ACR Blue Ribbon Panel Response to the *AJR* Commentary by Drs. Crues and Shellock on the ACR White Paper on Magnetic Resonance (MR) Safety


**Introduction**

Since its recent publication, the ACR White Paper on Magnetic Resonance (MR) Safety and its ACR MR Safe Practice Guidelines (1) have met with a continually growing wave of support that has proven to be most gratifying to all involved in its design and creation. There has been widespread support for the concept of standardization of MR safety practices throughout the MR industry in clinical and research settings as a means for helping to decrease the incidence of those adverse magnetic resonance (MR)-related events that are potentially avoidable. Generation of guidelines that would meet with universal approval would be difficult. Lenient guidelines result in criticism from those who believe that not enough was done to protect patients and MR health care workers from potentially avoidable adverse events. Stringent recommendations might invoke protests against excessive external controls, excessive expense of implementation, and restriction of the free practice of the art and science of medicine and diagnostic radiology. Indeed, each of these potential concerns is valid in its own right. The Safe Practice Guidelines presented in the ACR White Paper on MR Safety attempts to balance these concerns yet accomplish the stated objective of improving the safety with which MR examinations are performed.
It is for the above reasons that the comments by our colleagues, Drs. Shellock and Crues, in their Commentary (2) are most appreciated. Unfortunately there are several misunderstandings in the Commentary, which have introduced a note of confusion for some in our industry who wish to apply these guidelines to their own practices. It is the purpose of this response to clarify these issues.

**Conventional Clinical MR Scanners vs. Research or Dedicated Extremity**

Drs. Crues and Shellock suggest that the ACR Practice Guidelines apply only to conventional MR scanners and not to “unconventional” MR systems, such as dedicated extremity systems or those used predominantly for research. The MR Safe Practice Guidelines were indeed designed to apply to all MR imaging systems. Let’s use an extremity system as an example, the guidelines specifically state that Zone III of an MR system is that area wherein free access by unscreened non-MR personnel and/or ferromagnetic objects and equipment can result in serious injury or death. If the extremity MR system does not contain any such fringe magnetic fields that would produce such a risk, then such a system has no Zone III, and no Zone III- or Zone IV-related restrictions would be necessary.

Several MR safety-related incidents have occurred at MR sites where the MR imaging systems involved were predominantly used for research. At times these sites may be involved in MR studies where the technologist is supervised by a researcher who may not be familiar with MR safety considerations. With this in mind, research-oriented MR sites were considered when these guidelines were generated—where the guidelines would be a useful reference for those researchers and research sites reviewing their safety programs and policies in response to recent accidents. Since the same safety issues are present in clinical and research environments, it is reasonable to apply consistent safety methods for both.
Medical Director Qualifications and Training Curricula

The Commentary recommends that the ACR provide guidance as to the qualifications of the MR medical director and specific training recommendations of the MR technologists and other staff members. The guidelines do specifically state that the medical director will be one whose education and experience in MR safety qualifies him or her for designation as Level Two MR Personnel, whose more advanced level of education and training is described in the guidelines as well. Given that the MR safety field is continually progressing, as a matter of practicality it is left to the judgment of the medical director as to how level II MR personnel are to be educated, and who would be considered satisfactorily trained to this level.

Site Access and Zoning

The comments made by Drs. Shellock and Crues regarding the proposed zones associated with MR environments are somewhat confusing. While the naming convention differs slightly, the zonal designation and controlled access is common practice in radiation protection. Further, this methodology has been in place for over a decade at several large medical centers including the University of Pittsburgh Medical Center’s MR Center (3), and has been successful in preventing unscreened personnel and equipment from reaching the magnet room. Prior to implementation of these guidelines at the University of Pittsburgh Medical Center, there were several incidents whereby personnel and ferromagnetic devices inadvertently were allowed access to the MR magnet rooms. This structure has since considerably decreased the incidence of similar such events.

Drs. Crues and Shellock recommend that specific magnetic fields be provided to define the various zones. This concept was considered but not adopted by the ACR safety panel. While we all agree that defining zones by magnetic field strength would be easier, it is the static magnetic
field spatial gradient along with the field strength that are the primary determinants of the translational force, or projectile effect. Even if sites are aware of the 5-gauss line around their magnet, almost no sites are aware of the spatial static magnetic field gradient strengths and their distribution in space within their MR scan rooms.

The commentary also includes the following statement: “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 un-shielded 1.5-T MR system.” The magnetic field and spatial field gradient that is potentially harmful is determined by numerous variables, including (among others) the mass, geometry, spatial orientation, anatomic location and even rate of motion of the ferromagnetic object in question, as well as the configuration and extent of shielding. The spatial gradients associated with a 0.5T shielded system may match that of a higher field strength. Even 0.2T systems have substantial spatial gradients around the magnet for which access must be controlled. The field and gradient that might be safe for one type of implant might prove deadly for another. The MRI industry has already recognized the necessity to restrict the general public from inadvertently accessing the 5 gauss line. The ACR Safety Guidelines take this into consideration and are meant to supplement well-established practices, standards, and policies.

The clinical significance of the impact on shielding and tightly restricted static spatial field distributions goes even further. In MR installations with very tight fringe field spatial distributions, there might well be far less warning that the field was attracting the device to someone approaching the scanner with a ferromagnetic object on them—or in them. In such sites, as one approached, for example, a 0.2 Tesla shielded magnet at normal walking rates (roughly 4 feet per second), by the time one noticed a tugging on the device it might well be too late to correct the problem, because maximal or near maximal forces would already be present.
In other words, by the time one first noticed the effects of the magnetic field, the device might already be on its way flying into the magnet—or into the patient or accompanying health care worker. In the unshielded 1.5 Tesla magnet case, on the other hand, as one approached the magnet there may be a more gradual increase in spatial field gradient and, therefore, translational “tugging” forces on the device. There would thus be more warning to the individual in this Zone IV that the wrench or device was being pulled into the scanner. This warning may provide the individual bringing in this ferromagnetic device with sufficient opportunity and time to stop, reverse directions, and remove the offending and dangerous object from the room, or at least from the effects of the MR system’s magnetic fields.

Another reason that we did not recommend identifying only a static magnetic field line around an MR scanner is due to the variability of fields strengths, which can result in interference with some electrically or magnetically activated devices. For example, some modern pacemakers switch into asynchronous mode at roughly 5 to 7 gauss, while some pumps may be affected only at far greater magnetic fields.

Once past the door to the magnet room, one is past the last physical restriction between an object or individual and the MR imaging magnet with its strongest associated magnetic fields. We therefore unanimously agreed that the presence of a physical restriction of a door to the scan room was important, and that this zone merited special caution.

**Patient and Personnel Screening**

Drs. Crues and Shellock raise the point that patients can be screened by only one individual. While this may often be sufficient, there are many examples of individuals with potentially problematic implants or devices being identified only by a second person/screen. A common example is where the MR technologist is about to enter the magnet room with the patient and
only then identifies the presence of the patient’s implanted pacemaker—the presence of which the patient had denied earlier. The fact that this should have been discovered on a good initial screen does not change the reality that there will be instances where a second screen is beneficial. By “engineering” a second screening into the process, the site provides a safety net for those patients who may be confused or overwhelmed by the first screening.

All who practice emergent medicine recognize the unique patient care decisions that must accompany emergent needs and the very nature of the delivery of emergent health care. As with any other emergent medical care delivery, there are requirements for special consideration and handling that must be considered, including (and especially) the timeliness of the delivery of that emergent medical care. For example, in attempting to address the handling, diagnostic, and therapeutic needs of a patient who is suspected of having undergone a hyperacute stroke and in whom interventional or other therapies are being considered, the total window of time allotted for diagnostic MR imaging is on the order of minutes. Here the priority is to safely, rapidly, and efficiently get that patient through the minimum MR imaging studies necessary to permit rapid, accurate diagnosis. The guidelines recommend an extra level of safety for non-emergent studies by requiring a second screening process. However, the panel recognizes that the speed and efficiency of the delivery of diagnostic care is itself an integral part of the risk-benefit assessment for the emergent patient, and has made special considerations for emergent patients accordingly.

We thank the authors for making available a sample MR screening form. The ACR panel agrees that a screening form is very important and sought to provide a reasonable standard for this purpose. With standardization, we believe that minimum acceptable thresholds of safety can be satisfied. The input is appreciated as the ACR intends to continually update the screening form
as additional topics and needs are identified.

**MR Safe and MR Compatible**

Confusion regarding the terms MR-safe and MR-compatible is quite real. For example, as stated on the FDA/CDRH's Web page:

“Designation of a Separation Distance:

Portable devices requiring a separation distance between the device and the MR magnet should not be considered MR-safe, MR-compatible, or intended for use in the MR environment. Typically the 5 gauss line is the only location where the static magnetic field strength is specified around an MR scanner. Therefore labeling specifying a separation distance between the MR magnet and the device to ensure safe or proper operation of the device should be avoided.”

Thus, as long as the only way a device could be labeled as MR-compatible or safe is by restricting it to a fixed distance from the magnet and/or by bolting it to the floor, it would not seem to meet the criteria for these terms as outlined above. Yet, there are several instances of devices that are indeed labeled as MR safe or compatible—if kept beyond a certain distance.

We recognize that these terms do not satisfactorily address the needs of the MR industry. It is for this reason that some have recommended to the FDA that they consider adopting other labeling terminology. (Suggestions included “MR-Safe” if entirely safe such as plastic devices, “MR-Unsafe” if overtly ferromagnetic and dangerous, “MR-Conditional” for all others where testing conditions would be specified, for example, as follows: "MR tested for up to X static magnetic field and up to Y static spatial gradient field."). This is also addressed on page 1340 of the guidelines (1) in section 5, Device Object Screening, subsection e. The American Society of Testing and Materials (ASTM) and the FDA Center for Devices and Radiological Health
(CDRH) MR Working Group are currently working on new terminology for implants and other medical devices (personal communication, Terry Woods, Food and Drug Administration, June 2002; ASTM meeting, July 24, 2002).

**Patient Monitoring and RF Burns**

The Commentary criticizes the guidelines for overemphasizing the potential importance of RF burns with certain types of patient monitoring leads and equipment, stating that it has occurred in relatively few instances. These recommendations were specifically directed to the monitoring and scanning of unconscious, unresponsive, or anesthetized/sedated patients who might not be able to detect or respond to radiofrequency thermal injuries as they were occurring. Monitoring was not recommended for every patient being studied with MR technology.

**Powerful Hand Held Magnets**

The objective behind the recommendation that each MR site have ready access to a powerful hand-held magnet to assist in detecting possible ferromagnetic characteristics of devices about to be brought into Zones III or IV, is as a result of the success of this practice relayed by several large medical centers. Many instances of “MR-safe” equipment, such as oxygen tanks, which left the MR suite, were discovered to be ferromagnetic upon return from inpatient floors. Ready access to hand-held magnets allowed this equipment to be quickly tested by the MR technologist. The cost of these magnets is not high, and they are readily accessible (www.mrimagnet.com). It is important to note that the guidelines do not suggest that MR testing with a powerful hand magnet be performed by sites to determine that an object is safe, but rather as a means of trying to detect if it is NOT safe (Figure 1). The ACR therefore recommends their use to attempt to detect gross ferromagnetic properties. Over the past 18 years of clinical MR experience one of us (EK) has had many patients with superficial foreign bodies that have been successfully identified
as powerfully ferromagnetic by using powerful handheld magnets placed adjacent to the skin of
the patient above the suspected foreign body. In some circumstances this evaluation resulted in
cancellation of the study. In other instances it enabled a greater level of preparation by
explaining to the patient precisely what to expect, obtaining an informed consent to proceed, and
then securing the foreign body in place with a pressure bandage. This type of information is
invaluable to clinical practitioners in a busy clinical—or research—practice, and is readily
available by using such powerful hand-held magnets as recommended in these guidelines.

The hand held magnet’s function is to supplement data that might be available to positively
identify the ferromagnetic nature of a device. It is not meant to replace good history taking and
assessment of package insert or other reliable information that might otherwise be available
about an implant or device. Its primary purpose is for application to portable devices external to
the patient, and not within them.

**Device Labeling**

The labeling of devices that contain metal as green, MR-Safe or Red, Not-MR Safe is entirely in
keeping with the present FDA “MR-Safe” nomenclature. The panel felt that such color-coded
labeling would greatly assist in rapidly identifying and appropriately handling external devices
that might be found in Zone III and Zone IV regions.

The Commentary states that there are devices or accessories whose FDA-approved labeling
permits usage in Zone IV if appropriately positioned and anchored or fixed in place. As noted
above, this claim is based on an internal inconsistency with the FDA’s own published guidelines
regarding this matter that has caused considerable confusion to the entire industry. Thus, the
panel drafted the guidelines in a manner that does not preclude the introduction of ferromagnetic
objects into Zone IV while emphasizing the site’s heightened responsibility for ensuring patient safety in such situations.

**MR Technologist Qualifications**

The authors of the Commentary take exception to the recommendation that MR technologists be ARRT-certified. The decision of the ACR panel was that although additional MR certification was laudable, present manpower availability precluded MR sub-certification as a requirement. However, a minimal level of certification was felt to be necessary. We acknowledge the severe shortage of MR technologists – just as we do the severe nursing shortage throughout the country today. We still do not, however, condone the practice of having poorly or untrained personnel performing MRI examinations on patients or volunteers in this country. It is for this reason that we recommend that MR imaging be performed by ARRT-certified technologists.

**Auditory Protection**

We agree that hearing protection for all in the MR scan room is advisable, even for health care practitioners or family members outside the magnet but still in Zone IV. Nevertheless, the amplitude of the auditory noise induced by gradient switching in MR scanners has been demonstrated to be the greatest within the bore of the MR scanner itself. Measurements in and around MRI scan rooms have shown noise levels to be within OSHA guidelines. It was therefore not felt to be necessary to require hearing protection for those in attendance in the room with the patient during scanning, although we would certainly have no argument as to its advisability.

**Protection from Thermal Injuries**

The recommendation of placing ice packs or cold compresses on skin staples acknowledges that thermal injuries are not likely to occur when small electrical conductors are in place. Finally,
one of us has indeed experienced at least one incident of a patient who suffered pain/heating and localized erythema when skin staples from a recently placed dialysis access port were exposed to the RF irradiation volume during MR scanning at 1.5 Tesla (personal communication, E. Kanal, 1986). The same can be said regarding MR imaging of tattoos, where potentially injurious local thermal deposition can be at least partially dissipated by cold compresses or ice packs placed on them during MR scanning. This recommendation applies if (and only if) the tattoos are expected to be well within the volume of RF irradiation during the MR imaging examination. Indeed, this was the recommendation of not only one of us (EK) on the panel, but also of Dr. Shellock himself in a letter to the editor on this particular topic (5). We believe that attempting to identify only those tattoos that used an iron oxide pigment, as suggested by the commentary, is impractical, if not impossible, in virtually all instances.

**Claustrophobia, Sedation and Anesthesia**

Radiologists deal with anxious patients and patients with phobias and patients with difficulty cooperating or holding still on a routine basis. It was therefore not felt to be necessary to address this issue for which there are so many prior standards and practice guidelines already available and readily accessible to essentially all MR (and radiology) sites.

For sedation and anesthesia considerations specifically, the guidelines indeed do reference well-established standards in this area for further information as to their safe and effective administration, monitoring considerations, and recovery considerations.

**Conclusion**

We gratefully acknowledge the MR safety expertise and opinions of our colleagues, and agree that MR safety is a topic whose significance has grown over the years. We acknowledge the
numerous contributions to the MR safety literature of Dr. Shellock. This document was intended to be educational, and was not meant to provide an exhaustive reference set for the many MR safety publications that were reviewed prior to issuing these guidelines. With this in mind, many authors (on and off the panel) were not adequately referenced.

As MR systems and technology improve, the importance of safety considerations in the field will grow. With this growth, the responsibility of continued education and adherence to accepted methods that ensure safe MR practice is imperative to ensure a safe environment for all. It is our opinion that the American College of Radiology MR Safe Practice Guidelines define the minimum safety standards today. As the industry continues to develop and progress, these guidelines will need to be continually updated to keep pace with the ever-changing field that is magnetic resonance imaging.

**References:**


**Figure 1:**

A: Weak hand held magnet demonstrates no attraction to fire extinguisher hose connector.

B: Strong (1,000 gauss) heavy Alnico hand held magnet demonstrates no attraction to fire extinguisher hose connector.

C: Strong rare-earth neodymium 1,200 gauss hand held magnet demonstrates definite attraction to fire extinguisher hose connector.