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The American College of Radiology will periodically define new practice guidelines 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 guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline 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, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines 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 guideline and technical standard by those entities not providing these services is not authorized.

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## **ACR TECHNICAL STANDARD FOR MANAGEMENT OF THE USE OF RADIATION IN FLUOROSCOPIC PROCEDURES**

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### **PREAMBLE**

These standards are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these standards 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 standards, 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 standards 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 standards. However, a practitioner who employs an approach substantially different from these standards 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 standards 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 standards is to assist practitioners in achieving this objective.

### **I. INTRODUCTION**

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. Modern fluoroscopic equipment is capable of delivering very high radiation doses during prolonged procedures. There have been reports of serious skin injuries in some patients undergoing certain fluoroscopically guided procedures. Therefore, the use of fluoroscopy in medical institutions must be proactively managed to reduce patient radiation exposures to levels that are as low as reasonably achievable consistent with the medical demands of the procedures for which fluoroscopy is used. Management of the use of radiation must also ensure adequate safety of the medical personnel involved in these procedures.

### **II. GOAL**

The goal of this standard is to assist physicians, medical physicists, radiologic technologists, and other ancillary personnel in managing the use of radiation in fluoroscopic procedures to reduce radiation exposures to levels that are as low as reasonably achievable consistent with the medical demands of the procedures.

### III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

and, in addition to certification, education, and other credentials

#### A. Physician

Each facility should have a policy for credentialing all physicians who perform fluoroscopy.

The physician performing fluoroscopically guided procedures must have the following qualifications:

Certification in Radiology, Diagnostic Radiology or Radiation Oncology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec.

or

Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency/fellowship program or an American Osteopathic Association (AOA) approved residency program 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 a written examination in these areas.

or

Be credentialed for specific fluoroscopically guided procedures. The following is recommended:

Physicians whose residency did not include radiation physics, radiobiology, radiation safety, and radiation management may still be considered as satisfying the qualifications if they have performed at least 10 procedures of each type for which they intend to use fluoroscopic guidance under the direction of a qualified physician who has met these standards and who certifies that the trainee meets minimum fluoroscopy safety standards. They must also have documented evidence of at least 4 hours of didactic course lectures and laboratory instruction in radiation physics, radiobiology, radiation safety, and radiation management applicable to the use of fluoroscopy, and should have satisfactorily passed an examination in these areas. Physicians who perform interventional vascular, cardiovascular, biliary tract, genitourinary tract, or neurological procedures should have at least 15 hours of didactic training in radiation physics, radiobiology, radiation safety, and radiation management applicable to the use of fluoroscopy, and have satisfactorily passed an examination in these areas.

For fluoroscopic procedures to be performed safely, certain fundamental clinical knowledge and skills are required. 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 for whom a specific procedure is indicated. The physician should also be able to evaluate a patient's clinical status to anticipate those patients who might be at increased risk, who require additional preprocedure or postprocedure care, and who have relative contraindications to the procedure. The physician must also have undergone sufficient training in the operation of the equipment to be able to use dose management and image quality features effectively.

#### Maintenance of Competence

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 on new pieces of equipment as they arrive in a department or division.

#### Continuing Medical Education

Continuing education should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#) and should include continuing education in radiation protection related to the use of fluoroscopy.

#### B. 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 and 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 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 for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this standard are Diagnostic Radiological Physics or Radiological Physics.

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised 2008, Resolution 7)

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

The 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 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 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.

#### C. 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.

They should have received formal training in radiation management and should undergo a formal credentialing 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.

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 should have received formal training in radiation management. Those assisting with fluoroscopy should undergo a formal credentialing process, administered by the facility, for fluoroscopically guided interventional procedures.

#### 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 specific interventional fluoroscopic or other imaging guided procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state, and federal regulations. Individuals should be credentialed for specific fluoroscopic and other imaging guided interventional procedures and should have received formal training in radiation management and/or application of other imaging modalities as appropriate.

### IV. 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)

Only physicians, radiologist assistants, (or other ancillary personnel participating in specific interventional procedures as described in III.E) who have the qualifications outlined in this standard should operate a fluoroscopic system while exposing a patient to radiation, with the following exception: registered and/or licensed radiologic technologists or radiation therapists may perform fluoroscopy only as a positioning or localizing procedure provided they are monitored by a supervising physician who is personally and immediately available. Such a supervising physician must meet the qualifications of this standard. The procedure must have prior written approval by the medical director of the appropriate department or service, and there must be written authority, policy, and procedures for designating technologists who perform such procedures.

The radiation exposure to the patient shall be limited to that required for the procedure being performed. Appropriate collimation should be used for the imaging task to reduce the size of the irradiated area when possible. The patient should be positioned as close as reasonably possible to the image receptor. The distance between the patient and the X-ray tube should be maximized to the extent practicable. Electronic magnification modes and high-dose-rate modes should be used only when necessary. The lowest dose rate that is clinically acceptable should be used at all times. When electronic magnification is necessary, the lowest acceptable magnification factor should be used.

In order to reduce exposure rates, special attention should be given to the proper adjustment of the equipment setup with regard to the patient procedure. While automatic exposure control is always preferred, if manual settings are used, the proper adjustment of X-ray tube voltage, current, and spectral filtration is essential. Fluoroscopy should be used sparingly and only when real time imaging guidance is needed. The last-image-hold feature or loop replay should be used. Image acquisition should be activated only when higher quality image review is essential, and it should be limited to the frame rate and run duration necessary to accomplish the immediate task. In some cases, retrospectively stored fluoroscopy may reduce the need for image acquisition.

All personnel participating in the procedure share a responsibility for achieving radiation management and safety goals. Personnel should be able to recognize and correct unsafe practices or bring them to the attention of other personnel who can correct the situation.

All personnel in the room during fluoroscopic procedures must wear radiation protective garments appropriate to the procedure. Careful attention should be given to the kVp rating of the lead apron. In addition to a standard personnel radiation monitor, other monitors should be used at least periodically to measure radiation exposure under protective garments to ensure the adequacy of their protection, especially when light weight or nonstandard garments are legally used. Auxiliary shielding (ceiling, machine mounted or freestanding) may be substituted in whole or in part for personal protective garments.

Each person routinely involved in fluoroscopic procedures must also be provided with at least one personnel radiation monitor approved by NVLAP (National Voluntary Laboratory Accreditation Program). Individuals must comply with state regulations regarding monitor placement. If a single monitor is normally worn outside the apron at the collar level, the institution or facility should consider providing additional monitors to be worn behind the apron for personnel involved in vascular interventional procedures and for formally declared pregnant personnel. Physicians who perform procedures requiring their hands to be close to or in the radiation field should monitor the dose to their hands to assure that radiation levels do not exceed standards for safety defined by applicable laws and regulations. Finger monitors should be used during all fluoroscopically guided interventional brachytherapy procedures (e.g., yttrium-90 radioembolization). All monitors should be worn consistently in the same location.

Mobile X-ray fluoroscopic equipment shall be used only in an appropriately shielded environment.

## V. EQUIPMENT SPECIFICATIONS

Examinations must be performed only with fluoroscopic image intensification or with solid-state flat-panel image receptors and with radiographic equipment meeting all applicable federal and state radiation requirements.

All fluoroscopy equipment that is equipped with cumulative-air-kerma meters and/or kerma-area-product meters should have the meter calibrations verified periodically by a medical physicist.

Equipment must provide fluoroscopic image quality and recording (film, video, or digital) capability that is adequate for the procedures performed. Fluoroscopic equipment requirements for specific radiologic examinations are found in the guidelines or standards for those examinations. Equipment incapable of operating at tube voltages of at least 100 kVp or having a maximum source-image receptor distance of less than 45 cm must not be used for examinations other than for distal extremities.

Equipment performance monitoring should be in accordance with the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment](#).

## VI. DOCUMENTATION

It is desirable that radiation dose data be recorded for all fluoroscopy procedures. Direct patient care radiation dose-related information provided by dosimetry systems should be recorded in the patient's medical record. If cumulative air kerma or kerma-area-product data are not available, the fluoroscopic exposure time and the number of images acquired should be recorded in the patient's medical record.

If the cumulative air kerma at the reference point exceeds 3 gray, provisions should be made for follow-up of those areas for determination of radiation effects. (For specific classes of procedures, a different threshold for action can be established at individual institutions when supported by published literature.) In such circumstances there should be documentation in the medical record that the patient was advised of the potential for radiation injury to the skin and was given instructions for proper follow-up. In repeat high-dose procedures, e.g., TIPS, previous skin exposure should be considered.

## VII. 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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

The quality assurance (QA) program should include the review of personnel radiation monitor results and patient radiation dose-related information and/or complications. Practitioners should compare patient dose-related information against institutional and national benchmarks, if available, and evaluate outliers as part of an ongoing QA program.

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## Suggested Reading

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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, (e.g., 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.

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 getting different doses. The unit of effective dose is the sievert (Sv), though the older unit, the rem, is still in use.

Reference point: The air kerma reference point is also known as the (air) dose reference point. It is a point located along the axis between the focal spot and the image receptor where the machine automatically tracks the cumulative air kerma. For isocentric angiographic equipment that point is located 15 cm from isocenter on the side closest to the X-ray tube. For other equipment geometries, the location of the reference point is defined by the Food and Drug Administration [9].

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\*Guidelines and 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 guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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