tools or phantom and software
Displayed radiation metrics accuracy	Y	Y	N	Air kerma at a reference point (K_{ar}), Dose Area Product (DAP)/Air kerma Area Product (KAP)
Image receptor air kerma rate	Y – for all designated uses	Y – for selected uses (Image Intensifiers)	N	Fluoroscopic and acquisition modes
Patient entrance air kerma rate for a “typical” adult patient and a “typical” pediatric patient if applicable	Y – for all designated uses	Y –for selected uses	N	
Maximum patient entrance air kerma rate	Y	Y	N	Fluoroscopic and acquisition modes

Parameter	Acceptance Testing	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
Image receptor performance	Y	Y	N	
Image artifacts	Y	Y	Y	
PACS adequacy	Y	Y	N	

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

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