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

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care 1. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter 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 capabilities have changed dramatically in recent years. The same fluoroscope may provide a number of operational modes, each of which is tailored to a specific clinical task. Modern fluoroscopic equipment is capable of producing very high radiation output rates for extended periods of time. There have been reports of serious skin injuries in some patients undergoing certain fluoroscopically guided procedures [1-4]. Interventional procedures that do not result in a skin injury are not risk-free to the patient. The risk of a stochastic injury later in life is elevated or pediatric patients who have a longer projected life span and are more radiosensitive in the first decade of life than are adults [5]. Therefore, the use of fluoroscopy in medical institutions must be proactively managed so that the levels of patient radiation exposure are appropriate for the medical demands of the procedures, taking into account risks and benefits. 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.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

A fundamental clinical knowledge base and specific skills are required to perform fluoroscopic procedures safely [6]. 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 in order to anticipate whether the patient might be at increased risk for complications, require additional preprocedure or postprocedure 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. Local credentialing and privileging processes should include review of training records and of procedures that use fluoroscopy to determine that the physician is both properly trained and qualified in fluoroscopy. Physicians must comply with all applicable state and federal laws and regulation and with institutional policies and procedures for fluoroscopy licensure or certification [7, 8].

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

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

or

Completion of a residency/fellowship program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) that includes 6 months of 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.

or

Be privileged for qualified to perform specific fluoroscopically guided procedures. The following is 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 Minimum course duration for lectures and instruction should be 4 hours for noncomplex procedures and 8 hours for complex interventional procedures (eg, vascular, cardiovascular, neurological, urological). The course work and instruction should include use of fluoroscopy on pediatric and pregnant patients [9,10].

and

b. Performance of at least 10 procedures of each specific fluoroscopically guided procedure under the direction of a training physician qualified for that The training physician should certify that the trainee physician meets minimum clinical and fluoroscopy safety standards for each specific 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 on newly installed equipment or who are being newly introduced to existing equipment.

Continuing Medical Education

Continuing education 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 [11].

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 <u>ACR Practice Parameter for Continuing Medical Education</u> (<u>CME</u>). [11]

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)

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

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, and equipment performance evaluations of fluoroscopic equipment of the types being used to maintain competence in the performance of these activities. The Qualified Medical Physicist should maintain experience in the clinical applications of equipment by periodically observing clinical procedures.

C. Non-Physician 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

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management, and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

ARRT-registered radiologist assistants as recognized by the ACR and ASRT Joint Statement on the Radiologist Assistant, Roles and Responsibilities may perform specific fluoroscopic procedures under the direct supervision of a radiologist.

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

D. Radiologic Technologist and Radiation Therapist

Certification by the ARRT and/or unrestricted state license is required for radiologic technologists and radiation therapists.

Radiologic technologists or radiation therapists assisting with fluoroscopy should be thoroughly trained in radiography of the organ systems involved in a fluoroscopic procedure.

Radiologic technologists and radiation therapists must have received formal training in radiation management. Those assisting with fluoroscopy for fluoroscopically guided interventional procedures should undergo a formal authorization process, administered by the facility.

E. Other Ancillary Personnel

Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform fluoroscopic examinations or fluoroscopically guided imaging procedures. Supervision by a radiologist or other qualified physician must be direct or personal3, and must comply with local, state, and federal regulations.

All ancillary personnel using fluoroscopy should be credentialed for those fluoroscopic examinations or procedures and should have completed 40 hours of didactic education or its equivalent in digital image acquisition and display, contrast media, fluoroscopic unit operation and safety, image analysis, radiation biology, radiation production and characteristics, and radiation protection; and 40 hours of clinical experience supervised by a radiologist or medical physicist. Required CME for other ancillary personnel performing fluoroscopy should include education in radiation dosimetry, radiation protection, and equipment performance related to the use of fluoroscopy. (ACR Resolution 52, adopted in 2010)

F. Supervision

Only physicians or other ancillary personnel (as defined in Section II.E) 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 or radiation therapists 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. PROCEDURAL SPECIFICATIONS

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

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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 scope of practice requirements. (ACR Resolution 35, adopted in 2006)

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

Clinical management of radiation is essential for every procedure [8,12-14]. Ways of managing radiation are discussed in Appendix B.

IV. DOCUMENTATION

Informed consent should be documented as outlined in the ACR-SIR-SPR Practice Parameter on Informed

Consent for Image-Guided Procedures [15].

All available radiation dose data should be recorded in the patient's medical record [8,16,17]. 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.

If the cumulative air kerma at the reference point exceeds the substantial radiation dose level (SRDL), which is typically set at 5 gray (Gy), provisions should be made for patient follow-up to allow for detection and management of possible radiation effects [8,13,18]. (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 [16].) If follow- up for possible 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 and these steps should be documented in the medical record [8]. When potentially high-dose procedures are repeated, (eg, TIPS, or for neuroembolization), previous skin exposure should be considered [4].

All known grade 3 or higher fluoroscopically induced tissue reactions must be reviewed using the institution's quality processes [8]. (The NCI skin toxicity grade 3 skin reaction is defined as "moist desquamation other than skin folds or creases" [8]. For further information, see Appendix C.

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/Clinical-Resources/Practice-Parameters-and-Technical-Standards).

The quality assurance (QA) program should include the review of occupational radiation doses, patient radiation dosemetrics, and radiation-related complications [8]. Practitioners should compare patient radiation dose metrics against institutional and national benchmarks, if available, and evaluate outliers as part of an ongoing QA program [19].

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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.

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Appendix A

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 rad (radiation absorbed dose). 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 [20]. 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 Gy. 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 [13].

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

Effective dose (E): Effective dose must be calculated. It 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), though the older unit the rem is still in use.

Kerma-area-product: (More accurately, air kerma-area product, since 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. Kerma-area product is measured in units of Gy.cm2. The International Commission on Radiation Units and Measurements (ICRU) notation for this quantity is *PKA* [21]. It is sometimes abbreviated as KAP. Earlier publications used the term dose- area product and the abbreviation "DAP" for this dose metric [13].

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 [22].

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 [23]

Patient entrance reference point OR Interventional reference point [24]:

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 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
C-Arm type of fluoroscope – SID less than 45 cm	assembly. Measure at the minimum SSD.
Lateral type of fluoroscope	Measure at a point 15 cm from the centerline of the X-ray table.

Appendix B

The clinical management of radiation X-ray prescription and operator exposure encompasses three areas of necessary action on the part of the fluoroscopists, the Qualified Medical Physicist and other ancillary staff team members participating in a fluoroscopic procedure.

A. Fluoroscopy Equipment and Machine 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 minimum source-to-skin distance (SSD) and should have spacers to achieve the recommended SSD [8, 22, 25, and 26]. All interventional fluoroscopy equipment should be equipped with displays of air kerma rate, kerma area product and cumulative air kerma [25, 26]. 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 [27]. Examinations must be performed only with fluoroscopic image intensification or with solid state flat panel image receptors and with radiographic equipment that meets all applicable federal and state radiation requirements. Mobile X-ray fluoroscopic equipment should be used in an appropriately protected environment whenever feasible and as applicable by state or local regulations. When use in a protected environment 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 technical factors that are appropriate [8, 28-33]. Prior to clinical use, the fluoroscopy system must be configured to provide a lower dose rate to the patient consistent with the image-quality requirements of the operator selected specific protocol. A Qualified Medical Physicist can assist with the proper adjustment of the fluoroscope's radiation output. Fully automatic exposure controls should be used when possible. Of particular importance is the need for size specific acquisition protocols to be pre-configured on the X- ray system and available for any pediatric fluoroscopic use. Additional considerations are also needed for potentially lengthy procedures that will involve obese patients. 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> and the <u>ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment [34,35]</u>.

B. Patient Exposure Controls

The intended use of specific patient protocols is to be included as part of a 'time-out' that occurs prior to 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 [8]. The radiation exposure to the patient must be limited to that required for the procedure being performed [36]. 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 Adolescents and Women with Ionizing Radiation and in accordance with internationally recognized guidelines [9,10]. During a procedure, the operator's choice of X-ray settings (table- side controls) 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 determine patient dose and the controls that activate or adjust them. Behaviors that will reduce patient exposure include the following:

- 1. Use of fluoroscopy sparingly and only when real-time imaging guidance is needed.
- 2. Use of a lower acquisition (imaging-recording) frame rate.
- 3. Use of a low fluoroscopic pulse Items #1 and #2 adhere to the guideline: "Pause and Pulse."
- 4. When fluoroscope provides multiple dose rate modes for fluoroscopy and/or acquisition, select the lowest dose rate that provides adequate image quality.
- 5. Use of short duration of recorded exposure runs for image acquisition, which reduces the total number of images acquired and therefore the associated patient 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 of an electronic magnification mode for fluoroscopy or image recording only when the improved image quality is neccessary.
- 7. Collimate to the smallest area needed for the imaging task, to restrict the volume of tissue receiving a direct radiation dose.
- 8. To the extent that is practical, maximize the distance between the entrance plane of the patient and the focal spot of the X-ray tube.
- 9. Place the image receptor as close as reasonably possible to the patient.
- 10. Remove anti-scatter grid when imaging small bodies or body parts.
- 11. Use other available dose-reducing features.

C. Staff and Operator Exposures

Each person routinely exposed to radiation from fluoroscopic procedures must be provided with at least one personal radiation monitor approved by the National Voluntary Laboratory Accreditation Program (NVLAP). Individuals must comply with state regulations regarding wearing of radiation monitors. If a single monitor is normally worn outside the apron at the collar level, the institution or facility may consider providing an additional monitor to be worn underneath the apron for personnel involved in complex interventional procedures and use of a method to estimate occupational dose that accounts for the protection provided by the garments [8, 37]. Other testing should be used periodically to test the adequacy of protection provided by protective garments. The institution or facility must provide a radiation monitor, to be worn underneath any protective garments used, for each person who has declared her pregnancy. All monitors should be worn consistently, in the same location, and must be returned for collection at the appointed time for accurate readings to be obtained. 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 [8, 38-40]. Auxiliary shielding (ceiling mounted, machine 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. Principle behaviors to reduce staff and operator exposure include:

- 1. Wearing personal protective equipment and using auxiliary
- 2. Reducing patient exposure since staff exposure due to scatter is directly related to patient

- 3. Positioning the X-ray tube under the patient minimizes staff exposure due to For angled views, staff should be positioned on the side of the patient opposite to the X-ray tube. As a goal 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, DSA, Cine modes).

Appendix C

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 metric that exceeds the facility's SDRL. Each facility should have a written policy outlining quality processes for detecting and managing potential tissue reactions. This process must be sensitive enough to detect essentially all grade 3 and higher reactions [8] 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.

Skin Reaction Grades (Summarized from NCRP 168):

NCI Skin Toxicity Grade (NCI, 2006)	Description
1	Faint to moderate erythema
2	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema
3	Moist desquamation other than skin folds and creases
4	Skin necrosis or ulceration of full-thickness dermis; spontaneous bleeding from involved site

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 one 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 [8].

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 effects [13].

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). Available skin dose information should also be provided to the treating physician [8]. 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 Revised 1933 (FSE (FIG) 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.