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.

2023 (CSC/BOC)*

ACR-AAPM TECHNICAL STANDARD FOR MANAGEMENT OF THE USE OF RADIATION IN FLUOROSCOPIC PROCEDURES

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

Fluoroscopy is a technique that provides real-time X-ray imaging that is especially useful for guiding a variety of diagnostic and interventional procedures. In some cases, fluoroscopic images may be stored as part of the patient examination.

Fluoroscopy is frequently used to assist in a wide variety of medical diagnostic and therapeutic procedures, both within and outside of radiology departments. Fluoroscopic equipment is capable of producing very high patient radiation doses. There have been reports of serious tissue reactions (eg, skin injury, bone injury) in some patients undergoing certain fluoroscopically guided interventions [1-4]. Interventional procedures that do not result in a skin injury are not risk-free to the patient. Stochastic effects are a potential risk for all fluoroscopic procedures. The pediatric risk may be greater because pediatric patients have a longer projected life span and are more radiosensitive in the first decade of life than are adults, leading to an increased stochastic risk later in life [5]. Therefore, the use of fluoroscopy in medical institutions must be managed proactively so that the levels of patient radiation exposure are appropriate for the medical requirements of the procedures, considering both risks and benefits [6]. Management of the use of radiation must also ensure adequate safety of the medical personnel involved in these procedures. The intent of this standard is to assist physicians, Qualified Medical Physicists, radiologic technologists, and other ancillary personnel in achieving the above goal. This standard does not explicitly address the use of computed tomography (CT) fluoroscopy, although principles and practices discussed in this document could provide relevant guidance to its use.

For additional information on Definitions, see Appendix A.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

A fundamental clinical knowledge base and specific skills are required to perform fluoroscopic procedures safely [7]. In addition to a basic understanding of anatomy, physiology, and pathophysiology, the physician should have sufficient knowledge of the clinical and imaging evaluation of patients to identify those patients for whom a specific procedure is indicated. The physician should also be able to evaluate each patient's clinical status to anticipate whether the patient might be at increased risk for complications, require additional preprocedural or postprocedural care, or have contraindications to the procedure.

Each facility should have a policy for granting fluoroscopic privileges to all physicians who perform or supervise fluoroscopy. To ensure that the physician is both properly trained and qualified in fluoroscopy, local credentialing and privileging processes should include a review of physician training records to ensure that they include use of fluoroscopy. Physicians must also comply with all applicable laws and regulations and with institutional policies and procedures for fluoroscopy licensure or certification [8,9].

A physician qualified to perform or supervise fluoroscopically guided procedures should have the following initial qualifications:

1. Certification in Radiology, Diagnostic Radiology or Interventional Radiology/Diagnostic Radiology (IR/DR) by the ABR, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec.

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2. Completion of a residency/fellowship program approved by the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association that includes training in fluoroscopic imaging procedures.

Documentation of the successful completion of didactic course lectures and laboratory instruction in radiation physics, radiobiology, radiation safety, and radiation management applicable to the use of fluoroscopy, including passing applicable written examination in these areas, should be maintained.

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- 3. Be privileged or qualified to perform specific fluoroscopically guided procedures. The following are recommended:
 - a. Documentation of the successful completion of didactic course lectures and laboratory instruction in radiation physics, radiobiology, radiation safety, and radiation management applicable to the use of fluoroscopy, including passing a written examination in these areas. Course content for lectures and instruction may vary in depth for noncomplex procedures compared with complex interventional procedures (eg, vascular, cardiovascular, neurological, urological). The course work and instruction should include use of fluoroscopy on pediatric and pregnant patients and must comply with regulations [10,11].

and

Performance of a sufficient number of procedures of each specific type of fluoroscopically guided intervention under the direction of a preceptor qualified for that procedure to ensure competence in the procedure.

Maintenance of Competence

Maintenance of competence for fluoroscopy is the same as maintenance of competence for any other medical procedure. The physician should regularly perform fluoroscopic procedures in sufficient numbers to maintain success rates and limit complications consistent with the difficulty of and risk associated with the procedures.

Competence must also be assured by requiring training for all individuals who will be using newly installed fluoroscopes or who are being introduced to existing fluoroscopes.

Continuing Medical Education

CME should be in accordance with the <u>ACR Practice Parameter for Continuing Medical Education (CME)</u> and should include continuing education in radiation protection and other areas related to the use of fluoroscopy [12].

B. Qualified Medical Physicist

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 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 ACR Practice Parameter for Continuing Medical Education (CME) [12].

The appropriate subfield of medical physics for this standard is Diagnostic Medical Physics (previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f.)

The Qualified Medical Physicist must be familiar with the principles of imaging physics, radiation dosimetry, and radiation protection; the current guidelines of the National Council on Radiation Protection and Measurements (NCRP); laws and regulations pertaining to the performance of fluoroscopic equipment; the function, clinical uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments used for radiation measurement. The Qualified Medical Physicist should also have sufficient knowledge of the clinical methods and goals of relevant medical procedures to critically evaluate the use of the equipment with regard to patient and personnel safety as well as image quality.

The Qualified Medical Physicist should regularly perform a sufficient number of radiation measurements, dosimetric calculations (eg, peak skin dose [PSD], air kerma-area-product), and equipment performance evaluations of fluoroscopic equipment, to maintain competency in these areas. The competency tasks should be conducted in a manner that adequately reflects the fluoroscope diversity and clinical needs of the areas overseen by the Qualified Medical Physicist. The Qualified Medical Physicist should maintain experience in the clinical applications of equipment by periodically observing clinical procedures.

CME should include education in radiation dosimetry, radiation protection, and equipment performance related to the use of fluoroscopy.

C. Nonphysician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

1. Registered Radiologist Assistant (RRA)

An RRA is an advanced level radiographer who is certified and registered as a "Registered Radiologist Assistant" by the American Registry of Radiologic Technologists (ARRT) after successful completion of an advanced academic program encompassing an American Society of Radiologic Technologists (ASRT) RRA curriculum and a radiologist-directed clinical preceptorship.

Under radiologist supervision, the RRA may perform patient assessment, patient management, and selected examinations as delineated in the ACR Statement "Radiologist Assistant: Roles and Responsibilities" subject to state law (see the <u>ACR Digest of Council Actions Appendix H</u>). The RRA transmits to the supervising radiologist those observations that have a bearing on diagnosis. Performance of diagnostic interpretations (preliminary, final, or otherwise) remains outside the scope of practice of the RRA. RRAs performing invasive or non-invasive procedures should function under radiologist supervision and as part of radiologist-led teams. (adopted 2006, 2016 Resolution 1-c, 2020 Resolution 11).

ARRT registered radiologist assistants performing fluoroscopic procedures under the direct supervision² of a radiologist should have received formal training in radiation management and must undergo a formal authorization process, administered by the facility, for the specific fluoroscopically guided interventional (FGI) procedures they perform.

2. Other Ancillary Personnel Performing Fluoroscopic Procedures

It is the policy of the American College of Radiology Non-Physician Radiology Providers (NPRP) who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist perform fluoroscopic examinations or fluoroscopically guided imaging procedures. Supervision by a radiologist

² The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, revised 2017 Resolution 12c)

must be direct or personal², and must comply with local, state, and federal regulations.

All non-physician radiology providers (NPRP) using fluoroscopy should be credentialed for those fluoroscopic examinations or procedures and should have CME that meets applicable state or other laws and regulations to become competent in the following: digital image acquisition and display, contrast media, fluoroscopic unit operation and safety, image analysis, radiation biology, radiation production and characteristics, and radiation protection. Additionally, NPRP using fluoroscopy should have sufficient clinical experience supervised by a radiologist to demonstrate competency in those fluoroscopic examinations or procedures for which they are credentialed. Medical physicists should be involved in the radiation safety and image quality aspects of fluoroscopy. Required CME for NPRP performing fluoroscopy should include education in radiation dosimetry, radiation protection, and equipment performance related to the use of fluoroscopy; adopted 2010, amended 2020 (Res. 23-f).

D. Radiologic Technologist

Radiologic technologists must have received formal training in radiation management. Those assisting with fluoroscopy for FGI procedures should undergo a formal authorization process, administered by the facility. Additionally, those assisting with fluoroscopy should be thoroughly trained in radiography of the organ systems involved in a fluoroscopic procedure. Certification by the ARRT or unrestricted state license is required for radiologic technologists.

E. Supervision

Only physicians, NPRPs, or other ancillary personnel performing fluoroscopic procedures (as defined in Section II.C) who meet the above qualifications should operate a fluoroscopic system while exposing a patient to radiation.

The only exceptions are for registered and/or licensed radiologic technologists who perform fluoroscopy only as a positioning or localizing procedure. These procedures must be performed under the direct supervision of a physician who meets the above qualifications. In addition, these procedures must have prior written approval by the medical director of the appropriate department or service, and there must be written authority, policies, and procedures for designating technologists who perform such procedures.

III. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for fluoroscopic procedures should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35 adopted in 2006 revised in 2016, Resolution 12-b)

When practicable, the request should include key information on recently performed related procedures, including modality, date, findings, and location of the images.

The clinical management of radiation is essential for every procedure and important for both patients and staff [6,9,13-15]. This requires necessary action on the part of the fluoroscopists, the Qualified Medical Physicist, and other ancillary staff team members participating in a fluoroscopic procedure [6].

A. Fluoroscopy Equipment – Settings

Equipment must provide fluoroscopic image quality and recording capability that is adequate for the procedures performed. Fluoroscopic equipment requirements for specific radiologic examinations are found in the parameters or standards for those examinations. Equipment incapable of operating at tube voltages of at least 100 kVp or with a maximum source-image receptor distance of less than 45 cm must not be used for examinations other than for distal extremities. All equipment must have spacers to maintain the regulatory minimum source-to-skin distance (SSD) and should have spacers to achieve the recommended SSD [9,16-18]. All fluoroscopy units equipped with cumulative air kerma displays and/or air kerma-area-product displays should have their calibrations verified periodically by a Qualified Medical Physicist [19]. Examinations must be performed only with equipment that meets all applicable government requirements. Mobile X-ray fluoroscopic equipment should be used in a room with appropriate shielding and in accordance with all applicable regulations. When use in a shielded room is not practical, alternate precautions, such as keeping people not involved in the procedure as far away as their duties or conditions allow, should be employed.

Equipment that will be used to routinely image small or pediatric patients must provide operational modes with appropriate technical factors [9,20-25]. Before clinical use, these fluoroscopy systems must be configured to provide a lower dose rate to the patient consistent with the image quality requirements of the specific, operator-selected – protocol. A Qualified Medical Physicist can assist with the proper adjustment of the fluoroscope's radiation output [6]. Fully automatic exposure controls should be used when possible. Of particular importance is the need for size specific acquisition protocols to be preconfigured on the X-ray system and available for any pediatric fluoroscopic use. Additional considerations are also needed for potentially lengthy procedures that will involve patients with obesity.

Equipment performance monitoring should be performed in accordance with the <u>ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment</u> [26] and the <u>ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment</u> [27].

B. Patient Exposure Controls

Intentional selection of patient-specific protocols is to be included as part of a "time-out" that occurs before a fluoroscopic surgical procedure. All personnel participating in the procedure share the responsibility for achieving both patient and staff radiation management and safety goals. A culture of safety allows personnel to recognize and correct unsafe practices or bring them to the attention of other personnel who can correct the situation [9]. The radiation exposure to the patient must be limited to that required for the procedure being performed [28]. If it is necessary to perform a fluoroscopic or fluoroscopically guided procedure on a pregnant patient, it should be performed in accordance with the ACR—SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation and in accordance with internationally recognized guidelines [10,11]. During any procedure, the operator's choice of X-ray settings — can advantageously affect and substantially reduce patient exposure while maintaining fully acceptable image quality. The operator and any technologists helping to operate a fluoroscope should be familiar with the features of the specific machine that affect patient dose and the controls that activate or adjust them. Behaviors that will reduce patient exposure include the following [9,13,15,29]:

- 1. Use fluoroscopy sparingly and only when real-time imaging guidance is needed.
- 2. Use a lower acquisition (imaging, recording) frame rate or variable frame rate if available.
- 3. Use a low fluoroscopic pulse rate. Items #1 and #2 adhere to the Image Gently® [20] guideline: "Pause and Pulse."
- 4. Select the lowest dose rate that provides adequate image quality when multiple dose rate modes for fluoroscopy and/or acquisition are available.
- 5. Limit the duration of recorded exposure runs for image acquisition, which will reduce—the total number of images acquired and therefore the associated patient dose. Record images only when higher-quality images are essential for review and documentation. When lower-quality images are adequate for documentation, fluoroscopic images should be recorded instead.
- 6. Use electronic magnification mode for fluoroscopy or image recording only when the improved image quality is necessary.
- 7. Collimate to the smallest area needed for the imaging task to restrict the volume of tissue receiving a dose from the primary beam.

- 8. Maximize the distance between the entrance plane of the patient and the focal spot of the X-ray tube to the extent that is practical.
- 9. Place the image receptor as close as reasonably possible to the patient.
- 10. Remove antiscatter grid when imaging small bodies or body parts.
- 11. Use other available dose-reducing features (eg, added filtration).

C. Staff and Operator Exposures

Radiation monitoring requirements vary by jurisdiction [6]. Individuals must comply with all applicable regulations regarding the wearing of radiation monitors. [9,30,31]. The institution or facility must provide a radiation monitor, to be worn underneath any protective garments used, for each person who has declared pregnancy. All monitors should be worn consistently, in the same location, and must be returned for collection at the appointed time for accurate dosimetry reporting. Physicians who perform interventional procedures regularly should wear radiation protective eyewear and/or use ceiling-mounted shields to minimize the risk of developing radiation-induced cataracts [9,31-34]. Auxiliary shielding (eg, ceiling mounted, machine mounted, table mounted, or freestanding) should be used whenever practical and may be substituted in whole or in part for personal protective garments where regulations allow and with approval of a Qualified Medical Physicist. The adequacy of protection provided by protective garments should periodically be assessed. Principle behaviors to reduce staff and operator exposure include:

- 1. Wearing personal protective equipment and using auxiliary shields.
- 2. Reducing patient exposure because staff exposure due to scatter is directly related to patient exposure.
- 3. Positioning the X-ray tube under the patient minimizes staff exposure from scatter. For angled views, staff should be positioned on the side of the patient opposite to the X-ray tube. When possible, staff should maintain at least one meter distance from the point at which the X-ray beam enters the patient.
- 4. Directing staff to step back farther from the patient, move behind a shield, or leave the room during acquisition imaging (eg, digital subtraction angiography (DSA), cine modes).

Facilities should establish substantial radiation dose levels (SRDLs) and have a defined policy regarding when a Qualified Medical Physicist should calculate PSD (eg, when the established SRDL is exceeded) [6,9,35]. If indicated, provisions should be made for patient follow-up to allow for the detection and management of possible radiation effects [9,15,36]. (For specific classes of procedures, if a higher or lower SRDL is chosen, it should be supported by published literature or data collected by the facility [37].) If the potential for radiation injury is indicated, the patient should be advised on the potential for radiation injury to the skin and be given instructions for proper follow-up. These steps should be documented in the medical record [9]. When potentially high-dose procedures are repeated, (eg, transjugular intrahepatic portosystemic shunt (TIPS), neuroembolization), previous skin exposure within the last 60 days should be considered [1].

All known grade 3 or higher fluoroscopically induced tissue reactions must be reviewed using the institution's quality processes [9,14]. The National Cancer Institute skin toxicity grade 3 skin reaction is defined as "moist desquamation other than skin folds or creases" [9]. For further information, see Appendix B.

Radiation dose index management systems may be broadly classified as applications that retrospectively collect exposure and exposure index data along with technical parameters used to generate those exposures, mainly through the Radiation Dose Structured Report (RDSR) [38]. The RDSR, originally defined for fluoroscopy, is a standardized DICOM format to record all of the information related to an exposure event. Each exposure event creates an entry in the RDSR. Patient demographic information found in DICOM headers is also collected. Using dose index management systems, the patient exposure from a single examination can be investigated and compared with similar procedures performed within the organizations [6]. Dose index management systems allow for comparing individual exposures to the exposures from similar procedures performed at the facilities from which data is being collected. Imaging systems and protocols may also be compared with each other to detect outliers. In fluoroscopy, dose index management systems can provide substantial benefit in the recording, determination, and documentation of patient skin doses. These systems can be configured to provide alerts to appropriate individuals when the SRDL has been reached for a patient. Furthermore, they may assist in the calculation of PSD by recording exposure condition details throughout the procedure [39].

All fluoroscopy systems capable of generating the RDSR may also participate in ACR's Fluoroscopy Dose Index Registry

(DIR Fluoroscopy) [40]. DIR Fluoroscopy provides radiation dose index analytic and reporting capabilities in addition to functioning as a national registry. Participation in DIR Fluoroscopy allows organizations to compare their clinical facility data to that of their peers and contributes to the largest normative dataset for use of radiation in fluoroscopy procedures, enabling publication on reference levels and other practice patterns.

IV. DOCUMENTATION

Informed consent should be documented as outlined in the <u>ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u> [41] and the <u>ACR–SIR–SPR Practice Parameter on Informed Consent for Image-Guided Procedures</u> [42].

All available radiation dose data should be recorded in the patient's medical record [9,37,43]. Some fluoroscopes provide skin dose maps and estimates of PSD. PSD should always be recorded if available. If cumulative air kerma or air kerma-area-product data are not available, the fluoroscopic exposure time and the number of acquired images (radiography, cine, or digital subtraction angiography) should be recorded in the patient's medical record.

V. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC &Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

A comprehensive quality assurance (QA) program should include the review of occupational radiation doses, patient radiation dose index, and radiation-related complications [14]. Practitioners should compare patient radiation dose index against institutional and national benchmarks, if available, and evaluate outliers as part of an ongoing QA program [44].

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Quantities and Units – Definitions

Air kerma: The amount of energy released in air by radiation per unit mass of air. The unit of air kerma is the gray (Gy).

Dose (also known as absorbed dose): the amount of energy imparted by radiation to specified matter, (eg, soft tissue) per unit mass. The unit of dose is the gray. An older unit still used in the literature is the radiation absorbed dose (rad).

1 Gy = 100 rad.

Cumulative air kerma: Air kerma of the primary X-ray beam measured under specific conditions and expressed as the equivalent value at the Patient Entrance Reference Point [45]. It is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry during a procedure. It does not include backscatter and is measured in units of gray. Cumulative air kerma is also known as reference air kerma and sometimes referred to as reference dose. Earlier publications used the term "cumulative dose" and the abbreviation "CD" for this quantity [6,15].

Dose rate: the dose of radiation per unit of time.

Effective dose (E): Effective dose is a calculated quantity and cannot be measured. It is calculated by multiplying actual organ doses by tissue weighting factors, which indicate each organ's relative sensitivity to radiation, and adding up the total of all the weighted organ doses. The sum of the products is the effective dose. These weighting factors are designed so that the effective dose represents the dose the total body could receive (uniformly) that would yield the same stochastic risk as various organs receiving different doses. The unit of effective dose is the sievert (Sv), although the older unit, the rem, is still in use.

Kerma-area-product: (More accurately, air kerma-area product, because this quantity is usually determined in air.) The integral of air kerma across the entire X-ray beam emitted from an X-ray tube. Kerma-area product is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. A variety of units is used for Kerma-area-product, — including Gycm² and μ Gym². The International Commission on Radiation Units and Measurements notation for this quantity is P_{KA} [46]. It is sometimes abbreviated as KAP. Earlier publications used the term dose-area product and the abbreviation "DAP" for this dose index [15].

Isocenter for a C-arm fluoroscopy system: Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center [17].

Peak skin dose (PSD): The highest dose received by any area of the skin.

Substantial Radiation Dose Level (SRDL): An absolute action level (with regard to patient follow-up) below which skin injury is highly unlikely and above which skin injury is possible [6,47].

Patient entrance reference point OR Interventional reference point [48]:

*Some manufacturers may define the AKR at locations different from those listed in the table.

Type of Fluoroscopic Equipment	Point of AKR or Exposure Rate Measurement
Source below the table	Measure at a point 1 cm above the tabletop or cradle.
Source above the table	Measure at a point 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
C-Arm type fluoroscope	Measure at a point 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available source-to-image distance (SID), provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.
C-Arm type of fluoroscope: SID less than 45 cm	Measure at the minimum SSD.
Lateral type of fluoroscope	Measure at a point 15 cm from the centerline of the X-ray table

Detection and Management of Tissue Reactions

Patients should be monitored for significant skin reactions as part of the follow-up process when a fluoroscopic procedure results in a dose or dose **index** that exceeds the facility's SRDL. Each facility should have a written policy outlining quality processes for detecting and managing potential tissue reactions [14]. This process must be sensitive enough to detect essentially all grade 3 and higher reactions [9] and most grade 1 or grade 2 reactions. The inclusion in the quality process of transient prompt erythemas (those that appear and spontaneously resolve within a few days of the index procedure) with no later reactions should also be considered in the facility's policy. Lastly, it may be useful to include estimation of PSD by a Qualified Medical Physicist in the policy [6]. Such an estimation can alert a facility to the possibility that a tissue reaction might be likely so that appropriate follow-up can be triggered.

Skin Toxicity Grades (Summarized from Common Terminology Criteria for Adverse Events) [49]:

Adverse Effect Skin Toxicity Grade	Description
1 2	Faint erythema or dry desquamation Moderate to brisk erythema; patchy moist desquamation, mostly
3	confined to skin folds and creases; moderate edema Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion
4	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated

The protocols described in NCRP Statement 11 must be followed for major tissue reactions (grade 3 and 4). These protocols should be followed for minor tissue reactions (grades 1 and 2) [14].

NCRP 168 recommends that follow-up for significant tissue reactions remain the responsibility of the physician performing the fluoroscopic procedure for at least 1 year after the procedure; they also suggest that follow-up may be performed by another healthcare provider who remains in contact with the physician performing the procedure [9].

The Society of Interventional Radiology recommends providing patients receiving significant radiation doses written follow-up instructions upon discharge that informs them to notify the physician performing the procedure and/or the qualified medical physicist of the results of their self-examination of the irradiated area after a designated period of time. Clinical follow-up is then arranged if the examination is positive for findings of deterministic radiation effect [15].

NCRP 168 further recommends that all suspicious findings should be treated as a probable radiation effect unless an alternative diagnosis is established. Patients with skin injuries should be referred to a physician experienced in managing radiation injuries (eg, a radiation oncologist or properly trained dermatologist). Available skin dose information should also be provided to the treating physician [9]. Continuity of care is enhanced when the individual currently caring for a tissue reaction has substantially complete medical records documenting the index procedure and the history of prior relevant care.

These medical records must clearly identify the presence and intensity of tissue reactions and their locations on the patient's skin. Where practicable, patients (or family members) should have sufficient knowledge to alert providers of potential skin injury so that this information is available in the medical records.

Providers planning additional fluoroscopic guided interventional procedures should review existing medical records

for information on possible fluoroscopic (or radiotherapeutic) tissue reactions. Where appropriate, this information should also be collected as part of evaluating the patient's medical history.

*As of May 2015, all practice parameters and technical standards collaborative between ACR and AAPM 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). This collaborative medical physics technical standard (or practice parameter) document becomes effective on the first day of the first month following 60 days after final adoption by the ACR BOC. This document is scheduled to begin revision with the other practice parameters and technical standards adopted at ACR Council during the same year.

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