ACR-SPR PRACTICE PARAMETER FOR THE USE OF INTRAVASCULAR CONTRAST MEDIA

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 care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

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

I. INTRODUCTION

¹ Iowa 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, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

This practice parameter has been revised to promote the safe and effective administration of intravascular contrast media used for imaging studies and was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR).

For a complete discussion of the use of intravascular contrast media and potential adverse events related to contrast media administration (including, but not limited to, nephrotoxicity, extravasation, allergic-like reactions, pregnancy issues, and drug interactions, see the <u>ACR Manual on Contrast Media</u> [1].

The goals of personnel administering intravascular contrast media include using contrast media appropriately, optimizing image quality, and minimizing risk to the patient.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Provider(s) Responsible for Predefining Contrast-Enhanced Imaging Protocols

A standardized set of predefined imaging protocols for contrast-enhanced examinations should be available with specific instructions to facilitate asynchronous direction of personnel performing the examination. The party responsible for predefining standardized imaging protocols is typically a group but could be a single provider. This should include at least 1 physician (MD/DO) who is familiar with the various contrast media available and the indications and contraindications for each but might also include nonradiologist physicians, technologists, and/or radiologic physicists. Specific recommendations for information to be included in predefined protocols are included in section III: Specifications of the Procedure.

B. Provider Responsible for Ordering the Contrast-Enhanced Examination

The order for an imaging examination should be placed by a licensed provider who meets institutional, state, and federal requirements for performing this task. Some recommendations regarding the order for an imaging study are noted in ection III: Specifications of the Procedure.

All administrations of intravascular contrast material (including intravenous or intra-arterial injections of iodinated contrast media, gadolinium-based contrast agents (GBCAs), and other contrast media [eg, microbubble ultrasound contrast agents or superparamagnetic iron oxide particles]) should be directed by either a written or an electronic order. The order for an imaging examination may include the order for medications such as contrast material. Providers ordering contrast material must be:

- 1. A radiologist or other appropriately trained physician (see "Physician(s) Responsible for Defining the Contrast-Enhanced Imaging Protocol" below) working within the imaging department.
- 2. Another appropriately qualified and licensed care provider outside the imaging department ordering an examination that will be performed according to a predefined standardized imaging protocol (see "Physician(s) Responsible for Defining the Contrast-Enhanced Imaging Protocol" and "Specifications of the Procedure" below). In this latter case, the ordering provider takes on the responsibility for the decision to administer contrast material and should be familiar with contraindications.
- C. [2-5] Provider(s) Responsible for Assigning a Protocol to Contrast-Enhanced Examinations

An order for an imaging examination may or may not inherently request a specific imaging protocol for the examination, and a separate provider may assign a protocol. Providers assigning protocols for a contrastenhanced imaging study must have at least one of the following qualifications:

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

or

Completion of a radiology residency 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 imaging training on all body areas.

or

A physician whose residency or fellowship training did not include the above may still be considered qualified to protocol contrast media administration provided the individual can demonstrate sufficient knowledge of the pharmacology, indications, and contraindications for the use of contrast media to enable safe administration.

or

Appropriately experienced physicians currently in a radiology residency or fellowship 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 imaging training on all body areas, when so instructed by their supervising faculty and departmental/institutional policy.

A certified and/or licensed radiologic technologist, MRI technologist, ultrasound technologist, registered radiologist assistant, nurse, or physician assistant, under the supervision of a radiologist or his or her physician designee (see "Supervising Radiologist or Other Supervising Provider" below) [2-5] In some cases, a physician will directly define the imaging protocol at the time of the examination. In other cases, a provider will assign a protocol from a set of predefined imaging protocols that facilitate asynchronous direction of personnel performing the examination. If a predefined protocol is assigned, the assigning provider should be aware of pertinent risk factors that might increase the likelihood of adverse events from contrast media administration, should have knowledge of appropriate alternative imaging methods (see the <u>ACR Manual on Contrast Media [1]</u>), and should be familiar with strategies for mitigation of risk when alternative imaging methods are impractical (eg, premedication to mitigate the risk of contrast reaction and hydration to mitigate the risk of nephrotoxicity from iodinated contrast media). The provider should also be familiar with patient preparation for the examination, including any bowel preparation, and have knowledge of the volume and concentration of the appropriate contrast media required for a given examination.

 D. Provider(s) Responsible for Performing the Contrast-Enhanced Examination and Injecting Contrast Media The provider responsible for performing a contrast-enhanced examination may or may not be the same provider as is injecting the contrast media. Specific requirements of a person to perform a contrastenhanced imaging examination are beyond the scope of this practice parameter. However, requirements for pre-examination screening are provided below (see "Specifications of the Procedure").
While under supervision as outlined below (see "Supervising Radiologist or Other Supervising Provider") [2-5], injections may be performed by a certified and/or licensed radiologic technologist, MRI technologist, sonographer, registered radiologist assistant, nurse, physician assistant, physician, or other appropriately credentialed health care professional.

The injection technique must follow relevant institutional, state, and federal regulations. Training and proficiency in basic cardiopulmonary resuscitation and the management of adverse events related to intravascular contrast media administration are recommended for those who attend to patients undergoing contrast-enhanced examinations.

- E. Supervising Radiologist or Other Supervising Provider (ie, physician performing direct supervision) A radiologist (MD/DO) may provide direct supervision[1] of intravenous contrast material administration. When under the general supervision of a radiologist[2], the following providers may also provide direct supervision of intravenous contrast administration:
 - 1. Nonradiologist physicians (MD/DO)
 - 2. Advanced practice providers (nurse practitioner, physician assistant)
 - 3. Registered nurses following a symptom- and sign-driven treatment algorithm The radiologist or other provider directly supervising the injection of contrast media should be trained in, and periodically demonstrate competence in:
 - 4. Managing acute hypersensitivity and physiologic drug reactions. This may be done using diagnostic decision-making or by use of a symptom- and sign-driven treatment algorithm as is commonly used by nursing
 - 5. Appropriately administering reassurance, oxygen, antihistamine, intravenous fluids, beta2-agonist inhaler, epinephrine, and/or position changes

6. Understanding when to call for assistance and how to activate emergency response system(s)

- 7. Basic Life Support (BLS)
- F. This provider of direct supervision must be immediately available to furnish assistance and direction throughout the performance of the procedure [5,6]. This does not mean that the supervising provider or radiologist must be present in the room where and when the procedure is performed [5]. However, there should be at least one person who can recognize adverse events related to contrast media administration in attendance (in the room or in an adjacent control room) to observe the patient during and immediately after the injection and summon medical assistance as needed.

G. Other Participating Personnel

1. 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).

The appropriately credentialed NPRP performing injections of contrast media should comply with existing operating policies and procedures at the imaging facility in which the provider is working and must comply with state and federal regulations.

2. Technologist

Technologists performing injections of contrast media should comply with existing operating policies and procedures at the imaging facility in which they are working. At a minimum, the technologist should understand the general benefits of contrast media administration, follow protocols for safe intravascular injection of contrast media, understand contraindications to intravascular injection of contrast media, and recognize adverse events following contrast media administration. Certification by the American Registry of Radiologic Technologists (ARRT), the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT), American Registry for Diagnostic Medical Sonography (ARDMS), Cardiovascular Credentialing International (CCI) or an unrestricted state license is required.

3. Pharmacist

In some settings, a pharmacist may review the contrast medium order for appropriateness and/or dispense the contrast media. The reviewing pharmacist should be familiar with the various contrast media available and the indications and contraindications for each. However, pharmacist review may not be necessary for some settings that meet the Joint Commission

Medication Management Standards. It may be possible to meet Joint Commission standards by properly constructed and approved institutional policies and procedures that permit administration of intravascular contrast media without pharmacist review of each individual order.

[1] For the purpose of this parameter, direct supervision means that the physician must be present and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where and when the procedure is performed.

[2] For the purpose of this parameter, general supervision is defined by the Centers for Medicare & Medicaid Services (CMS) meaning that "the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure."

III. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for an examination using intravascular contrast media should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

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

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

Each facility or imaging department should have written policies, protocols, and procedures regarding administration of intravascular contrast media. In some cases, a physician or provider will directly define an imaging protocol at the time of the examination. However, a standardized set of predefined imaging protocols for contrast-enhanced examinations should be available with specific instructions to facilitate asynchronous direction of personnel performing the examination. Predefined protocols should include the type, timing, dosage, rate of injection, and route of administration of contrast media as well as timing and number of imaging acquisitions relative to contrast injection. Imaging protocols should be based on clinical indication and relevant history as provided in the request for examination.

Appropriate history and preprocedural screening should be performed by personnel familiar with the risk factors for adverse events, contraindications to contrast media administration, examination preparation, and premedication strategies. Relevant history and laboratory results should be reviewed by the personnel performing the injection prior to contrast media injection (see "Provider Responsible for Ordering the Contrast-Enhanced Examination" and "Provider(s) Responsible for Performing the Contrast-Enhanced Examination and Injecting Contrast Media,").

All imaging facilities should have policies and procedures to identify pregnant patients prior to imaging. Prior to contrast media administration, possible risks to the fetus and benefits of the procedure should be evaluated by a radiologist or other appropriately trained physician (see "Providers Responsible for Assigning a Protocol to Contrast-Enhanced Examinations" above) and discussed with the patient and referring clinician. For recommendations on when informed consent of a pregnant patient might be appropriate, please see the corresponding section in the <u>ACR Manual on Contrast Media [1]</u>.

Vascular access should be established or confirmed using the facility's protocol. Adequate access should be ascertained prior to contrast media injection including:

Determining whether the catheter type is appropriate for power injection or manual injection and verifying that the catheter type and location is appropriate for the injection rate and volume.

Facility or department protocols should be in place for treating patients with adverse events.

A clinically significant event and its treatment should be documented in the radiology report and/or the patient's medical record in compliance with the imaging facility's operating policies and procedures (see the <u>ACR Practice</u> <u>Parameter for Communication of Diagnostic Imaging Findings</u>[7]). Counseling about future contrast media administration and the possible need for future premedication should be directly communicated to the patient as well as the patient's referring provider, if possible.

IV. DOCUMENTATION

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging</u> <u>Findings</u> [7]. The use of contrast media (including for radiation therapy planning) should be documented in an appropriate record.

V. EQUIPMENT SPECIFICATIONS

Appropriate emergency equipment and medications must be immediately available to treat adverse events related to contrast media administration (see the <u>ACR Manual on Contrast Media</u> [1]). The equipment and medications should be monitored for inventory and drug expiration dates regularly. The equipment, medications, and other emergency support must be appropriate for the range of ages and/or sizes in the patient population.

VI. 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 Quality Control & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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

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