ACR-SPR-SRU PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF DIAGNOSTIC ULTRASOUND EXAMINATIONS

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

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

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

PREAMBLE

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

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

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

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the Society for Pediatric Radiology (SPR), and the Society of Radiologists in Ultrasound (SRU). Recommendations for physician requirements, written request for the examination, procedure documentation, and quality control vary between the three organizations and are addressed by each separately. Diagnostic ultrasound is an established, effective diagnostic imaging technique that uses high-frequency sound

waves for both anatomic (grayscale) and color/power/spectral Doppler (anatomic and hemodynamic) evaluation. This document applies to all diagnostic ultrasound examinations performed by qualified personnel; specific standards may supersede this general diagnostic ultrasound standard (eg, for breast ultrasound indications and qualifications and responsibilities of personnel, refer to the <u>ACR Practice Parameter for the Performance of a Breast Ultrasound Examination [1]</u>). The use of ultrasound contrast agents with sonographic studies is discussed in the <u>ACR-AIUM-SRU Practice Parameter for the Performance of Contrast Enhanced Ultrasound [2]</u>. Diagnostic ultrasound as described in this standard is considered separate from point-of-care ultrasound. Diagnostic ultrasound is protocol driven with defined standardized views and accessible, documented images and interpretation, along with a formal quality assurance program.

Extensive experience has shown that ultrasound is a safe and accurate diagnostic procedure. Although no harmful effects of ultrasound have been demonstrated at the power levels used for diagnostic studies, quality assurance studies and best practice models dictate that all clinical studies be performed using appropriate equipment and techniques according to the as low as reasonably achievable (ALARA) principle, that is, using the lowest possible ultrasound power settings to acquire the necessary diagnostic information. Diagnostic ultrasound examinations should be performed only when there is an appropriate clinical indication. All diagnostic ultrasound examinations should be supervised and interpreted by trained and qualified physicians.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Physicians who supervise, perform, and/or interpret diagnostic ultrasound examinations should be licensed medical practitioners who have a thorough understanding of the indications for ultrasound examinations as well as a familiarity with the physical principles and limitations of ultrasound technology. This should include an understanding of ultrasound instrumentation, power output, equipment calibration, and safety. The physician should be familiar with alternative and complementary imaging and diagnostic procedures (including laboratory tests) and should be capable of correlating this additional medical information with the sonographic findings.

Physicians interpreting diagnostic ultrasound examinations should be able to demonstrate familiarity with anatomy, physiology, and pathophysiology of those organs or areas that are being examined. These physicians should be able to provide evidence of the training and competence needed to supervise, perform, and interpret diagnostic ultrasound examinations successfully.

Physicians performing and/or interpreting diagnostic ultrasound examinations should meet at least one of the following criteria:

Certification in Radiology, Diagnostic Radiology, Interventional Radiology/Diagnostic Radiology (IR/DR), Nuclear Radiology, or Nuclear Medicine by one of the following organizations: 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, and involvement with the supervision, interpretation, and reporting of ultrasound examinations $\frac{2}{2}$.

or

Completion of a diagnostic radiology or interventional radiology residency program approved by the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association to include involvement with the supervision and/or performance, interpretation, and reporting of ultrasound examinations $\frac{2}{3}$.

or

Physicians performing, interpreting, and reporting ultrasounds of a specific anatomic area who have not completed a diagnostic or interventional radiology residency program should meet the following criteria:

Completion of an ACGME-approved residency program that included specialty-specific diagnostic ultrasound examinations as part of the specialty training requirements, fellowship training requirements, and/or board

certification requirements at the time of their board certification.

If ultrasound examinations were not included during the physician's training program, physicians should attend additional training provided by a national imaging/ultrasound organization or their own specialty organization including sufficient Category I CME in the performance and interpretation of those ultrasound examinations specific to their area of subspecialty per their respective national certifying body requirements. A sufficient number of supervised cases and mentored performance, interpretation, and reporting of such cases should occur to the satisfaction of their board certifying organization. Knowledge and ability to identify all components within the specialty-specific ultrasound examination being performed is necessary to ensure patient safety.

Maintenance of Competence

All physicians performing ultrasound examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. Continued competency should be monitored for technical success, accuracy of interpretation, and appropriateness of evaluation.

Continuing Medical Education

The physician's continuing education should be in accordance with the <u>ACR Practice Parameter for Continuing Medical Education (CME)</u> [4] or in accordance with the applicable society's standards.

² Completion of an accredited radiology residency will be presumed to be satisfactory experience for the performance, reporting, and interpreting requirement.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Diagnostic Medical Sonographer

Sonographers performing ultrasound examinations should be qualified with appropriate training. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (eg, American Registry for Diagnostic Medical Sonography or American Registry of Radiologic Technologists). The sonographer should have ongoing continuing education in ultrasound.

III. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for an ultrasound examination 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 – revised in 2016, Resolution 12-b) Quality may be enhanced by having the ultrasound practice undergo an accreditation process.

IV. DOCUMENTATION

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging Findings</u> [3].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. Images should be labeled, using DICOM or directly on each image header, with the following: (1) patient identification, (2) facility identification, (3) examination date,

(4) sonographer's initials, and (5) image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

V. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the <u>ACR-AAPM Technical Standard for</u> <u>Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [5].</u>

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).

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters — Ultrasound of the ACR Commission on Ultrasound and the Committee on Practice Parameters — Pediatric Radiology of the ACR Commissions on Pediatric Radiology in collaboration with the SPR, and the SRU. Writing Committee - members represent their societies in the initial and final revision of this practice parameter

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Revisefice partificient allowed 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> Adopted 1992 (Resolution 9)

Amended 1995 (Resolution 53)

Revised 1995 (Resolution 22)

Revised 2000 (Resolution 36)

Revised 2006 (Resolution 37, 34, 35, 36)

Revised 2011 (Resolution 7)

Amended 2014 (Resolution 39)

Revised 2017 (Resolution 32)

Amended 2018 (Resolution 44)

Revised 2023 (Resolution 32)