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.

Revised 2017 (Resolution 20)*

ACR-ASNR-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF FUNCTIONAL MAGNETIC RESONANCE IMAGING (fMRI) OF THE BRAIN

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 was revised collaboratively by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), and the Society for Pediatric Radiology (SPR).

Functional magnetic resonance imaging (fMRI) using blood oxygenation level dependent imaging (BOLD) technique is a proven and useful tool for localizing eloquent cortex in relation to a focal brain lesion, such as a neoplasm or vascular malformation. fMRI should be performed only for a valid medical reason [1-13].

II. INDICATIONS

Primary indications for fMRI include, but are not limited to, the following:

- 1. Assessment of intracranial neoplasm and other targeted lesions
 - a. Presurgical planning and operative risk assessment
 - b. Assessment of eloquent cortex (eg, language, sensory, motor, visual centers) in relation to a tumor or another focal lesion
 - c. Surgical planning (biopsy or resection)
 - d. Therapeutic follow-up
- 2. Evaluation of preserved eloquent cortex
- 3. Assessment of eloquent cortex for epilepsy surgery
- 4. Assessment of radiation treatment planning and post-treatment evaluation of eloquent cortex

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [14].

The physician supervising and interpreting fMRI must be clinically informed and understand the specific questions to be answered prior to the procedure in order to plan and perform it safely and effectively. Additionally, physicians performing and interpreting this procedure should have experience or formal training in performing and processing fMRI [15,16].

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the <u>ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI)</u> [14], the <u>ACR Manual on Contrast Media</u> [17], and the <u>ACR Guidance Document on MR Safe Practices</u> [18].

Peer-reviewed literature pertaining to magnetic resonance (MR) safety should be reviewed on a regular basis.

V. SPECIFICATIONS OF THE EXAMINATION

The supervising physician must have complete understanding of the indications, risks, and benefits of the examination, as well as alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI, including potential adverse reactions to contrast media. The physician should be familiar with relevant ancillary studies that the patient may have undergone. The physician performing MRI interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.

The supervising physician must also understand the pulse sequences to be used and their effect on the appearance of the images, including the potential generation of image artifacts. Standard imaging protocols may be established and varied on a case-by-case basis when necessary. These protocols should be reviewed and updated periodically.

The written or electronic request for fMRI 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)

A. Patient Selection

The physician responsible for the examination should supervise patient selection and preparation, and be available in person or by phone for consultation. Patients should be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment.

Certain indications require the administration of intravenous (IV) contrast media as part of the diagnostic MRI procedure. IV contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution's policy on IV contrast utilization. (See the <u>ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media</u>) [19].

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate sedation may be needed to achieve a successful examination. If moderate sedation is necessary, refer to the <u>ACR–SIR Practice Parameter for Sedation/Analgesia</u> [20].

The use of sedation in patients having an fMRI may impair their ability to perform the required tasks, thereby interfering with activation of cortical areas of interest and limiting the data acquired.

B. Facility Requirements for Emergency Situations

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. 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 also be appropriate for the range of ages and sizes in the patient population.

- C. Examination Technique
 - 1. Prescanning

Communication with the referring physician to determine the appropriate type of fMRI task to be performed needs to take place prior to the study. Patients should be appropriately trained in performing the selected fMRI tasks before scanning takes place. Also, the patient's ability to comply with the task should be evaluated. Reading level, handedness, sensory impairments, and ability to focus all require an assessment prior to the scan. A mock scanner may be particularly helpful, especially for children, to acquaint patients with the scanner environment itself and what to expect during the study [21].

2. Scanning procedure

Hardware: Imaging can be performed with an MRI scanner having a 1.5 Tesla or higher field strength, depending on availability, and using a head coil with 1 or more channels. Use of a high performance head coil is recommended for improved signal-to-noise ratio (SNR). Dedicated stimulus presentation hardware

and software are necessary for presentation of stimuli, recording of patient responses, and synchronizing the stimulus paradigm with scan acquisition.

Pulse sequence: fMRI is typically performed using a gradient echo or asymmetrical spin echo echoplanar (EPI) pulse sequence. Imaging parameters may be customized to take advantage of the capabilities of a specific scanner. The following imaging parameters may be used as an example: matrix size = 64×64 ; recovery time (TR) = 2 to 3 seconds; (TE) = 20 to 50 ms; field of view (FOV) = 22 to 24 cm; number of slices to include whole brain; slice thickness = 2 to 5 mm.

Stimulus presentation: The imaging is typically performed using the well-established block design, although an event related design could be used. The following paradigm parameters may be used as an example for a 1.5 Tesla MRI scanner. In a block design study the subjects are presented with 6 separate blocks of activation conditions alternating with 6 rest period blocks, depending on the task. During each block (20 to 30 seconds long), 10 volumes of EPI images are acquired, depending upon the chosen TR, yielding a total of 120 EPI volumes. As an example, the patients may be asked to engage in sequential movement of finger to thumb or hand squeezes using both the dominant and nondominant hands, or they may be tested for language function and vision. Non-tasked based fMRI such as resting state fMRI can also be performed. For resting state fMRI studies, local consistency in patient environment should be observed (eg, eyes open or eyes closed for a period of approximately 6 to 10 minutes) when possible. If there is a question of neurovascular uncoupling that could cause false negative BOLD activation, a cerebral vascular reserve study such as a breath hold task using a block design could be performed [22]. Documentation of patient compliance with the tasks conducted is necessary after the study. Patient response data and direct observation of the patient may be used to determine patient compliance with the paradigm and to aid in result interpretation.

D. Postprocedure Processing

The fMRI images should be postprocessed using programs readily available. Typical postprocessing steps include, but are not limited to:

- 1. Head motion assessment and/or correction
- 2. Coregistration of the fMRI data with anatomic data
- 3. Data filtering and/or smoothing
- 4. Statistical modeling
- 5. Generation of statistical activation maps
- 6. Overlaying of statistical activation map and anatomic data

Functional activation maps should be reviewed over multiple statistical thresholds with attention to both the voxel-wise statistical significance and the anatomic extent of activations. Consideration may be given to statistical correction for multiple comparisons. These statistical maps can be overlaid in color onto the patient's grayscale anatomical images for better delineation of the tumor or other lesion margins and location of the activation regions. Color values representing different statistical thresholds are also typically assigned to these final postprocessed fMRI images.

VI. DOCUMENTATION

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging</u> <u>Findings</u> [23].

In addition to describing and interpreting the relevant findings, it is recommended that the fMRI report specify the following items:

- 1. Clinical indication as relevant to task selection
- 2. Tasks performed
- 3. Patient assessment and training

- 4. An assessment of fMRI data quality based on available patient behavioral observations and measurements
- 5. Discussion of the basic anatomy and pathology
- 6. Description of important functional activations and their anatomic relationship to relevant pathology in the brain
- 7. Patient handedness

VII. EQUIPMENT SPECIFICATIONS

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic strength (minimum field strength, 1.5 Tesla), maximum rate of change of the magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels. Scanners used for fMRI examinations should exhibit appropriate temporal signal stability. MRI-compatible presentation equipment should be present at the scanner for reliable fMRI acquisition.

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) [18,24,25].

Specific policies and procedures related to MRI safety should be in place along with documentation that is updated annually and compiled under the supervision and direction of the supervising MRI physician. Guidelines should be provided that deal with potential hazards associated with the MRI examination of the patient as well as to others in the immediate area. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination.

Equipment monitoring should be in accordance with the <u>ACR–AAPM Technical Standard for Diagnostic Medical</u> <u>Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [26]</u>.

To optimize performance of fMRI, specific monitoring for temporal stability of the EPI signal is useful.

It is important that practitioners of clinical fMRI understand the impact of statistical thresholding, cluster size thresholding, and correction for multiple comparisons on the resulting activation maps. Although the exact statistical methodology employed may differ among post-processing software packages, it is important that statistical parameters be adjusted to appropriately control for false positive (type 1) and false negative (type 2) errors. This should be done with the realization that differences in patient cerebral vascular reactivity and overall imaging goals may require customization of statistical parameters on a case by case basis. The field of clinical fMRI will continue to investigate and implement optimization of fMRI techniques and work towards standardization of this technology [27-29].

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (<u>http://www.acr.org/guidelines</u>) by the Committee on Practice Parameters – Neuroradiology of the ACR Commission on Neuroradiology and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with ASNR and the SPR.

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

ACR

Scott H. Faro, MD, Chair Asim Z. Mian, MD Feroze Mohamed, PhD Sumit Pruthi, MBBS <u>ASNR</u> Shira E. Slasky, MD Raymond K. Tu, MD, FACR Kirk M. Welker, MD <u>SPR</u> Shankar Srinivas Ganapathy, MD Jason N. Nixon, MD Nancy K. Rollins, MD

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

John E. Jordan, MD, MPP, FACR, Chair Merita A. Bania, MD Kristine A. Blackham, MD Brian A. Conley, MD H. Simms Hardin IV, MD Steven W. Hetts, MD Jacqueline C. Junn, MD Stephen A. Kieffer, MD, FACR Robert McDonald, MD Alexander M. McKinney IV, MD David M. Mirsky, MD Robin J. Mitnick, MD A. Orlando Ortiz, MD, MBA, FACR Robert J. Rapoport, MD, FACR Glenn H. Roberson, MD Rathan M. Subramaniam, MD, PhD, MPH Raymond K. Tu, MD, FACR Max Wintermark, MD

<u>Committee on Practice Parameters – Pediatric Radiology</u> (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

Alexander M. Norbash, MD, FACR, Chair, Commission on Neuroradiology 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

<u>Comments Reconciliation Committee</u> I. Raymond Kirk, III, MD, FACR, Chair McKinley Glover, IV, MD, MHS, Co-Chair Jacqueline A. Bello, MD, FACR Kavita K. Erickson, MD Scott H. Faro, MD Shankar Srinivas Ganapathy, MD Marta Hernanz-Schulman, MD, FACR William T. Herrington, MD, FACR John E. Jordan, MD, MPP, FACR Alexander M. McKinney, IV, MD Asim Z. Mian, MD

Feroze Mohamed, PhD Beverley Newman, MB, BCh, BSc, FACR Jason N. Nixon, MD Alexander M. Norbash, MD, FACR Sumit Pruthi, MBBS Matthew S. Pollack, MD, FACR Nancy K. Rollins, MD Shira E. Slasky, MD Timothy L. Swan, MD, FACR, FSIR Raymond K. Tu, MD, FACR Kirk M. Welker, MD

REFERENCES

- 1. Binder JR. Functional MRI is a valid noninvasive alternative to Wada testing. *Epilepsy Behav* 2011; 20:214-222.
- 2. Bizzi A, Blasi V, Falini A, et al. Presurgical functional MR imaging of language and motor functions: validation with intraoperative electrocortical mapping. *Radiology* 2008; 248:579-589.
- 3. Gulati S, Berntsen EM, Solheim O, et al. Surgical resection of high-grade gliomas in eloquent regions guided by blood oxygenation level dependent functional magnetic resonance imaging, diffusion tensor tractography, and intraoperative navigated 3D ultrasound. *Minim Invasive Neurosurg* 2009; 52:17-24.
- 4. Hirsch J, Ruge MI, Kim KH, et al. An integrated functional magnetic resonance imaging procedure for preoperative mapping of cortical areas associated with tactile, motor, language, and visual functions. *Neurosurgery* 2000; 47:711-721; discussion 721-712.
- 5. Janecek JK, Swanson SJ, Sabsevitz DS, et al. Language lateralization by fMRI and Wada testing in 229 patients with epilepsy: rates and predictors of discordance. *Epilepsia* 2013; 54:314-322.
- 6. Kundu B, Penwarden A, Wood JM, et al. Association of functional magnetic resonance imaging indices with postoperative language outcomes in patients with primary brain tumors. *Neurosurg Focus* 2013; 34:E6.
- 7. Lee CC, Ward HA, Sharbrough FW, et al. Assessment of functional MR imaging in neurosurgical planning. *AJNR Am J Neuroradiol* 1999; 20:1511-1519.
- 8. Medina LS, Aguirre E, Bernal B, Altman NR. Functional MR imaging versus Wada test for evaluation of language lateralization: cost analysis. *Radiology* 2004; 230:49-54.
- 9. Medina LS, Bernal B, Dunoyer C, et al. Seizure disorders: functional MR imaging for diagnostic evaluation and surgical treatment--prospective study. *Radiology* 2005; 236:247-253.
- 10. Partovi S, Jacobi B, Rapps N, et al. Clinical standardized fMRI reveals altered language lateralization in patients with brain tumor. *AJNR Am J Neuroradiol* 2012; 33:2151-2157.
- 11. Petrella JR, Shah LM, Harris KM, et al. Preoperative functional MR imaging localization of language and motor areas: effect on therapeutic decision making in patients with potentially resectable brain tumors. *Radiology* 2006; 240:793-802.
- 12. Pillai JJ, Zaca D. Relative utility for hemispheric lateralization of different clinical fMRI activation tasks within a comprehensive language paradigm battery in brain tumor patients as assessed by both threshold-dependent and threshold-independent analysis methods. *Neuroimage* 2011; 54 Suppl 1:S136-145.
- 13. Wood JM, Kundu B, Utter A, et al. Impact of brain tumor location on morbidity and mortality: a retrospective functional MR imaging study. *AJNR Am J Neuroradiol* 2011; 32:1420-1425.
- American College of Radiology. ACR practice parameter for performing and interpreting magnetic resonance imaging (MRI). Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Perf-Interpret.pdf</u>. Accessed December 23, 2015.
- 15. O'Shaughnessy ES, Berl MM, Moore EN, Gaillard WD. Pediatric functional magnetic resonance imaging (fMRI): issues and applications. *J Child Neurol* 2008; 23:791-801.
- 16. Kim PE, Singh M. Functional magnetic resonance imaging for brain mapping in neurosurgery. *Neurosurg Focus* 2003; 15:E1.
- 17. American College of Radiology. ACR manual on contrast media, version 10.1. Available at: <u>http://www.acr.org/~/media/37D84428BF1D4E1B9A3A2918DA9E27A3.pdf</u>. Accessed December 23, 2015.
- 18. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J Magn Reson Imaging 2013; 37:501-530.
- American College of Radiology. ACR-SPR practice parameter for the use of intravascular contrast media. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IVCM.pdf</u>. Accessed December 23, 2015.
- 20. American College of Radiology. ACR-SPR practice parameter for sedation/analgesia. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Sed-Analgesia.pdf. Accessed December 23, 2015.
- 21. Leach JL, Holland SK. Functional MRI in children: clinical and research applications. *Pediatr Radiol* 2010; 40:31-49.
- 22. Pillai JJ, Mikulis DJ. Cerebrovascular reactivity mapping: an evolving standard for clinical functional imaging. *AJNR Am J Neuroradiol* 2015; 36:7-13.

- 23. American College of Radiology. ACR practice parameter for communication: diagnostic imaging findings. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CommunicationDiag.pdf</u>. Accessed December 23, 2015.
- 24. Shellock FG. *Reference Manual for Magnetic Resonance Safety, Implants, and Devices*. Los Angeles, Calif: Biomedical Research Publishing; 2005.
- 25. Shellock FG, Crues JV. MR procedures: biologic effects, safety, and patient care. *Radiology* 2004; 232:635-652.
- 26. American College of Radiology. ACR-AAPM technical standard for diagnostic medical physics performance monitoring of magnetic resonance imaging (MRI) equipment. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Equip.pdf</u>. Accessed December 23, 2015.
- 27. Bennett CM, Wolford GL, Miller MB. The principled control of false positives in neuroimaging. Soc Cogn Affect Neurosci 2009; 4:417-422.
- 28. Eklund A, Nichols TE, Knutsson H. Cluster failure: Why fMRI inferences for spatial extent have inflated false-positive rates. *Proc Natl Acad Sci U S A* 2016; 113:7900-7905.
- 29. Loring DW, Meador KJ, Allison JD, et al. Now you see it, now you don't: statistical and methodological considerations in fMRI. *Epilepsy Behav* 2002; 3:539-547.

*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.

Development Chronology for this Practice Parameter 2007 (Resolution 3) Revised 2012 (Resolution 18) Amended 2014 (Resolution 39) Amended 2017 (Resolution 20)