Revised 2017 (Resolution 14)*

# ACR–SIR–SPR PRACTICE PARAMETER FOR PERFORMANCE OF ARTERIOGRAPHY

## 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole purpose of this document is to assist practitioners in achieving this objective.

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

## I. INTRODUCTION

This parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR) [1].

For purposes of this parameter, the term "arterial intervention" refers to all catheter-based procedures performed on arteries, and it may be referred to elsewhere as "interventional procedure" or "endovascular surgery".

Diagnostic arteriography is an established, safe, and accurate method of evaluating vascular disease. It is considered the diagnostic gold standard by which the accuracy of other vascular imaging modalities should be judged. However, diagnostic arteriography is an invasive procedure with a small risk of complications **[2]**. Because of the varying skill levels and training of physicians performing arteriographic procedures, the potential exists for variation in success rates, complication rates, and diagnostic study quality. The indications for arteriography have developed over time, and there may be considerable variation in practice.

This parameter was developed to help practicing angiographers ensure that patients undergo arteriography for appropriate reasons, that the methods used and the periprocedural care provided are adequate to minimize complications, and that the quality of the studies obtained is adequate to answer the clinical questions that prompted them. It is intended to provide guidance in both the indications for and the performance of arteriography in vessels other than the coronary or cervicocerebral circulation. Similar documents have been published for the coronary arteries [3] and the cervicocerebral circulation (see the ACR–ASNR–SIR–SNIS Practice Parameter for the Performance of Diagnostic Cervicocerebral Catheter Angiography in Adults [4]). Patients will benefit when appropriate selection criteria, preprocedure and postprocedure care, and monitoring are used. In all cases, the type of care provided should be directed by the operating physician, and treatment decisions should be made after individual consideration of each case. Variation from this parameter may be necessary and appropriate depending on the specific clinical circumstances.

## II. DEFINITIONS

For the purposes of this parameter, the following definitions are used:

Diagnostic arteriography – a procedure involving percutaneous passage of a needle and/or catheter into an artery, followed by injection of contrast material and imaging of the vascular distribution in question using digital imaging or serial film systems

Indicator – a specific, quantifiable, and objective measure of quality; for example, when measuring the safety of a procedure as one aspect of quality, specific complications would be the indicators

Moderate sedation – defined by the ACR–SIR Practice Parameter for Sedation/Analgesia [5]

Success – the completion of the arteriogram, including gaining access to the artery, obtaining a set of complete images together with other pertinent data (eg, hemodynamics) sufficient to support further medical decision-making, and the timely and accurate interpretation of the findings. Successful arteriography does not necessarily imply that the procedure is complication free; one may have successful arteriography with or without complications. For example, in the instance of atherosclerotic vascular disease, a complete set of images in the lower extremity is defined as imaging that includes the entire arterial circulation of a lower extremity, including the arterial supply to the foot.

Threshold – the specific level of an indicator that would cause a review to be performed. For example, if the incidence of contrast media–associated nephrotoxicity is used as an indicator of the quality of arteriography, exceeding a defined threshold, in this case 0.2%, should trigger a review of the individual or department to determine causes and to implement changes to lower the incidence.

## III. ALTERNATIVE DIAGNOSTIC STUDIES, INDICATIONS, AND CONTRAINDICATIONS

The lists below summarize most of the appropriate indications for diagnostic arteriography. The threshold for the department and for each individual is 95% (ie, 95% of procedures should be performed for one of the indications listed below). In addition, for diagnostic arteriography to be considered appropriate, its performance should have the potential for enhancing further medical decision-making in the clinical care of the patient.

A. As there are continual advances in medical diagnostic, therapeutic, and imaging technology, many of the indications listed below may also be investigated by alternative diagnostic technologies, including, but not limited to:

1. Ultrasound
2. Magnetic resonance imaging (including magnetic resonance angiography)
3. Computed tomography (including computed tomography angiography)
4. Nuclear medicine, including positron emission tomography
5. Functional and perfusion imaging
6. Physiologic testing (eg, pulse volume recording)
7. Segmental blood pressure measurements

It is incumbent upon the physician to determine the relative benefit and risk of diagnostic arteriography compared with the alternative diagnostic techniques for each patient prior to suggesting and/or performing diagnostic arteriography.

Some of these alternative tests may be used as an adjunct to diagnostic arteriography. The use of serial tests in medical decision-making is well recognized and, in appropriate clinical circumstances, is justified. Such appropriate use of serial testing should be documented in the medical record.

B. Indications

1. Pulmonary arteriography [6-14]
    a. Suspected acute pulmonary embolus, in particular when other diagnostic tests are inconclusive or discordant with clinical findings
        i. High-probability ventilation-perfusion imaging study when there is a contraindication to anticoagulation
        ii. Indeterminate ventilation-perfusion imaging study or nondiagnostic CT scan in a patient suspected of having a pulmonary embolus
        iii. Low-probability ventilation-perfusion imaging study in a patient with a high clinical suspicion of pulmonary embolus
        iv. Ventilation-perfusion imaging study or CT pulmonary angiography scan cannot be performed.
    b. Known or suspected chronic pulmonary thromboembolism
    c. Other suspected pulmonary abnormalities, such as vasculitis, congenital and acquired vascular anomalies, tumor encasement, and vascular malformations
    d. Foreign body retrievals within the pulmonary vasculature
    e. Prior to, during, or after arterial intervention
    f. Spontaneous hemorrhage

2. Spinal arteriography [15,16]
    a. Spine and spinal cord tumors
    b. Vascular malformations
    c. Spinal trauma
    d. Preoperative evaluation prior to open or endovascular aortic or spinal surgery
    e. Prior to, during, or after arterial intervention
    f. Spontaneous hemorrhage

3. Bronchial arteriography [9,10,17-19]
    a. Hemoptysis
    b. Suspected congenital cardiopulmonary anomalies
    c. Assessment of distal pulmonary artery circulation (through collaterals) in patients who are potential candidates for pulmonary thromboendarterectomy
    d. Prior to, during, or after arterial intervention
    e. Bronchial artery aneurysm
    f. Spinal arteriovenous malformations

4. Aortography [17,20]
    a. Abnormalities including acute traumatic injury, dissection, aneurysm, occlusive disease, aortitis, and congenital anomaly
    b. Evaluation of the aorta and its branches prior to selective studies
    c. Prior to, during, or after arterial intervention
    d. Spontaneous hemorrhage

5. Abdominal visceral arteriography [21-27]
    a. Acute or chronic gastrointestinal hemorrhage
    b. Blunt or penetrating abdominal trauma
    c. Intra-abdominal tumors
    d. Acute or chronic intestinal ischemia
    e. Evaluation of mesenteric, splenic, and portal vein patency in the setting of suspected portal hypertension
    f. Primary vascular abnormalities, including aneurysms, vascular malformations, occlusive disease, and vasculitis
    g. Preoperative evaluation prior to open surgical procedures
    h. Preoperative and postoperative evaluation of organ transplantation
    i. Iatrogenic vascular injury
    j. Prior to, during, or after arterial intervention
    k. Spontaneous hemorrhage

6. Renal arteriography [28,29]
    a. Renovascular occlusive disease (eg, for hypertension or progressive renal insufficiency)
    b. Renal vascular trauma
    c. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis
    d. Renal tumors
    e. Hematuria of unknown cause
    f. Preoperative and postoperative evaluation for renal transplantation
    g. Iatrogenic vascular injury
    h. Prior to, during, or after arterial intervention
    i. Spontaneous hemorrhage

7. Pelvic arteriography [24,30]
    a. Atherosclerotic aortoiliac disease
    b. Gastrointestinal or genitourinary bleeding
    c. Trauma
    d. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis
    e. Male impotence caused by arterial occlusive disease
    f. Pelvic tumors
    g. Benign prostatic hyperplasia
    h. Uterine leiomyoma; adenomyosis
    i. Postpartum hemorrhage

j. Iatrogenic vascular injury
k. Prior to, during, or after arterial intervention
l. Spontaneous hemorrhage
m. Assessment of arterial anatomy, such as in prior to free flap harvesting or organ transplantation

8. Extremity arteriography [31-37]
   a. Atherosclerotic vascular disease, including aneurysms, emboli, occlusive disease, and thrombosis
   b. Vascular trauma
   c. Preoperative planning and postoperative evaluation
   d. Evaluation of surgical bypass grafts and dialysis grafts and fistulas
   e. Other primary vascular abnormalities, such as vascular malformations, vasculitis, entrapment syndrome, and thoracic outlet syndrome
   f. Extremity tumors
   g. Iatrogenic vascular injury
   h. Prior to, during, or after arterial intervention
   i. Spontaneous hemorrhage

There may be circumstances where arteriography prior to, during, or after arterial intervention is justified on other vessels not cited above.

The threshold for these indications is 95%. When fewer than 95% of procedures are for these indications, the department will review the process of patient selection. These indications apply to both adult and pediatric patients unless otherwise specified.

C. Contraindications

There are no absolute contraindications to diagnostic arteriography. Relative contraindications include:

1. Severe hypertension
2. Uncorrectable coagulopathy or thrombocytopenia
3. Clinically significant sensitivity to iodinated contrast material
4. Renal insufficiency based on the estimated glomerular filtration rate (eGFR).
5. Congestive heart failure
6. Certain connective tissue disorders (reported complications at the puncture site)

For optimum patient management, these relative contraindications should be addressed prior to the procedure. Every effort should be made to correct or control these clinical situations before the procedure, if feasible.

## IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Image-based diagnosis and treatment planning require integrating the angiographic findings with the patient's history, physical findings, and prior imaging studies. Therefore, the physician must be clinically informed and understand the specific questions to be answered by diagnostic arteriography prior to the procedure in order to plan and perform it safely and effectively.

The physician performing a diagnostic arteriogram must fully appreciate the benefits, alternatives, and risks of the procedure. He or she must have a thorough understanding of vascular anatomy (including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety considerations, and physiologic monitoring equipment and have access to an adequate supply of catheters, guidewires, and personnel to perform the procedure safely.

Diagnostic arteriography examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications pertinent to the scope of services to be provided and the specific privileges sought:

1. Certification in Radiology, Diagnostic Radiology or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of arteriography procedures to demonstrate competency as attested by the supervising physician(s) [38,39].

   or

2. Successful completion of radiology residency training 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) to include interventional radiology residency and/or interventional/vascular radiology fellowship, and must have a minimum of 12 months training in a service that is primarily responsible for the performance of percutaneous peripheral, visceral, and neurovascular diagnostic arteriography. Documented formal training in the performance of invasive catheter angiographic procedures must be included. During this training, the physician should have performed (with supervision) a sufficient number of arteriography procedures to demonstrate competency as attested by the supervising physician(s) [38].

   or

3. Successful completion of an ACGME-approved nonradiology residency or fellowship training, and must have a minimum of 12 months of training on a service that is primarily responsible for the performance of percutaneous peripheral, visceral, or neurodiagnostic arteriography and vascular/interventional radiology. Documented formal training in the performance of invasive catheter arteriographic procedures must be included. During this training the physician should have performed 100[2] peripheral, visceral, or neurodiagnostic arteriograms, 50 as primary operator, and these cases must be documented so the director of the training program can certify that the physician is proficient in the performance of the procedures, with acceptable success and complication rates within the quality assurance threshold rates laid out in this parameter [38].

   and

4. Physicians meeting any of the qualifications in 1, 2, or 3 above must also have written substantiation that they are familiar with all of the following:
   a. Indications and contraindications for the procedure.
   b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and complications. For pediatric cases, this includes dedicated training in pediatric angiography and the

[2] When these numbers are used for credentialing, they apply to a complete patient encounter regardless of the number of vessels selected or treated during a given encounter [35].

underlying causes of pediatric vascular disease as well as knowledge of age-based normal ranges for vital signs, and signs and symptoms of complications; or the availability of team members with such expertise (such as pediatric sedation and monitoring personnel). This also includes knowledge of the normal amounts of fluids that can be administered during the procedure (including fluids going through sheaths) to prevent volume overload.

c. Pharmacology of drugs used for sedation and analgesia, and recognition and treatment of adverse reactions and complications. For pediatric cases, this includes knowledge of weight based pediatric dosages, age-based normal values for vital signs, contraindications and signs and symptoms of adverse reactions and complications.
d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, digital subtraction, and other electronic imaging systems.
e. Principles of radiation protection, the hazards of radiation, and radiation monitoring requirements as they apply to patients and personnel, including appropriate dose-reduction strategies for children [40].
f. Pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
g. Percutaneous needle and catheter introduction techniques. Ultrasound guidance may be used for access, most often in children. For neonates this also implies the potential use of the umbilical artery as a possible catheter access site for angiographic procedures.
h. Technical aspects of performing the procedure, including the use of alternative catheter and guide-wire systems, invasive monitoring devices such as pressure transducers, selective angiographic methods, appropriate injection rates and volumes of contrast media (weight-based in children), and imaging sequences [41].
i. Recognition of periprocedural complications and knowledge of treatment options for these complications (eg, stenting, embolization, thrombolysis, suction embolectomy, surgery).
j. Anatomy, physiology, and pathophysiology of peripheral and visceral arterial vasculature, including normal variants.
k. Interpretation of diagnostic arteriographic studies including common artifacts (eg, standing wave, bone subtraction artifact).

The written substantiation should come from the chief of interventional radiology, the chief of neuroradiology, the chief of interventional neuroradiology, or the chair of the department of the institution in which the physician will be providing these services[3]. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional, neurointerventional, or neuroradiology chief, or the chair who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of diagnostic arteriographic procedures to maintain their skills, with acceptable success and complication rates as laid out in this parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician's continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [42].

[3] At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ (43).

B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team. Their participation in angiography procedures should be specifically under the supervision of appropriately qualified and credentialed physicians. See the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [43].

C. 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 in 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, or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [42]

The appropriate subfield of medical physics for this parameter is Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, or Diagnostic Imaging Physics.)

D. 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)

E. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position[4] the patient for the arteriographic procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

[4] 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, Resolution 12m)

*For the purposes of this parameter, "personally and immediately available" is defined in manner of the "personal supervision" provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001

The technologist should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the diagnostic arteriography procedure.

F. Nursing Services

Nursing services are an integral part of the team for periprocedural and intraprocedural patient management and education and are recommended in monitoring the patient during the procedure.

## V. SPECIFICATIONS OF THE EXAMINATION

Several technical requirements are necessary to ensure safe and successful diagnostic arteriograms. These include adequate arteriographic equipment, institutional facilities, physiologic monitoring equipment (including intravascular pressure measurement systems), and personnel.

A. Arteriographic Equipment and Facilities

The following are considered the minimal arteriographic equipment required for obtaining diagnostic arteriograms. In planning arteriographic facilities, equipment and facilities more advanced than those outlined below may be desired to produce higher-quality studies with reduced risk and time of study. In general, the facility should include at a minimum:

1. A high-resolution flat-panel detector or image intensifier and television chain with standard arteriographic filming capabilities, including large-format image intensifiers (14 inch or greater) with minimum 1,024-image matrix. Smaller image intensifiers may be used in primarily pediatric settings. Digital angiographic systems are strongly recommended, as they allow for reduced volumes of contrast material, reduced examination times, and reduction of radiation dose. Features such as last image hold, pulsed fluoroscopy, and road mapping capabilities are strongly recommended for dose reduction. Imaging and image recording must be consistent with the "as low as reasonably achievable" radiation safety guidelines. Appropriate shielding for the operator should be available on all angiographic systems [44]. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of noncardiac angiography because they cause an unacceptably high patient and operator radiation dose.
2. The equipment should be capable of recording the radiation dose received by the patient so it can be made part of the patient's permanent medical record [45].
3. Adequate angiographic supplies such as catheters, guidewires, needles, and introducer sheaths
4. An angiographic injector capable of varying injection volumes and rates, with appropriate safety mechanisms to prevent overinjection
5. An angiography suite that is large enough to allow safe transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
6. An area for preprocedural preparation and postprocedural observation and monitoring of the patient**.** At this location, there should be personnel to provide care as outlined in section V.E below (patient care), and there should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present in the arteriography suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. If the patient receives sedation, the ACR–SIR Practice Parameter for Sedation/Analgesia should be followed [5].
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The

equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

3. If peripheral or pulmonary arteriography is regularly performed, physiologic pressure monitors should be available for determining intra-arterial pressures.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the arteriographic equipment should assist in performing and imaging the procedure. They should be able to demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. Technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive sedation, a member of the procedural team should be assigned to periodically assess the patient's status. If the patient undergoes sedation, a nurse or other appropriately trained individual should monitor the patient as his or her primary responsibility. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information. Nursing personnel should be qualified to administer sedation (see the ACR–SIR Practice Parameter for Sedation/Analgesia [5]). For pediatric cases, personnel should be experienced and qualified in pediatric sedation, monitoring, and airway maintenance. Having Pediatric Advanced Life Support (PALS) training and current certification is recommended. Children may easily slip between depths of sedation during the case. Therefore, there must be experienced and qualified personnel available to manage the airway and rescue children from deep sedation or apnea should this occur (see the ACR–SIR Practice Parameter for Sedation/Analgesia [5]). Anesthesia team support should be considered as an alternative to sedation in patients if nursing staff is uncomfortable with sedation of patients or if there are extensive comorbidities.

D. Surgical Support

For additional information, see the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [43].

Although complications of diagnostic arteriography only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly. Ideally, this would be an acute care hospital with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding center, detailed protocols for the rapid transport or admission of patients to an acute care hospital should be formalized in writing. It is preferred that pediatric angiography be performed at institutions with appropriate pediatric subspecialty and supportive care.

E. Patient Care

1. Preprocedural care

The indications for elective arteriographic studies should be documented as described below. For emergency procedures, a note should be written summarizing the indications for the study, the pertinent history and physical findings, if available, and the proposed procedure.

a. Clinically significant history, including indications for the procedure
b. Clinically significant physical examination, including an awareness of clinical or medical conditions that may necessitate specific care. For most patients with chronic lower-extremity atherosclerotic disease, ankle/brachial systolic pressure ratios should be measured prior to arteriography. However, there are instances, such as in patients with advanced multilevel disease, when ankle/brachial systolic pressure ratios are of less value than objective physical findings. In selected cases, measurement of

segmental pressures or pulse-volume recordings may help define the level of disease and assist in planning the arteriographic approach.

c. Laboratory evaluation may be indicated, including measurement of hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters.

Informed consent must be in compliance with state laws and the ACR–SIR Practice Parameter on Informed Consent for Image-Guided Procedures [46].

2. Procedural care

a. Adherence to the Joint Commission's current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures.
The organization should have processes and systems in place for reconciling differences in staff responses during the "time-out."

b. All patients should have cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs should be maintained.

c. All patients should have intravenous access for the administration of fluids and medications as needed.

d. If the patient receives sedation, pulse oximetry should be used in addition to 2b above. Carbon dioxide capnography is strongly recommended. A registered nurse or other appropriately trained personnel should be present, and his or her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration.

e. In certain circumstances, intra-arterial pressure measurements are very helpful in the assessment of peripheral vascular disease, in pulmonary arteriography, and in other diagnostic vascular procedures. Their use is encouraged when indicated.

f. A physician should be available during the immediate postprocedure period to ensure that there is adequate hemostasis at the puncture site and that the patient is stable prior to transfer to the postprocedure care area.

g. In all patients, an ongoing tally of contrast material administered should be performed to avoid contrast nephropathy.

3. Postprocedural care

a. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If sedation was administered prior to and during the procedure, safe and adequate recovery from sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician, a physician assistant, or a nurse. See the ACR–SIR Practice Parameter for Sedation/Analgesia [5]. Postprocedure documentation should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [47].

A procedure note should be written in the patient's chart summarizing the major findings of the study and any immediate complications. This note may be brief if an official interpretation will be available within a few hours. However, if the official interpretation is not likely to be in the medical record the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the site and size of the vascular access, the means by which hemostasis was achieved, puncture-site stability, and the patient's medical condition.

c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site and the status of the distal vascular circulation.
d. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications that may need to be addressed further.
e. The initial ambulation of the patient must be supervised. Vascular perfusion, puncture-site stability, and independent patient function and mobility must be ensured.
f. When the treatment of vascular access requires manipulation in the ascending or transverse thoracic aorta or brachiocephalic vessels, neurologic status should be assessed periodically and changes from baseline reported immediately.
g. Additional sedation and postprocedural observation may be indicated and necessary for the safety of pediatric patients, depending on age and morbidities.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be individualized. Arteriography can be performed on many patients with a short period of postprocedure observation (less than 8 hours) prior to discharge to home; others require overnight care. Short-term observation should be considered only when all of the following conditions can be met:

1. A patient capable of independent ambulation prior to the procedure demonstrates stable, independent ambulation after the procedure. Alternatively, nonambulatory patients should have adequate assistance after discharge to provide care as needed.
2. Prior to discharge, the patient's mental status has returned to baseline, with the patient, guardian, or supervising adult capable of following instructions and detecting changes in symptomatology.
3. The patient, guardian, or supervising adult is provided with instructions on how to recognize potential complications (eg, bleeding at the puncture site, neurologic deficit, decreased urinary output, pain, and discoloration distal to the puncture site) and how to obtain medical assistance in the event of such complications.
4. A responsible adult is provided with information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.
5. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
6. The patient has recovered from the effects of the sedation to a level as defined in the ACR–SIR Practice Parameter for Sedation/Analgesia [5].

G. Relative Contraindications to Short-Term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Some of the relative contraindications to short-term observation are listed below. This list is not meant to be comprehensive, and any clinical circumstance that might predispose the patient to significant complication should prompt overnight admission.

1. Patients with poorly controlled hypertension in whom there appears to be increased risk of hematoma formation may benefit from overnight observation.
2. Patients with significant risk of contrast media–associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration
3. Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.
4. Insulin-dependent diabetics who have labile serum glucose levels in the periprocedure period should be hospitalized until stable.
5. Complications occurring during or after arteriography, including large hematoma, anuria, persistent nausea, vomiting, or unexpected alteration in neurological status compared to baseline, should prompt observation until symptoms resolve.

6. Patients who exhibit hemodynamic instability or significant arrhythmia during or after the procedure should be hospitalized until stable.
7. Travel time to the hospital or to another acute care facility should be less than 1 hour from where the patient is to spend the first postprocedure night.
8. For pediatric patients, inadequate parent or guardian ability or availability for monitoring for early postprocedure or postanesthesia complications, in addition to the patient's inability to follow instructions, potentially places the patient at higher risk.

The decision regarding short-term or longer-term postprocedure observation must be individualized, and a patient's care may vary from the above criteria for sound clinical reasons. The decision in each case must be made by the operating physician and the referring physician after review of all pertinent data.

## VI. DOCUMENTATION

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [47].

## VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)
http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

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

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

Radiation safety deserves particular attention when fluoroscopically guided procedures are performed on children [45,48]. The Image Gently coalition has provided useful guidance in this regard, including the Step Lightly

campaign [49]. The Image Wisely campaign has been formed to provide similar guidance for radiation safety in adult patients.

As noted in the ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures [50]: "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 [45,48,51]. (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 [52].) If follow-up for possible radiation injury is indicated, the patient should be advised of 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 [45]. When potentially high-dose procedures are repeated, (eg, TIPS, or for neuroembolization), previous skin exposure should be considered [53]." The SIR–CIRSE Cardiovascular and Interventional Radiological Society of Europe guidelines for patient radiation dose management recommend that follow-up should be performed if the cumulative air kerma at the reference point exceeds 5 Gy [48,50].

## VIII. 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 (http://www.acr.org/guidelines).

These data should be used in conjunction with the thresholds described in section IX below to assess diagnostic arteriography procedural efficacy and complication rates and to trigger institutional review when those thresholds are exceeded.

## IX. QUALITY IMPROVEMENT

These parameters are to be used in quality improvement (QI) programs to assess diagnostic arteriography. The most important processes of care are patient selection, performance of the procedure, and monitoring the patient. The major outcome measures for diagnostic arteriography include complete imaging of the pathology, success rates, and complication rates. Outcome measures are assigned threshold levels.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, in addition to QI case reviews customarily conducted after individual procedural failures or complications, outcome measure thresholds should be used to assess diagnostic arteriography in ongoing QI programs.

For the purpose of these parameters, a threshold is a specific level of an indicator that, when reached or crossed, should prompt a review of departmental policies and procedures. Procedure thresholds or overall thresholds refer to a group of outcome measures for a procedure (eg, major complications for diagnostic arteriography). Individual complications may also be associated with complication-specific thresholds (eg, fever or hemorrhage).

When outcome measures such as success rates or indications fall below a minimum threshold or when complication rates exceed a maximum threshold, a departmental review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own QI program needs.

Complications can be stratified on the basis of outcome. Major complications may result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged

hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation, generally overnight (see Appendix A). The complication rates and thresholds refer to major complications, unless otherwise noted.

A. Measure of Success

The rate for successful completion of a diagnostic arteriogram is 95%.

B. Complication Rates and Thresholds

Complications from diagnostic arteriography are uncommon. Digital subtraction angiography may allow reduced contrast load and reduced time of study, and it may result in lower incidence of complications [54]. Arteriographic complications may be divided into 3 groups: puncture site, systemic, and catheter induced. Puncture site complications such as arterial spasm, thrombosis, and hematoma may be more frequent in infants and small children, given the small size of their vessels relative to the size of sheaths and catheters.

By far, the most frequent puncture site complication is hematoma. Although the incidence of minor hematomas is quite variable and may be as high as 10%, major hematomas are unusual [54-56]. A major hematoma, defined as one requiring transfusion, surgical evacuation, or delay in discharge, occurs in 0.5% of femoral punctures and 1.7% of axillary punctures [57]. Other puncture-site problems, including dissection, thrombosis, pseudoaneurysm, and arteriovenous fistula, are also rare, occurring in less than 1% of femoral punctures. There is some variation in the number of complications, depending on the puncture site chosen [56]. For example, a small hematoma at an axillary puncture site may cause neural injury and require surgical evacuation earlier than a similar femoral hematoma.

Vascular closure devices (VCDs) have been developed to reduce the cost of a hospital stay as well as complications [58]. The use of VCDs is currently indicated for retrograde femoral arterial access. Some studies have shown that there is a higher risk of pseudoaneurysm and hematoma with VCDs, as well as an increased risk of complications in patients with peripheral arterial disease [58,59]. There are other studies, however, showing either noninferiority or a decreased rate of major complications of VCDs compared to manual compression for peripheral arterial interventions or cardiac interventions [60,61]. VCDs can be used to improve patient satisfaction, decrease hospital stay, and encourage patient mobilization without prolonged bed rest [58,61,62]. VCDs are not approved for use in pediatric patients and their use should be cautioned [41].

Clinically significant infection at the puncture site with bacteremia is very rare, occurring most often in repeated punctures of the same artery over a short period of time or with long-term sheath access, as in endovascular procedures. Although antibiotic prophylaxis is not generally required for diagnostic arteriography [63,64], it may be warranted in patients who are at risk for infection (eg, diabetic, immunocompromised) or who undergo vascular closure placement or in patients subjected to lengthy procedures [65].

Systemic complications occur in less than 5% of cases. Among the most common are nausea, vomiting, and vasovagal syncope. Minor nausea without associated vomiting occurs more frequently but usually with mild symptoms that pass in a few moments. This generally is not listed as a complication, as the episode is self-limited, is not associated with changes in pulse or blood pressure, and does not require specific therapy. Nausea may also be a symptom of vasovagal hypotension, which is usually characterized by lightheadedness, bradycardia, diaphoresis, and hypotension. Idiosyncratic (allergic) contrast reactions, which include urticaria, periorbital edema, wheezing, etc, complicate less than 3% of arteriographic procedures [66]. Most reactions are mild; more than half require no therapy and less than 1% necessitate hospitalization. There are fewer reactions with lower-osmolality agents, particularly for patients with a history of a previous contrast reaction or more than 1 other major risk factor [67-70]. See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [71] and the ACR Manual on Contrast Media [72].

The incidence of contrast media–associated nephrotoxicity is difficult to determine from a review of the literature, in part because of the varying definitions that have been used [73-76]. Preexisting renal insufficiency is a risk factor for the development of contrast media–induced nephrotoxicity. Other predisposing risk factors include insulin-dependent diabetes, possibly dehydration, and large contrast volume. Digital subtraction arteriographic systems have allowed lower contrast doses and, as a result, may lower the risk of renal injury [54]. Low-osmolar contrast medium has a small but definite benefit over high-osmolar contrast media for patients with preexisting azotemia [77]. Preprocedural hydration may have a protective effect in high-risk patients. Some newer drugs and hydration protocols may also have a role in protection from contrast media–associated nephrotoxicity, but they require further study. In pediatric angiography, knowledge of weight-based contrast media volume limits and familiarity of alternative contrast media such as carbon dioxide are useful to minimize complications.

For the purposes of this parameter, contrast media–associated nephrotoxicity as a major complication is clinically defined as an elevation of serum creatinine requiring care that unexpectedly delays discharge or results in unexpected admission, readmission, or permanent impairment of renal function. This definition focuses on the outcome of renal impairment, which is the central issue in any monitoring program. The threshold chosen is 0.2% for contrast media–associated nephrotoxicity requiring renal replacement therapy, such as dialysis, and is based on consensus and a review of the pertinent literature. It is very dependent on the patient population, and practitioners are encouraged to modify this threshold to reflect the circumstances of their practice.

Complications related to catheter manipulation are the third group of complications in arteriography. These include subintimal passage of the guidewire or catheter and dissections or emboli caused by catheter manipulation or contrast injection. These have been reported to occur in 0.5% to 2.0% of cases, with the most recent series reporting a frequency of less than 0.5% [54,56,78].

Pediatric angiography holds additional unique potential complications, including arterial stenosis and occlusion due to vasospasm, which may lead to limb length discrepancy. In recent years, these types of complications have decreased in frequency, in part because of advances in guidewire, sheath, and catheter technology. For pediatric complication rates, detailed discussion is available elsewhere [41].

Other complications can be stratified on the basis of outcome. Major complications may result in admission to a hospital for therapy (for outpatient procedures); an unplanned increase in the level of care, resulting in prolonged hospitalization; permanent adverse sequelae; or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation, generally overnight (see Appendix A). The complication rates and thresholds listed below refer to major complications unless otherwise noted. Any death within 24 hours of the procedure or a puncture-site infection should be reviewed as part of the institution-wide QI program.

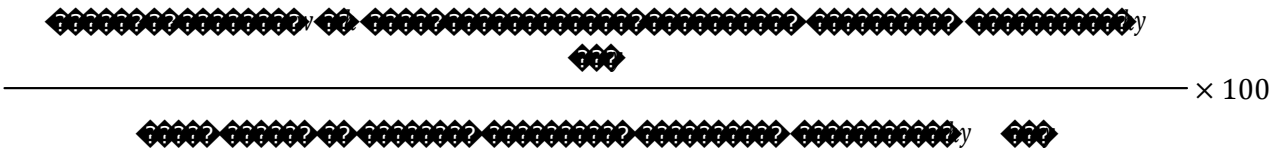
Indicators and thresholds for complications in diagnostic arteriography are listed in Table 1 [41]. The thresholds listed were determined by consensus after review of the pertinent literature. The thresholds are recommendations only and may require alteration to meet the needs of each institution after consideration of the patient population, the procedure mix, and the skills of the physicians involved. The departmental indicators should be used for all procedures performed within the department**.** Each physician should be appropriately monitored. The actions taken when the thresholds are exceeded should be set by each department and stated in the department's QI program summary.

**Table 1**
**Indicators and Thresholds for Complications in Diagnostic Arteriography [54-57,63,64,66-70,72-87]**

| Department Indicators | Reported Rates | Major Adverse Event Threshold |
|---|---|---|
| **Puncture-site complications** | | |
| Hematoma (requiring transfusion, surgery, or delayed discharge) | 0.0% to 0.68% | 0.5% |

| Department Indicators | Reported Rates | Major Adverse Event Threshold |
|---|---|---|
| Occlusion | 0.0% to 0.76% | 0.2% |
| Pseudoaneurysm or arteriovenous fistula | 0.04% to 0.3% | 0.2% |
| **Vascular closure device–associated complications Access site infection** | 0.5% to 2.4% | 2.0% |
| **Catheter-induced complications in the aorta or principal branches (other than puncture site)** | | |
| Distal emboli | 0.0% to 0.10% | 0.2% |
| Arterial dissection / subintimal passage | 0.43% | 0.5% |
| Subintimal injection of contrast media | 0.0% to 0.44% | 0.5% |
| **Other procedure-related complications** | | |
| Major contrast media reactions | 0.0% to 3.58% | 0.5% |
| Contrast media–induced nephrotoxicity requiring renal replacement therapy (such as dialysis) | 0.2% to 3.0% | 0.2% |
| Overall procedure threshold for major complications | 1.0% | 1.0% |

The overall procedure threshold for major complications is determined by the following formula:



Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small number of patients (eg, early in a QI program). In this situation, the overall procedure threshold is more appropriate for use in a QI program.

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

ACR
Minhajuddin S. Khaja, MD, MBA, Chair
Timothy J. Carmody, MD, FACR
Matthew D. Hermann, MD
Wael Saad, MD, FSIR

SIR
Mark J. Hogan, MD
Jason W. Mitchell, MD
Waleska M. Pabon-Ramos, MD, MPH
Rajeev Suri, MBBS

SPR
Leah E. Braswell, MD
Jared R. Green, MD
Craig Johnson, MD

Committee on Practice Parameters – Interventional and Cardiovascular Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Clayton K. Trimmer, DO, FACR, FAOCR, SIR, Chair
Chaitanya Ahuja, MBBS
Drew M. Caplin, MD
Sean R. Dariushnia, MD
Jeremy L. Friese, MD, MBA
Joshua A. Hirsch, MD, FACR, FSIR
Kelvin Hong, MD, FSIR
Elizabeth A. Ignacio, MD, FSIR
Sanjeeva P. Kalva, MD, FSIR
Minhajuddin S. Khaja, MD, MBA
Margaret Hsin-Shung Lee, MD
Susan K. O'Horo, MD, FSIR
John D. Prologo, MD
Stephen P. Reis, MD
Wael Saad, MD, FSIR
Beth A. Schueler, PhD, FACR, FAAPM
Sanjit Tewari, MD
Joan C. Wojak, MD, FACR, FSIR

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Lorna P. Browne, MB, BCh
Timothy J. Carmody, MD, FACR
Brian D. Coley, MD, FACR
Lee K. Collins, MD
Monica S. Epelman, MD
Lynn Ansley Fordham, MD, FACR
Kerri A. Highmore, MD
Sue C. Kaste, DO
Tal Laor, MD
Terry L. Levin, MD
Marguerite T. Parisi, MD, MS
Sumit Pruthi, MBBS
Nancy K. Rollins, MD
Pallavi Sagar, MD

Philip S. Cook, MD, FACR, FSIR, Chair, Commission on Interventional and Cardiovascular Radiology
Marta Hernanz-Schulman, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline A. Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Richard Strax, MD, FACR, Chair
Eric B. Friedberg, MD, FACR, Co-Chair
Jacqueline A. Bello, MD, FACR
Leah E. Braswell, MD
Timothy J. Carmody, MD, FACR
Philip S. Cook, MD, FACR, FSIR
Jared R. Green, MD
Matthew D. Hermann, MD
Marta Hernanz-Schulman, MD, FACR
William T. Herrington, MD, FACR
Mark J. Hogan, MD
Craig Johnson, MD
Sanjeeva P. Kalva, MD
Minhajuddin S. Khaja, MD, MBA
Jason W. Mitchell, MD
Beverley Newman, MB, BCh, BSc, FACR
Waleska M. Pabon-Ramos, MD, MPH
Matthew S. Pollack, MD, FACR
Michael I. Rothman, MD, FACR
Wael Saad, MD, FSIR
Rajeev Suri, MBBS
Timothy L. Swan, MD, FACR, FSIR
Clayton K. Trimmer, DO, FACR, FAOCR, SIR

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## Appendix A

**Society of Interventional Radiology**
**Standards of Practice Committee**
**Classification of Complications by Outcome**

**Minor Complications**

A. No therapy, no consequence
B Nominal therapy, no consequence; includes overnight admission for observation only

**Major Complications**

A. Require therapy, minor hospitalization (<48 hours)
B. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
C. Permanent adverse sequelae
D. Death

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

Development Chronology for this Parameter
1993 (Resolution 8)
Amended 1995 (Resolution 14)
Revised 1997 (Resolution 5)
Revised 1999 (Resolution 9)
Revised 2002 (Resolution 12)
Amended 2004 (Resolution 25)
Amended 2006 (Resolution 16g**,** 17, 34, 35, 36)
Revised 2007 (Resolution 9)
Amended 2009 (Resolution 11)
Revised 2012 (Resolution 5)
Amended 2014 (Resolution 39)
Revised 2017 (Resolution 14)
Amended 2018 (Resolution 44)