

# Commentary

## MR Safety and the American College of Radiology White Paper

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**A**s long-time, active members of the American College of Radiology (ACR), we are pleased to offer commentary on the “American College of Radiology White Paper on MR Safety” [1], a document that “is intended to be used as a template for MR facilities to follow in the development of an MR safety program.” As such, it should be noted that these are not actual rules but, rather, recommendations that may be implemented or modified by the MR facility on the basis of its specific requirements (notably, the ACR White Paper was approved by the ACR leadership but does not carry the same meaning as an ACR standard that has gone through the consensus process).

Since the introduction of MR imaging as a clinical modality in the early 1980s, an enormous number of diagnostic procedures—estimated to be more than 100 million—have been completed with relatively few major incidents [2–10]. The few serious injuries or deaths that have occurred have been mostly attributed to the inadvertent presence of ferromagnetic implants or objects (e.g., ferromagnetic aneurysm clip, oxygen tank) and cardiac pacemakers [8, 9, 11, 12].

The topic of safety in the MR environment has long merited attention. A conservative esti-

mate of the medical literature pertaining to MR safety and bioeffects indicates that more than 250 peer-reviewed articles have been published to date. Additionally, there are at least three recently published textbooks [4, 6, 9] and two Web sites ([www.MRIsafety.com](http://www.MRIsafety.com) [13] and [www.radiology.upmc.edu/MRsafety/](http://www.radiology.upmc.edu/MRsafety/) [14]) devoted to MR safety. Unfortunately, it took the tragic loss of a child’s life in a New York hospital to bring the topic of MR safety the current notoriety that it rightfully deserves [11, 12].

The first contributions by organized radiology to provide MR safety guidelines and recommendations to the MR community occurred in 1991 and continued until 1994 [15–17]. Unfortunately, additional documents have not been forthcoming from MR specialty or other professional organizations despite the continuing worldwide proliferation of MR systems. Therefore, it is particularly timely for the ACR to formally contribute to the field of MR safety, and we applaud and support this important effort.

After carefully reviewing the “American College of Radiology White Paper on MR Safety,” we identified several critical areas that require further consideration. Therefore, we respectfully offer a point-by-point discussion of several aspects of the ACR White Paper with the intent of clarifying the recommendations or, in some

cases, offering a differing viewpoint based on our 17 years of experience and the available peer-reviewed literature.

### Overall Recommendations

The ACR’s MR safety recommendations evidently apply to conventional clinical MR systems, not to specialized MR systems (e.g., dedicated extremity MR systems, niche MR systems, and interventional MR systems) or those used predominantly for research (e.g., with magnetic field strengths from 3.0 to 8.0 T). This important aspect of the recommended policies and procedures should be emphasized from the onset to avoid confusion or misinterpretation of the information. Obviously, the basic premises discussed in this ACR White Paper may apply to MR facilities that use specialized MR systems, but they need to be substantially modified in consideration of the unique requirements of unconventional scanners.

The ACR White Paper indicates that the medical director should be primarily responsible for the MR-safety training program. We believe that the value of this ACR White Paper would be markedly enhanced if it would provide guidance regarding the qualifications for the medical director and specific training curricula for the MR

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technologists and other staff members, especially for MR facilities that are not under the control of formally trained MR radiologists.

### Zoning

The concept of designating various zones to help control site access relative to the static magnetic field of the MR system, although interesting, has no precedent in the MR imaging literature nor empiric support for its usefulness in preventing MR imaging-related accidents. Importantly, the zoning of the MR environment as proposed in the ACR White Paper is not intuitive and, thus, may be confusing to MR personnel and others (e.g., why is zone IV “synonymous with the MR scanner magnet room”?) or impractical to implement. It is essential to know what upper limit of the magnetic fringe field corresponds to the various zones proposed in the ACR White Paper because this limit will influence the recommendations provided. Furthermore, the zone associated with the operational aspect of the MR system (i.e., within the bore) should be considered because this area directly impacts MR safety. Therefore, we recommend that the zone associated within the MR system itself be considered because it is the most important zone of the MR environment. Zones removed from the MR system should be designated on the basis of the relative importance to the specific MR system (e.g., adjusted on the basis of MR system field strength and other considerations). Notably, the so-called zone IV area is not as potentially hazardous for a shielded 0.2-T MR system as it is for an unshielded 1.5-T MR system; therefore, the MR site will need to adjust policies and procedures on the basis of its specific MR environment.

### Patient and Nonpersonnel Screening

We disagree with the ACR White Paper’s suggestion that nonemergent patients should be screened by “a minimum of two separate individuals” and that emergent patients may be screened only once. (Why isn’t it sufficient for nonemergent and emergent patients to undergo thorough screening by a level II individual?) In fact, in the clinical MR setting, it is uncommon and probably unnecessary for a patient to be screened by two different individuals, especially if the screening process is thorough and involves written and verbal evaluations [7, 17]. This important topic was the subject of recent extensive review that included comprehensive guidelines and a thorough MR screening form [7]; this form can be downloaded from [www.MRIsafety.com](http://www.MRIsafety.com) [13].

### Implants, Devices, Objects: MR Safety and MR Compatibility

The ACR White Paper tends to use the terms “MR safety [safe]” and “MR compatibility [compatible]” individually as well as interchangeably without defining these terms or providing a supporting reference, which causes undue confusion. For those in the MR imaging community who are unfamiliar with these terms, they are defined as follows [18].

MR-safe means that the device, when used in the MR environment, has been shown to present no additional risk to the patient or other individual but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the term “MR-safe” because a device that is safe under one set of conditions may not be safe in more extreme MR conditions.

A device is considered “MR-compatible” if it is MR-safe and if it has been shown to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device when used in the MR environment. The MR conditions in which the device was tested should be specified in conjunction with the term “MR-compatible” because a device that is compatible under one set of conditions may not be compatible under more extreme MR conditions.

MR-safety testing of an implant or object involves assessment of magnetic field interactions, heating, and induced electric currents while MR-compatibility testing requires all of these as well as the characterization of artifacts [1, 4, 5, 15–20]. Additionally, the operation or function of the device is evaluated for MR-compatibility testing.

### Monitoring Patients

Monitoring patients during MR procedures has been the subject of several reviews and book chapters [25–28]. Currently, a variety of MR-compatible monitoring devices (labeled as having been approved by the United States Food and Drug Administration [FDA]) are commercially available to record virtually every important physiologic parameter [5, 6, 9, 25–28], including one that records the ECG using fiberoptic technology (thus, removing the concern of thermal injury stated in the ACR White Paper).

The improper use of ECG recording equipment has been reported to cause thermal injuries, but this type of injury has occurred in a relatively small number of patients [5, 6, 9, 10, 25–28]. Therefore, the ACR White Paper appears to overemphasize this issue, especially in

consideration of the fact that guidelines to prevent such injuries have been previously published [5, 6, 9, 25–30]. We suggest that MR health care professionals review the prior recommendations and implement a strategy to prevent possible patient burns as part of their MR-safety policies and procedures.

### Device and Object Screening

The ACR White Paper recommends that the MR facility have a strong (>1000 G) handheld magnet available for testing and clearing external and even superficial internal devices or implants. This recommendation greatly oversimplifies MR-safety testing of implants and devices because it does not consider other crucial aspects of MR safety (stated earlier) and, importantly, because there is no published evidence to support the sensitivity or usefulness of this procedure (particularly for identifying superficial implanted devices).

For example, a problem could occur using the handheld magnet to “clear” an external fixation device (nonmagnetic but made from conductive metal) that could realistically pose a hazard to a patient undergoing MR imaging. Additionally, in our opinion, MR health care professionals may not want to be responsible for MR testing of equipment and implants, nor is this really necessary. Many commercially available patient support devices and accessories have already undergone such evaluation (which are designated as MR-safe or MR-compatible using red labels), and there is MR-safety or MR-compatibility information available for more than 950 implants [4, 6]. This information is readily available online to all MR users [13].

Furthermore, various accessories made with ferromagnetic components have labeling approved by the FDA that permits them to be used in zone IV (i.e., in the MR system room) as long as they are specifically positioned relative to the fringe field (e.g., not to exceed 200 G) and are anchored or fixed in position. This conflicts with the information in the ACR White Paper.

### Labeling of Devices by MR Personnel

The ACR White Paper indicates that MR personnel should label “approved” devices with a green label and “unapproved” devices with a red label. Unfortunately, this recommendation conflicts with labeling that already exists for many devices (stated earlier). This issue is likely to cause confusion; therefore, we urge the ACR to reconsider this matter and to be consistent with current labeling for commercially available MR-safe and MR-compatible devices and accessories.

## MR Safety

### MR-Safe Practice Guidelines and the MR Technologist

The suggestions of the ACR White Paper to have only technologists who have been certified by the American Registry of Radiologic Technologists (ARRT) (should they also be MR-certified within the ARRT?) performing MR imaging and to have at least two individuals present during routine MR procedures is impractical and unrealistic given the present shortage of MR technologists and personnel (which is unlikely to change in the foreseeable future). Many sites in the United States have highly capable MR technologists performing MR imaging who are not ARRT-registered.

### Auditory Considerations

A recent comprehensive review was published on the topic of auditory considerations in the MR environment [31]. In general, acoustic noise may be problematic only for MR systems operating above 0.5-T or during the use of pulse sequences that use small fields of view, thin sections, short TRs, and short TEs [31, 32]. However, the ACR White Paper makes general statements about auditory considerations, suggesting that all patients and volunteers should use ear protection, without acknowledging the factors responsible for excessive acoustic noise or recommending a decibel level that represents a potentially hazardous threshold. In addition to auditory considerations for patients, the exposure of staff and other health care workers in the MR environment is of concern [31, 32]. Therefore, we also recommend that earplugs or other hearing protection be worn by health care workers and other individuals who may need to remain in the room (e.g., those involved in interventional MR procedures or who remain in the room for patient treatment reasons) during the operation of MR systems that generate excessive acoustic noise [31, 32].

### Time-Varying Radiofrequency Magnetic Field-Related Issues (Thermal)

The various recommendations in the ACR White Paper to prevent thermal injuries have been previously reported in the peer-reviewed literature and elsewhere [5, 6, 9, 30]. We believe that it is appropriate to acknowledge the original source of these guidelines.

### Skin Staples and Superficial Metallic Sutures

The recommendation that patients with skin staples or superficial metallic sutures have a

cold compress or ice pack applied to serve as a "heat sink" and decrease the likelihood of a significant thermal injury or burn is surprising. Many investigations have reported that little or no heating occurs for small implants (e.g., clips, wires) even if they form conductive loops, which are inherently small [4, 33–35]. In addition, there is no report in the peer-reviewed literature that we are aware of that heating of staples or sutures caused a patient injury or that application of a cold compress or ice pack could prevent such an injury.

### MR Imaging and Tattoos

Excessive heating of tattoos rarely occurs in patients undergoing MR procedures and has been reported only in cases involving the use of iron oxide for the tattoo pigment [36–40]. Therefore, the general recommendation of using cold compresses or ice packs for all patients with tattoos is not supported by the medical literature.

### Claustrophobia and Anxiety

The ACR White Paper provides no recommendations regarding the management of patients with claustrophobia, anxiety, or emotional distress associated with MR imaging other than commenting about the use of medications. This is an oversight because in many instances patients with these problems may be able to undergo MR procedures without being medicated if the MR health care professionals recognize and implement appropriate strategies to manage these cases [5, 6, 41]. Therefore, we encourage MR facilities to include recommended techniques for managing patients with claustrophobia, anxiety, or emotional distress related to MR procedures in their policies and procedures (Appendix 1).

### MR Procedures and Patients with Aneurysm Clips

The ACR White Paper provides extensive guidelines regarding performing MR procedures in patients with aneurysm clips. This information is especially useful because of the confusion and controversy regarding this matter. Similar recommendations have appeared several times in the literature [4, 6, 7, 9, 42–45].

### Concluding Remarks

Maintaining a safe MR environment is a daily challenge and a crucial responsibility for all MR health care professionals. We respect-

fully acknowledge the work of the ACR's Blue Ribbon Task Force on Patient Safety. We encourage the MR community to create or update their policies and procedures pertaining to MR safety on the basis of this information as well as the findings in the relevant medical literature. Additional consideration should also be given to the points we raised in our commentary.

### References

1. Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology white paper on MR safety. *AJR* 2002;178:1335–1347
2. New PFJ, Rosen BR, Brady TJ, et al. Potential hazards and artifacts of ferromagnetic and non-ferromagnetic surgical and dental materials and devices in nuclear magnetic resonance imaging. *Radiology* 1983;147:139–148
3. Shellock FG, Crues JV. High-field-strength MR imaging and metallic biomedical implants: an *in vivo* evaluation of deflection forces. *AJR* 1988; 151:389–392
4. Shellock FG. *Pocket guide to metallic implants and MR procedures: update 2000*, 7th ed. New York: Lippincott-Raven Healthcare, 2001:1–159
5. Shellock FG, Kanal E. *Magnetic resonance: bio-effects, safety, and patient management*, 2nd ed. New York: Lippincott-Raven, 1996
6. Shellock FG. *Reference manual for magnetic resonance safety: 2002 edition*. Salt Lake City: Amirsys, 2002
7. Sawyer-Glover A, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices. *J Magn Reson Imaging* 2000;12:92–106
8. Schenck JF. Health effects and safety of static magnetic fields. In: Shellock FG, ed. *Magnetic resonance procedures: health effects and safety*. Boca Raton, FL: CRC, 2001:1–31
9. Shellock FG. *Magnetic resonance procedures: health effects and safety*. Boca Raton, FL: CRC, 2001
10. Medical device report [database online]. Washington, DC: Center for Devices and Radiological Health, U.S. Food and Drug Administration, Mar 4, 2002. Updated monthly
11. Kerr JD. MRI safety: everyone's job. *Radiol Manage* 2001;23:36–39
12. ECRI hazard report: patient death illustrates the importance of adhering to safety precautions in magnetic resonance environments. *Health Devices* 2001;30:311–314
13. MRIsafety.com. Available at: www.MRIsafety.com. Accessed April 5, 2002
14. Magnetic resonance safety site. Available at: www.radiology.upmc.edu/MRIsafety/. Accessed April 5, 2002
15. Shellock FG, Kanal E. Policies, guidelines, and recommendations for MR imaging safety and patient management. *J Magn Reson Imaging* 1991; 1:97–101
16. Kanal E, Shellock FG. Policies, guidelines, and recommendations for MR imaging safety and patient management: patient monitoring during MR examinations. *J Magn Reson Imaging* 1992;2: 247–248

## Shellock and Crues

17. Shellock FG, Kanal E. Guidelines and recommendations for MR imaging safety and patient management. III. Questionnaire for screening patients before MR procedures. *J Magn Reson Imaging* **1994**;4:749–751
18. American Society for Testing and Materials. Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment. In: *Annual book of ASTM standards*. West Conshohocken, PA: American Society for Testing and Materials, **2001**:1576–1580 (section 13, vol. 13.01, designation F 2052)
19. Kangarlu A, Shellock FG. Aneurysm clips: evaluation of magnetic field interactions with an 8.0 T MR system. *J Magn Reson Imaging* **2000**;12:107–111
20. Rezaei AR, Finelli D, Nyenhuis JA, et al. Neurostimulator for deep brain stimulation: ex vivo evaluation of MRI-related heating at 1.5-Tesla. *J Magn Reson Imaging* **2002**;15:141–150
21. Shellock FG, Shellock VJ. Vascular access ports and catheters tested for ferromagnetism, heating, and artifacts associated with MR imaging. *Magn Reson Imaging* **1996**;14:443–447
22. Shellock FG, Detrick MS, Brant-Zawadski M. MR-compatibility of Guglielmi detachable coils. *Radiology* **1997**;203:568–570
23. Shellock FG, Shellock VJ. MR-compatibility evaluation of the Spetzler titanium aneurysm clip. *Radiology* **1998**;206:838–841
24. Shellock FG, Shellock VJ. Evaluation of cranial flap fixation clamps for compatibility with MR imaging. *Radiology* **1998**;207:822–825
25. Kanal E, Shellock FG. Patient monitoring during clinical MR imaging. *Radiology* **1992**;185:623–629
26. Holshouser B, Hinshaw DB, Shellock FG. Sedation, anesthesia, and physiologic monitoring during MRI. *J Magn Reson Imaging* **1993**;3:553–558
27. Shellock FG. Magnetic resonance safety: recommendations and guidelines for pre-procedure screening. In: *Special cross-specialty categorical course in diagnostic radiology: practical MR safety considerations for physicians, physicists, and technologists*. Oak Brook, IL: Radiological Society of North America, **2001**:33–39
28. Shellock FG. Safety, bioeffects, and patient monitoring. In: Gronemeyer H, Lufkin R, Seibel J, eds. *Open-field MRI*. Heidelberg, Germany: Springer-Verlag, **1998**:14–29
29. Kanal E, Shellock FG. Burns associated with clinical MR examinations. (letter) *Radiology* **1990**;175:585
30. Shellock FG, Kanal E. Burns associated with the use of monitoring equipment during MR procedures. *J Magn Reson Imaging* **1996**;6:271–272
31. McJury M, Shellock FG. Acoustic noise and MR procedures: a review. *J Magn Reson Imaging* **2000**;12:37–45
32. Shellock FG, Ziarati M, Atkinson D, Chen DY. Determination of gradient magnetic field-induced acoustic noise associated with the use of echo planar and three-dimensional, fast spin echo techniques. *J Magn Reson Imaging* **1998**;8:1154–1157
33. Davis PL, Crooks L, Arakawa M, McRee R, Kaufman L, Margulis AR. Potential hazards in NMR imaging: heating effects of changing magnetic fields and RF fields on small metallic implants. *AJR* **1981**;137:857–860
34. Shellock FG. Metallic marking clips used after stereotactic breast biopsy: ex vivo testing of ferromagnetism, heating, and artifacts associated with MR imaging. *AJR* **1999**;172:1417–1419
35. Shellock FG. Metallic neurosurgical implants: evaluation of magnetic field interactions, heating, and artifacts at 1.5 Tesla. *J Magn Reson Imaging* **2001**;14:295–299
36. Tope WD, Shellock FG. Magnetic resonance imaging and permanent cosmetics tattoos: survey of complications and adverse events. *J Magn Reson Imaging* **2002**;15:180–184
37. Carr JJ. Danger in performing MR imaging on women who have tattooed eyeliner or similar types of permanent cosmetic injections. *AJR* **1995**;165:1546–1547
38. Kreidstein ML, Giguere D, Freiberg A. MRI interaction with tattoo pigments: case report, pathophysiology, and management. *Plast Reconstr Surg* **1997**;99:1717–1720
39. Wagle WA, Smith M. Tattoo-induced skin burn during MR imaging. (letter) *AJR* **2000**;174:1795
40. Vahlensieck M. Tattoo-related cutaneous inflammation burn grade I in a mid-field MR scanner. (letter) *Eur Radiol* **2000**;10:97
41. Gollub R, Shellock FG. Claustrophobia, anxiety and emotional distress. In: Shellock FG, ed. *Magnetic resonance procedures: health effects and safety*. Boca Raton, FL: CRC, **2001**:197–216
42. Shellock FG, Kanal E. Yasargil aneurysm clips: evaluation of interactions with a 1.5 Tesla MR system. *Radiology* **1998**;207:587–591
43. Kanal E, Shellock FG. Aneurysm clips: effects of long-term and multiple exposures to a 1.5 Tesla MR system. *Radiology* **1999**;210:563–565
44. Shellock FG. Patient monitoring in the MR environment. In: *Special cross-specialty categorical course in diagnostic radiology: practical MR safety considerations for physicians, physicists, and technologists*. Oak Brook, IL: Radiological Society of North America, **2001**:40–48
45. Pride GL, Kowal J, Mendelsohn DB, Chason DP, Fleckenstein JL. Safety of MR scanning in patients with nonferromagnetic aneurysm clips. *J Magn Reson Imaging* **2000**;12:198–200

### APPENDIX I. Recommended Techniques for Managing Patients with Claustrophobia, Anxiety, or Emotional Distress Related to MR Procedures

1. Prepare and educate the patient concerning specific aspects of the MR examination (e.g., MR system dimensions, gradient noise, intercom system).
2. Allow an appropriately screened relative or friend to remain with the patient during the MR procedure.
3. Maintain physical or verbal contact with the patient during the MR procedure.
4. Use MR-compatible headphones to provide music to the patient and to minimize gradient magnetic field-induced noise.
5. Use an MR-compatible monitor to provide a visual distraction to the patient.
6. Use a virtual reality environment system to provide audio and visual distraction.
7. Place the patient in a prone position inside the MR system.
8. Position the patient feetfirst instead of headfirst into the MR system.
9. Use special mirrors or prism glasses for the patient.
10. Use a blindfold so that the patient is not aware of the close surroundings.
11. Use bright lights inside and at both ends of the MR system.
12. Use a fan inside the MR system to provide adequate air movement.
13. Use lemon- or vanilla-scented oil or other similar aroma therapy so that the patient can comfortably experience olfactory stimulation.
14. Use relaxation techniques such as controlled breathing or mental imagery.
15. Use systematic desensitization.
16. Use medical hypnosis.

(Adapted with permission from [41])