The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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

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

Amended 2014 (Resolution 39)*

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

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

I. INTRODUCTION

This practice parameter has been developed 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 of potential adverse events related to contrast media administration (e.g., nephrotoxicity, extravasation, allergic-like reactions pregnancy issues, and other concerns [e.g., drug interactions], see the <u>ACR Manual on Contrast Media</u> [1].

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

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The health care professional performing the injection must be a certified and/or licensed radiologic technologist, MRI technologist, registered radiologist assistant, nurse, physician assistant, physician, or other appropriately credentialed health care professional under the direct supervision² of a radiologist or his or her physician designee [2-4]. The injection technique must be in compliance with relevant institutional, state, and federal regulations. Training and proficiency in cardiopulmonary resuscitation are recommended for those who attend to patients undergoing contrast-enhanced examinations.

A. Physician

1. The physician should be a licensed physician with 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 the Collège des Médecins du Québec.

or

Completion of a 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 he or she can demonstrate sufficient knowledge of the pharmacology, indications, and contraindications for the use of contrast media to enable safe administration, and can recognize and initiate treatment for adverse events.

- 2. The physician should be familiar with the various contrast media available and the indications and contraindications for each. The physician should be aware of specific relative contraindications and pertinent risk factors that might increase the likelihood of adverse events from contrast media administration, and should have appropriate knowledge of alternative imaging methods (see the <u>ACR Manual on Contrast Media</u> [1]). The physician should also be familiar with patient preparation for the examination, including any necessary hydration or bowel preparation. He or she should have knowledge of the volume and concentration of the appropriate contrast media required for a given examination.
- 3. The physician is responsible for defining the examination protocol, including specifying the type, timing, dosage, rate of injection, and route of administration of contrast media.

 $^{^{2}}$ 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 the procedure is performed.

B. Physician Performing Direct Supervision

The physician supervising the injection of contrast media should be knowledgeable in the recognition and treatment of adverse events related to contrast media administration (see the <u>ACR Manual on Contrast Media</u> [1]).

C. Registered Radiologist Assistant [5]

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)

D. Technologist

Technologists performing injections of contrast media should be in compliance 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 that involve 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), or an unrestricted state license is required.

E. Nurse or Other Healthcare Professional

The certified and/or licensed nurse or other appropriately credentialed health care professional performing injections of contrast media should be in compliance with the existing operating policies and procedures at the imaging facility in which he or she is working and must be in compliance with state and federal regulations.

F. 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. The Joint Commission has stated that "a hospital's radiology services (including hospital-associated ambulatory radiology) will be allowed to define, through protocol or policy, the role of the licensed independent practitioner in the direct supervision of a patient during and after IV contrast media is administered. The protocol policy is to be approved by the medical staff." [6]

III. WRITTEN REQUEST FOR THE EXAMINATION

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 scope of practice requirements. (ACR Resolution 35, adopted in 2006)

IV. PROCEDURE

Each facility or imaging department should have written policies, protocols, and procedures regarding administration of intravascular contrast media.

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 physician (see section II A) prior to contrast media injection.

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 and discussed with the patient and referring clinician. See the section on administration of contrast medium to pregnant or potentially pregnant patients in the <u>ACR Manual on Contrast Media</u> [1].

Vascular access should be established or confirmed using the facility's protocol. Adequate access should be ascertained prior to contrast media injection (e.g., verifying that the catheter is appropriate for the injection, assessing the access for backflow of blood, saline flush, and/or test injection with a power injector).

The health care professional performing the injection should be aware of the signs and symptoms of an adverse event and should monitor the patient for the development of these signs and symptoms. Patients should be assessed during and for some time after contrast media injection, in ways that are reasonably able to detect adverse events.

A physician must be immediately available to respond promptly to an adverse event (see section II B). 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 operating policies and procedures of the imaging facility (see the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [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 physician, if possible.

V. DOCUMENTATION

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

VI. 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 on a regular basis. The equipment, medications, and other emergency support must be appropriate for the range of ages and/or sizes in the patient population.

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 appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (http://www.acr.org/guidelines).

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web site (<u>http://www.acr.org/guidelines</u>) by the Committee on Drugs and Contrast Media of the ACR Commission on General, Small, and Rural Practice, and the Committee on Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the SPR.

Collaborative Committee - members represent their societies in the initial and final revision of this guideline

<u>ACR</u> Laurence Needleman, MD, FACR, Chair Mervyn D. Cohen, MD, MB, ChB, FACR Mathew Davenport, MD James H. Ellis, MD, FACR Brian R. Herts, MD <u>SPR</u>

Jonathan R. Dillman, MD David B. Larson, MD John M. Racadio, MD

<u>Committee on Drugs and Contrast Media</u> (ACR Committee responsible for sponsoring the draft through the process)

Richard H. Cohan, MD, FACR, Chair Matthew S. Davenport, MD Jonathan R. Dillman, MD James H. Ellis, MD, FACR Robert P. Hartman, MD Brian R. Herts, MD Syed Z.H. Jafri, MD, FACR Amy B. Kolbe, MD Laurence Needleman, MD, FACR Jeffrey H. Newhouse, MD, FACR Arthur J. Segal, MD, FACR Claude B. Sirlin, MD Carolyn L. Wang, MD Neil F. Wasserman, MD, FACR Jeffrey C. Weinreb, MD, FACR

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

Marta Hernanz-Schulman, MD, FACR, Chair Sara J. Abramson, MD, FACR Brian D. Coley, MD Kristin L. Crisci, MD Eric N. Faerber, MD, FACR Kate A. Feinstein, MD, FACR Lynn A. Fordham, MD S. Bruce Greenberg, MD J. Herman Kan, MD Beverley Newman, MD, MB, BCh, BSC, FACR Marguerite T. Parisi, MD, MS Sumit Pruthi, MBBS Nancy K. Rollins, MD Manrita K. Sidhu, MD

Lawrence A. Liebscher, MD, FACR, Chair, Commission on GSR Donald Frush, MD, FACR, Chair, Commission on Pediatric Imaging

Comments Reconciliation Committee Philip L. Lund, MD, FACR, Co-Chair Richard Strax, MD, FACR, Co-Chair Kimberly E. Applegate, MD, MS, FACR Leonard Berlin, MD, FACR Lynn S. Broderick, MD, FACR Richard H. Cohan, MD, FACR Mervyn D. Cohen, MD, MB, ChB, FACR Matthew Davenport, MD Jonathan R. Dillman, MD James H. Ellis, MD, FACR Howard B. Fleishon, MD, MMM, FACR Donald P. Frush. MD. FACR Marta Hernanz-Schulman, MD, FACR Brian R. Herts, MD David B. Larson. MD Paul A. Larson, MD, FACR Lawrence A. Liebscher, MD, FACR Debra L. Monticciolo, MD, FACR Laurence Needleman, MD, FACR John M. Racadio, MD Richard A. Szucs, MD, FACR Julie K. Timins, MD, FACR

REFERENCES

- 1. American College of Radiology. ACR Manual on Contrast Media<u>http://www.acr.org/Quality-Safety/Resources/Contrast-Manual</u>, v7. http://www.acr.org/SecondaryMainMenu Categories/quality_safety/contrast_manual.aspx. Accessed August 9, 2011.
- 2. CMS Again Revises Supervision Requirements for Hospital Outpatient Services. http://www.hallrender.com/library/ articles/718/HLN_11_23_10.html. Accessed Aug. 17, 2011.
- 3. Medicare program: hospital outpatient prospective payment system and CY 2011 payment rates; ambulatory surgical center payment system and CY 2011 payment rates; payments to hospitals for graduate medical education costs; physician self-referral rules and related changes to provider agreement regulations; payment for certified registered nurse anesthetist services furnished in rural hospitals and critical access hospitals. Final rule with comment period; final rules; and interim final rule with comment period. *Fed Regist* 2010; 75:71799-72580.
- 4. CMS Finalizes Supervision Option, Eases 'Immediately Available' Requirement. *Health Business Daily*. Vol 19: AISHealth; 2010.
- 5. American College of Radiology. Radiologist Assistant. http://www.acr.org/secondarymainmenucategories/ quality_safety/radiologistassistant.aspx. Accessed August 17, 2011.
- 6. Approved: interim action for Standard MM.4.10, Element of Performance 1, for critical access hospitals and hospitals: modifications for the emergency department and radiology practitioners. *Jt Comm Perspect* 2007;27:9.

7. American College of Radiology. <u>ACR practice guideline for communication of diagnostic findings</u>. <u>http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/comm_diag_rad.aspx</u>. Accessed Aug. 17, 2011.

*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.

<u>Development Chronology for this Practice Parameter</u> 2001 (Resolution 51)

Revised 2006 (Resolution 51, 34, 35, 36) Revised 2007 (Resolution 38) Revised 2012 (Resolution 3) Amended 2014 (Resolution 39)