Since its recent publication, the “American College of Radiology [ACR] White Paper on MR Safety” and its “ACR Magnetic Resonance [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 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 of helping to decrease the incidence of those adverse 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 is being done to protect patients and MR health care workers from potentially avoidable adverse events. Stringent recommendations might invoke protests against excessive external controls and the expense of implementation and restriction of the free practice of medicine and diagnostic radiology. Each of these potential concerns is valid in its own right. The “ACR Magnetic Resonance Safe Practice Guidelines” presented in the “American College of Radiology White Paper on MR Safety” attempt to balance these concerns yet accomplish the stated objective of improving the safety of MR examinations.

It is for these reasons that the comments by our colleagues, Shellock and Crues [2], in their commentary are most appreciated. Unfortunately several misunderstandings in the commentary have introduced a note of confusion to 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 Versus Research or Dedicated Extremity

Shellock and Crues [2] 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 designed to apply to all MR imaging systems. Let us use an
extremely system as an example: the guidelines specifically state that zone III of an MR system is that area in which free access by unscreened non-MR personnel and 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 restrictions would be necessary.

Several MR safety–related incidents have occurred at MR sites in which the MR imaging systems involved were predominantly used for research. At times these sites may be involved in MR studies in which the technologist is supervised by a researcher who may not be familiar with MR safety. We had this possibility in mind when we generated these guidelines, so we considered research-oriented MR sites—in which the guidelines would be a useful reference for those researchers and research sites reviewing their safety policies in response to recent accidents. Because the same safety issues are present in clinical and research environments, it is reasonable to apply consistent safety methods to both.

**Medical Director Qualifications and Training Curricula**

The commentary [2] recommends that the ACR provide guidance as to the qualifications of the MR medical director and specific training recommendations for 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 qualify him or her for designation as level II MR personnel, whose more-advanced level of education and training is described in the guidelines. Because the MR safety field is continually progressing, as a matter of practicality the medical director may judge 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 Shellock and Crues [2] regarding the proposed zones associated with MR environments are somewhat confusing. Whereas the naming convention differs slightly, the zonal designation and controlled access are common practice in radiation protection. Further, this methodology has been in place for more than a decade at several large medical centers, including the MR Center at the University of Pittsburgh Medical Center [3], and has been successful in preventing unscreened personnel and equipment from reaching the magnet room. Before implementation of these guidelines at the University of Pittsburgh Medical Center, several incidents occurred in which personnel and ferromagnetic devices inadvertently were allowed access to the MR magnet rooms. The designation of these zones has since considerably decreased the incidence of similar events.

Shellock and Crues [2] recommended that specific magnetic fields be provided to define the various fields. This concept was considered but not adopted by the ACR safety panel. Although 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 is the primary determinant of the translational force, or projectile effect. Even if sites are aware of the 5-G line around their magnet, almost no sites are aware of the spatial static magnetic field gradient strengths and their distribution in space in their MR scanning 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 unshielded 1.5-T MR system” [2]. The magnetic field and spatial field gradient that are potentially harmful are 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 0.5-T shielded system may match those of a higher field strength. Even 0.2-T 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 MR imaging industry has already recognized the necessity to restrict the general public from inadvertently accessing the 5-G line. The ACR safety guidelines take this fact into consideration and are meant to supplement well-established practices, standards, and policies.

**Patient and Personnel Screening**

Shellock and Crues [2] raise the point that patients may be screened by only one individual. Whereas one individual may often be sufficient, there are many examples of patients with potentially problematic implants or devices being identified only by a second screener. A common example is when 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—which the patient had denied earlier to another screener. The fact that this should have been discovered on a good initial screen does not change the reality that there will be instances in which a second screening is beneficial. By “engineering” a sec-
first screening.

All who practice emergency medicine recognize the unique patient care decisions that must accompany emergency health care. As with any other emergency medical care delivery, the timeliness of the delivery must be considered. For example, in attempting to address the handling, diagnostic, and therapeutic needs of a patient who is suspected of having undergone a hyperacute stroke, minutes are allotted for diagnostic MR imaging. Here the priority is to safely, rapidly, and efficiently perform the minimal MR imaging studies necessary for accurate diagnosis. The guidelines recommend an extra level of safety for nonemergency studies by requiring a second screening process. However, the panel recognizes that the speed and efficiency of the delivery of diagnostic care are an integral part of the risk–benefit assessment for the emergency patient and made special considerations for emergency patients accordingly.

We thank the authors (Shellock and Crues) of the commentary for making available a sample MR screening form. The ACR panel agrees that a screening form is important and sought to provide a reasonable standard for this purpose. With standardization, we believe that minimal acceptable thresholds of safety can be satisfied. The input of the commentators (Shellock and Crues) is appreciated because 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 in the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Web page [4]:

Designation of a Separation Distance:

Portables 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, if a device could only be labeled MR compatible or safe by restricting it to a fixed distance from the magnet and/or by bolting it to the floor, the device would not seem to meet the criteria for these terms as outlined previously. Yet, there are several instances of devices that are 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 it 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 in which testing conditions would be specified—for example, “MR-tested for up to x static magnetic field and up to y static spatial gradient field.”) This labeling is also addressed in section 5 of the guidelines, “Device/Object Screening” (subsection c) [1]. The American Society of Testing and Materials and the FDA–CDRH MR Working Group are presently working on new terminology for implants and other medical devices (Woods T, personal communication, 2002).

Patient Monitoring and Radiofrequency Burns

The commentary criticizes the guidelines for overemphasizing the potential importance of radiofrequency burns with certain types of patient-monitoring leads and equipment, stating that they have occurred in relatively few instances. These recommendations in the guidelines were specifically directed to the monitoring and scanning of unconscious, unresponsive, or anesthetized or 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 Handheld Magnets

The objective behind the recommendation that each MR site have ready access to a powerful handheld magnet to assist in detecting possible ferromagnetic characteristics of devices about to be brought into zones III or IV is a result of the success of this practice relayed by several large medical centers. Many instances of MR-safe equipment, such as oxygen tanks, were discovered to be ferromagnetic upon return from inpatient floors. Ready access to handheld 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). The guidelines do not suggest that MR testing with a powerful handheld 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 (Fig. 1). Therefore, the ACR recommends the use of these magnets to detect gross ferromagnetic properties. Over the past 18 years of clinical MR experience, one of the authors has had many patients with superficial foreign bodies that have been successfully identified as powerfully ferromagnetic with 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 gave the practitioner a greater level of preparation by enabling him to explain to the patient precisely what to expect, obtain an informed consent to proceed, and then secure 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 using such powerful handheld magnets as recommended in these guidelines.

The handheld magnet’s function is to supplement data that might be available to identify positively the ferromagnetic nature of a device. It is not meant to replace good history-taking and the assessment on package inserts 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 patients, not in 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 believed that such color-coded labeling would greatly assist in rapidly identifying and appropriately handling external devices that might be found in zones III and IV.

The commentary states that there are devices whose FDA-approved labeling permits use in zone IV if appropriately positioned and anchored or fixed in place. As noted previously, 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 [2] take exception to the recommendation that MR technologists should be certified by the American Registry of Radiologic Technologists (ARRT). The decision of the ACR panel was that although additional MR certification was laudable, present manpower availability precluded MR subcertification as a requirement. However, a minimal level of certification was thought 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 trained or untrained personnel performing MR imaging 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 scanning 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 shown to be the greatest in the bore of the MR scanner itself. Measurements in and around MR imaging scan rooms have shown noise levels to be within the guidelines of the Occupational Safety and Health Administration. We did not believe it necessary to require hearing protection for those in the room with the patient during scanning, although we would certainly have no argument as to its advisability.

**Protection from Thermal Injuries**

Our recommendation of placing ice packs or cold compresses on skin staples also acknowledges the fact that thermal injuries are not likely to occur when small electrical conductors are in place. Finally, one of us has 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 radiofrequency irradiation volume during MR scanning at 1.5 T. The same can be said regarding MR imaging of tattoos, in which 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 radiofrequency irradiation during the MR imaging examination. This was the recommendation of not only one of us on the panel, but also of Shellock himself [5] in a letter to the editor on this particular topic. 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**

On a routine basis, radiologists deal with anxious and phobic patients or with patients having difficulty cooperating or holding still. Therefore, we did not believe it necessary to address this issue with so many prior standards and practice guidelines already accessible to all MR (and radiology) sites. For safe and effective administration of sedation and anesthetics specifically, the guidelines do reference well-established standards for monitoring and recovery.

**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 by 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 we reviewed before issuing these guidelines. With this intention 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 is imperative to ensure a safe environment for all. The “ACR Magnetic Resonance Safe Practice Guidelines” [1] define the minimal safety standards today. As the industry continues to develop, these guidelines should be continually updated to keep pace with the ever-changing MR imaging field.

References