#### INTRODUCTION

There are potential risks in the MR environment, not only for the patient, <sup>1,2</sup> but also for the accompanying family members, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. There have been reports in the medical literature and print media detailing MRI adverse incidents involving patients, equipment, and personnel that spotlighted the need for a safety review by an expert panel. The following is the combined paper of 2 reports<sup>3,4</sup> issued by the American College of Radiology Blue Ribbon Panel on MR Safety, chaired by Emanuel Kanal, MD, FACR. The panel originally met in November 2001 and was charged with reviewing the existing MR safe practices and guidelines<sup>5-9</sup> and issuing new ones as appropriate for MR examinations. The panel consisted of the following members: A. James Barkovich, MD, Charlotte Bell, MD (Anesthesia Patient Safety Foundation), James P. Borgstede, MD, FACR, William G. Bradley, MD, PhD, FACR, Joel Felmlee, PhD, Jerry W. Froelich, MD, Ellisa M. Kaminski, RT(R)(MR), Emanuel Kanal, MD, FACR, Elaine K. Keeler, PhD (NEMA), James W. Lester, MD, Elizabeth Scoumis, RN, BSN, Loren A. Zaremba, PhD (FDA), Jeffrey Hayden (ACR staff), and Marie D. Zinninger (ACR staff). Upon Dr Keeler's retirement, Shawn Etheridge was appointed to represent NEMA.

After reviewing substantial feedback from the field and installed base, as well as changes that had transpired throughout the MR industry in the interim, the panel reconvened in 2002 and 2003 and agreed to several modifications and updates to the original document.

The following MR safe practice guidelines document, which incorporates both prior papers, is intended to be used as template for MR facilities to follow in the development of an MR safety program. These MR safe practice guidelines were developed to help guide MR practitioners regarding these issues and to provide a basis for them to develop and implement their own MR policies and practices. It is intended that these MR safe practice guidelines (and the policies and procedures to which they give rise) be reviewed and updated on a regular basis as the field of MR safety continues to evolve.

This white paper does not attempt to deal with all aspects of MR safety, but rather those that apply to an already installed, active site, whether a clinical or research facility. With the increasing advent and use of 3.0-T and higher strength magnets, users need to recognize that one should never assume MR compatibility or safety information about a device if it is not clearly documented in writing. Decisions based on published MR safety and compatibility claims should recognize that all such claims apply only to specifically tested conditions, such as static magnetic field strengths, static gradient magnetic field strengths and spatial distributions, and the strengths and rates of change of gradient and radiofrequency (RF) magnetic fields.

Finally, there is a whole host of other issues that should be considered during the site-planning stages and that is not dealt with in this manuscript. These include, among many others, cryogen emergency vent locations and pathways, 5-G line—siting considerations, patient access pathways, and considerations regarding fringe field blooming that may result in the event there is a failure of an actively shielded MRI system. These issues, and many others, should be reviewed with those experienced in MR site planning and familiar with the patient safety and patient flow considerations prior to committing construction to a specific site design. In this regard, enlisting the assistance of an architectural firm experienced in this area, and doing so early in the design stages of the planning process, may prove most valuable.

It remains the intent of the ACR that these MR safe practice guidelines will prove helpful as the field of MRI continues to evolve and mature, providing MR services that are among the most powerful, yet safest, of all diagnostic procedures to be developed in the history of modern medicine.

### ACR Magnetic Resonance Safe Practice Guidelines Combined Papers of 2002 and 2004

#### A. Establish, Implement, and Maintain Current MR Safety Policies and Procedures

- All clinical and research MR sites should maintain MR safety policies and procedures, which are
  to be established, implemented, maintained, and routinely reviewed and updated, as appropriate.
  The level of compliance by staff will be assessed and documented annually. The policies and
  procedures manual should be readily available to the MR professionals on site at all times of
  operation.
- 2. These policies and procedures should also be reviewed concurrently with the introduction of any significant changes in the safety parameters of the MR environment of the site (eg, adding faster or stronger gradient capabilities or higher RF duty cycle studies) and updated as needed. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing local guidelines, policies, and procedures.
- 3. Each site will name an MR medical director whose responsibilities will include ensuring that these MR safe practice guidelines are established and maintained as current and appropriate for the site. It is the responsibility of the site's administration to ensure that the policies and procedures that result from these MR safe practice guidelines are implemented and adhered to at all times by all of the site's personnel.
- 4. Procedures should be in place to ensure that any and all adverse events, MR safety incidents, or "near incidents" that occur in the MR site are reported to the medical director in a timely fashion (eg, within 24 hours, or 1 business day, of their occurrence) and are used in continuous quality improvement efforts.

#### B. Static Magnetic Field Issues: Site Access Restriction

### 1. Zoning:

The MR site is conceptually divided into 4 zones (see Figure 1 and Appendix 1):

- a. Zone I: This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.
- b. Zone II: This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Typically, patients are greeted in Zone II and are not free to move throughout Zone II at will, but rather are under the supervision of MR personnel (see section B.2.b, below). It is in Zone II that the answers to MR-screening questions, patient histories, medical insurance questions, etc are typically obtained.
- c. Zone III: This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the MR scanner's particular environment. These interactions include, but are not limited to, those involving the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, MR personnel (see section B.2.b, below). Specifically identified MR personnel (typically—but not necessarily only—the MR technologists) are to be charged with ensuring that this MR safe practice guideline is strictly adhered to for the safety of the patients and other non-MR personnel, the health care personnel, and the

equipment itself. This function of the MR personnel is directly under the authority and responsibility of the MR medical director or the level 2–designated (see section B.2.b, below) physician of the day for the MR site.

Zone III should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method that can differentiate between MR personnel and non-MR personnel. The use of combination locks is discouraged as combinations often become more widely distributed than initially intended, resulting in site restriction violations being more likely with these devices. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III.

There should be *no* exceptions to this guideline. Specifically, this includes hospital or site administration, physician, security, and other non-MR personnel (see section B.2.c, below). Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves. Zone III, or at the very least the area within it wherein the static magnetic field's strength exceeds 5 G, should be demarcated and clearly marked as being potentially hazardous.

d. Zone IV: This area is synonymous with the MR scanner magnet room itself, ie, the physical confines of the room within which the MR scanner is located. Zone IV, by definition, will always be located within Zone III, as it is the MR magnet and its associated magnetic field that generates the existence of Zone III. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. As part of the Zone IV site restriction, all MR installations should provide for direct visual observation by level 2 MR personnel to access pathways into Zone IV. By means of illustration only, the MR technologists would be able to directly observe and control, via line of site or via video monitors, the entrances or access corridors to Zone IV from their normal positions when stationed at their desks in the scan control room.

Zone IV should be clearly marked with a red light and lighted sign stating, "the magnet is on." Except for resistive systems, this red light and sign should be illuminated at all times and should be provided with a backup energy source to continue to illuminate for at least 24 hours in the event of a loss of power to the site.

In case of cardiac or respiratory arrest or other medical emergency within Zone IV for which emergent medical intervention or resuscitation is required, appropriately trained and certified MR personnel should immediately initiate basic life support or CPR as required by the situation *while* the patient is being emergently removed from Zone IV to a predetermined, magnetically safe location. *All* priorities should be focused on stabilizing (eg, basic life support with cardiac compressions and manual ventilation) and then evacuating the patient as rapidly and safely as possible from the magnetic environment that might restrict safe resuscitative efforts.

Further, for logistical safety reasons, the patient should always be moved from Zone IV to the prospectively identified location where full resuscitative efforts are to continue.

Quenching the magnet (for superconducting systems only) is not routinely advised for cardiac or respiratory arrest or other medical emergency, since quenching the magnet and having the magnetic field dissipate could easily take more than a minute. Furthermore, as quenching a magnet can theoretically be hazardous, ideally one should evacuate the magnet room, when possible, for an intentional quench. One should rather use that time wisely to initiate life support measures while moving the patient from Zone IV to a location where the strength of the magnetic field is insufficient to be a medical concern. Zones III and IV site access

restriction *must* be maintained during resuscitations and other emergent situations for the protection of all involved.

### 2. MR personnel and non-MR personnel (see Appendix 1):

a. All individuals working within at least Zone III of the MR environment should be documented as having successfully completed at least one of the MR safety live lectures or prerecorded presentations approved by the MR medical director. Attendance should be repeated at least annually, and appropriate documentation should be provided to confirm these ongoing educational efforts. These individuals shall be referred to henceforth as MR personnel.

### b. There are 2 levels of MR personnel:

- (1) Level 1 MR personnel: Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III will be referred to henceforth as level 1 MR personnel.
- (2) Level 2 MR personnel: Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to henceforth as level 2 MR personnel. It is the responsibility of the MR medical director not only to identify the necessary training, but also to identify those individuals who qualify as level 2 MR personnel. It is understood that the medical director will have the necessary education and experience in MR safety to qualify as level 2 MR personnel.
- c. All those not having successfully complied with these MR safety instruction guidelines shall be referred to henceforth as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

#### 3. Patient and non-MR personnel screening:

- a. *All* non-MR personnel wishing to enter Zone III must first pass an MR safety–screening process. Only MR personnel are authorized to perform an MR safety screen prior to permitting non-MR personnel into Zone III.
- b. The screening process and screening forms for patients, non-MR personnel, and MR personnel should be essentially identical. Specifically, one should not assume that non-MR personnel, health care practitioners, or MR personnel will not enter the bore of the MR imager during the MRI process.

This might be the case if a pediatric patient cries for his mother, who then leans into the bore, or if the anesthetist leans into the bore to manually ventilate a patient in the event of a problem.

#### c. Metal detectors:

The usage of metal detectors in MR environments is *not* recommended. Reasons for this recommendation include, among others:

- (1) They have varied—and variable—sensitivity settings.
- (2) The skills of the operators can vary.

- (3) Today's metal detectors cannot detect, for example, a 2×3-mm, potentially dangerous ferromagnetic metal fragment in the orbit or near the spinal cord or heart.
- (4) Today's metal detectors do not differentiate between ferromagnetic and nonferromagnetic metallic objects, implants, or foreign bodies.
- (5) Metal detectors should not be necessary for the detection of large metallic objects, such as oxygen tanks on the gurney with the patients. These objects are fully expected to be detected—and physically excluded—during the routine patient-screening process.
- d. Non-MR personnel should be accompanied by, or under the immediate supervision of and in visual and verbal contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or IV. However, it is acceptable to have them in a changing room or restroom in Zone III without visual contact as long as the personnel and the patient can communicate verbally with each other.
  - Level 1 MR personnel are permitted unaccompanied access throughout Zones III and IV. Level 1 MR personnel are also explicitly permitted to be responsible for accompanying non-MR personnel into and throughout Zone III, excluding Zone IV. However, level 1 MR personnel are *not* permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.
  - In the event of a shift change, lunch break, etc, no level 2 MR personnel shall relinquish their responsibility to supervise non-MR personnel still within Zone III or IV until such supervision has been formally transferred to another of the level 2 MR personnel.
- e. Nonemergent patients should be MR safety–screened on site by a minimum of 2 separate individuals. At least one of these individuals should be level 2 MR personnel. At least one of these 2 screens should be performed verbally or interactively.
  - Emergent patients and their accompanying non-MR personnel may be screened only once, provided the screening individual is level 2 MR personnel. There should be no exceptions to this.
- f. Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices on or in them, eg, watches, jewelry, pagers, cell phones, body piercings (if removable), contraceptive diaphragms, metallic drug-delivery patches (see section I), cosmetics containing metallic particles (such as eye makeup), and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads. It is therefore advisable to require patients or research subjects to wear a site-supplied gown with no metal fasteners during the MR procedure when feasible. Inquiries regarding drug-delivery patches or pads have led the panel to review this issue and comment as noted in section I, below.
- g. All patients and non-MR personnel with a history of potential ferromagnetic foreign object penetration must undergo further investigation prior to being permitted entrance to Zone III. Examples of acceptable methods of screening include patient history, plain X-ray films, prior CT or MR studies of the questioned anatomic area, or access to written documentation of the type of implant or foreign object that might be present. Once positive identification has been made as to the type of implant or foreign object that is within a patient, best effort assessments should be made to identify the MR compatibility or MR safety of the implant or object. Efforts at identification might include written testing on the implant prior to implantation (preferred), product labeling regarding the implant or object, and peer-reviewed publications regarding MR compatibility and MR safety testing of the make, model, or type

of the object. MR safety testing would be of value only if the object or device had not been altered since such testing had been published.

All patients who have a history of orbit trauma by a potential ferromagnetic foreign body *for* which they sought medical attention are to have their orbits cleared by either plain X-ray orbit films<sup>10,11</sup> (2 views) or by a radiologist's review and assessment of contiguous cut prior CT or MR images (obtained since the suspected traumatic event), if available.

h. Conscious, nonemergent patients and research and volunteer subjects are to complete written MR safety–screening questionnaires prior to their introduction to Zone III. Family or guardians of nonresponsive patients or of patients who cannot reliably provide their own medical histories are to complete a written MR safety–screening questionnaire prior to their introduction to Zone III. These completed questionnaires are then to be reviewed orally with the patient, guardian, or research subject in their entirety prior to permitting the patient or research subject to be cleared into Zone III.

The patient, guardian, or research subject as well as the screening MR staff member must both sign the completed form. This form should then become part of the patient's medical record. No empty responses will be accepted—each question *must* be answered with a "yes" or "no," or specific further information must be provided as requested. A sample pre-MR screening form is provided (see Appendix 2). This is the minimum information to be obtained; more may be added if the site so desires.

- i. Screening of the patient or non-MR personnel with, or suspected of having, an intracranial aneurysm clip should be performed per the separate MR safe practice guideline addressing this particular topic (see section M, below).
- j. Screening of patients for whom an MR examination is deemed clinically indicated or necessary but who are unconscious or unresponsive or who cannot provide their own reliable histories regarding prior possible exposure to surgery, trauma, or metallic foreign objects and for whom such histories cannot be reliably obtained from others:
  - (1) If no reliable patient metal exposure history can be obtained, and if the requested MR examination cannot reasonably wait until a reliable history might be obtained, it is recommended that such patients be physically examined by level 2 MR personnel. All areas of scars or deformities that might be anatomically indicative of an implant, such as on the chest or spine region, and whose origins are unknown and which may have been caused by ferromagnetic foreign bodies, implants, etc, should be subject to plain-film radiography (if recently obtained plain films or CT or MR studies of such areas are not already available). The investigation described above should be made to ensure there are no potentially harmful embedded or implanted metallic foreign objects or devices. All such patients should also undergo plain-film imaging of the skull or orbits and chest to exclude metallic foreign objects (if recently obtained radiographic or MR information is not already available).
  - (2) Monitoring patients in the MR scanner is sometimes necessary. The potential for thermal injury from excessive RF power deposition exists. Sedated, anesthetized, or unconscious patients may not be able to express symptoms of such injury. This potential for injury is greater on especially higher field whole-body scanners (eg, 1 T and above). Much patient monitoring information can be satisfactorily acquired via pulse oximetry or other means without the utilization of electrocardiographic tracing and its inherent thermal injury risks. Patients who require EKG monitoring and who are unconscious, sedated, or anesthetized should be examined after each imaging sequence with potential

repositioning of the EKG leads and any other electrically conductive material with which the patient is in contact. Alternatively, cold compresses or ice packs could be placed upon all necessary electrically conductive material that touches the patient during scanning.

- k. Final determination of whether or not to scan any given patient with any given implant, foreign body, etc is to be made by the level 2-designated, attending MR radiologist, the MR medical director, or specifically designated level 2 MR personnel following criteria for acceptability predetermined by the medical director.
- 1. All non-MR personnel (eg, patients, volunteers, and varied site employees and professionals) with implanted cardiac pacemakers, autodefibrillators, diaphragmatic pacemakers, or other electromechanically activated devices upon which the non-MR personnel is dependent should be precluded from Zone IV and physically restrained from the 5-G line unless specifically cleared in writing by a level 2–designated attending radiologist or the medical director of the MR site. In such circumstances, specific defending risk-benefit rationale should be provided in writing and signed by the authorizing radiologist.

Should it be determined that non-MR personnel wishing to accompany a patient into an MR scan room require their orbits to be cleared by plain-film radiography, a radiologist must first discuss with the non-MR personnel that plain X-ray films of their orbits are required prior to permitting them access to the MR scan room. Should they still wish to proceed with access to Zone IV or within the 5-G line, and should the attending radiologist deem it medically advisable that they do so (eg, for the care of their child about to undergo an MR study), written informed consent should be provided by these accompanying non-MR personnel prior to undergoing X-ray examination of their orbits.

- m. MR scanning of patients, prisoners, or parolees with metallic prisoner-restraining devices or RF ID or tracking bracelets could lead to theoretical adverse events, including: (1) ferromagnetic attractive effects and resultant patient injury, (2) possible ferromagnetic attractive effects and potential damage to the device or its battery pack, (3) RF interference with the MRI study and secondary image artifact, (4) RF interference with the functionality of the device, (5) RF power deposition and heating of the bracelet or tagging device or its circuitry and secondary patient injury (if the bracelet would be in the anatomic volume of the RF transmitter coil being imaged). Therefore, in cases where requested to scan a patient, prisoner, or parolee wearing RF tagging bracelets or metallic handcuffs or anklecuffs, request that the patient be accompanied by the appropriate authorities who can and will remove the restraining device prior to the MR study and be charged with its replacement following the examination.
- n. Firefighter, police, and security safety considerations: For the safety of firefighters and other emergent services responding to an emergent call at the MR site, it is recommended that all fire alarms, cardiac arrests, or other emergent service response calls originating from or located in the MR site should be forwarded simultaneously to a specifically designated individual from amongst the site's MR personnel. This individual should, if possible, be on site prior to the arrival of the firefighters or emergent responders to ensure that they do not have free access to Zone III or IV. The site might consider assigning appropriately trained security personnel, who have been trained and designated as MR personnel, to respond to such calls.

In any case, all MR sites should arrange to prospectively educate their local fire marshals, firefighter associations, and police or security personnel about the potential hazards of responding to emergencies in the MR suite.

It should be stressed that, even in the presence of a true fire (or other emergency) in Zone III or IV, the magnetic fields may be present and fully operational. Therefore, free access to Zone III or IV by firefighters or other non-MR personnel with air tanks, axes, crowbars, other firefighting equipment, guns, etc might prove catastrophic or even lethal to those responding or others in the vicinity.

As part of the Zones III and IV restrictions, all MR sites must have readily accessible, clearly marked, MR-compatible fire extinguishing equipment physically stored within Zone III or IV. All non–MR-compatible fire extinguishers and other firefighting equipment should be restricted from Zone III.

For superconducting magnets, the helium (and the nitrogen, as well, in older magnets) is not flammable and does not pose a fire hazard directly. However, the liquid oxygen that can result from the supercooled air in the vicinity of the released gases might well increase the fire hazard in this area. If there are appropriately trained and knowledgeable MR personnel available during an emergency to ensure emergency response personnel are kept out of the MR scanner or magnet room and 5-G line, quenching the magnet during a response to an emergency or fire should not be a requirement.

However, if the fire is in such a location that Zone III or IV needs to be entered for whatever reason by firefighters or emergency response personnel and their firefighting and emergent equipment, such as air canisters, crowbars, axes, and defibrillators, a decision to quench a superconducting magnet should be *very* seriously considered to protect the health and lives of the emergency response personnel. Should a quench be performed, appropriately designated MR personnel still need to ensure that *all* non-MR personnel (including and especially emergency response personnel) continue to be restricted from Zones III and IV until the designated MR personnel has personally verified that the static field is either no longer detectable or at least sufficiently attenuated to no longer present a potential hazard to one moving by it with, for example, large ferromagnetic objects such as oxygen tanks or axes.

For resistive systems, the magnetic field of the MR scanner should be shut down as completely as possible and verified as such prior to permitting the emergency response personnel access to Zone IV. For permanent, resistive, or hybrid systems whose magnetic fields cannot be completely shut down, MR personnel should be available to warn the emergency response personnel that a very powerful magnetic field is still operational in the magnet room.

#### 4. MR personnel screening:

All MR personnel are to undergo an MR-screening process as part of their employment interview process to ensure their safety in the MR environment. For their own protection, and for the protection of the non-MR personnel under their supervision, all MR personnel must immediately report to the MR medical director any trauma, procedure, or surgery they experience or undergo where a ferromagnetic metallic object or device may have been introduced within or on them. This will permit appropriate screening to be performed on the employee to determine the safety of permitting that MR personnel—designated employee into Zone III.

#### 5. Device and object screening:

As part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (≥1000 G). This will enable the site to test external, and even some superficial internal, devices or implants for the presence of grossly detectable ferromagnetic attractive forces.

- a. All portable metallic or partially metallic devices that are on or external to the patient (eg, oxygen cylinders) are to be positively identified in writing as nonferromagnetic and either MR safe or MR compatible prior to permitting them into Zone III. For all device or object screening, verification and positive identification *should* be in writing. Examples of devices that need to be positively identified include fire extinguishers, oxygen tanks, and aneurysm clips.
- b. External devices or objects demonstrated to be ferromagnetic and MR unsafe or MR incompatible may still, under specific circumstances, be brought into Zone III if, for example, they are deemed by MR personnel to be necessary and appropriate for the care of the patient. They should only be brought into Zone III if they are under the direct supervision of specifically designated level 1 or 2 MR personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction to Zone III. The safe utilization of these devices while they are present in Zone III will be the responsibility of a specifically named level 1 or 2 MR personnel. The devices must be appropriately physically secured or restricted at all times during which they are in Zone III to ensure that they do not inadvertently come too close to the MR scanner and accidentally become exposed to static magnetic fields or gradients that might result in their becoming either hazardous projectiles or no longer accurately functional.
- c. Never assume MR compatibility or safety information about the device if it is not clearly documented in writing. All unknown external objects or devices being considered for introduction to Zone III should be tested with a strong handheld magnet (≥1000 G) for ferromagnetic properties prior to permitting them entry to Zone III. The results of such testing, as well as the date, time, and name of the tester and the methodology used for that particular device, should be documented in writing. If a device has not been tested, or if its MR compatibility or safety status is unknown, it should *not* be permitted unrestricted access to Zone III.
- d. All portable metallic or partially metallic objects that are to be brought into Zone IV must be labeled with either a green "MR safe" label or a red "not MR safe" label. As noted in the introduction to section B.5, above, testing for the purpose of this labeling is to be accomplished by the site's MR personnel exposing the metallic object to a handheld magnet (≥1000 G). If grossly detectable attractive forces are observed between the metallic object or any of its components and the handheld magnet, it is to be labeled with a red label. If no such forces are observed, a green label is to be affixed to the device or object prior to its introduction to Zone IV.
- e. Decisions based on published MR compatibility or safety claims should recognize that all such claims apply to specifically tested static field and static gradient field strengths. For example, "MR compatible up to 3.0 T at gradient strengths of 400 G/cm" or "MR safe tested up to 1.5 T up to maximum static gradient fields experienced in an unshielded 1.5 T [manufacturer name] whole-body MR scanner tested 1.5 feet within the bore."
- f. It should be noted that alterations performed by the site on MR safe or compatible equipment or devices may alter the MR safety or compatibility properties of the device. For example, tying a ferromagnetic metallic twisting binder onto a sign labeling the device as MR compatible might result in artifact induction—or worse—if introduced to the MR scanner.

### C. MR Technologist

- 1. MR technologists should be ARRT registered technologists (RTs). Furthermore, all MR technologists must be trained as level 2 MR personnel during their orientation, prior to being permitted free access to Zone III.
- 2. All MR technologists will maintain current certification in American Heart Association basic life support at the health care provider level.
- 3. Except for emergent coverage, there will be a minimum of 2 MR technologists or one MR technologist and one other individual with the designation of MR personnel in the immediate Zone II through Zone IV environment. For emergent coverage, the MR technologist can scan with no other individuals in their Zone II through Zone IV environment as long as there is inhouse, ready emergent coverage by designated department of radiology MR personnel (eg, radiology house staff or radiology attendings).

### D. Pregnancy-Related Issues

1. Health care practitioner pregnancies:

Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning.

#### 2. Patient pregnancies:

- a. Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel—designated attending radiologist, the risk-benefit ratio for the patient warrants that the study be performed. The radiologist should confer with the referring physician and document the following in the radiology report or the patient's medical record:
  - (1) The information requested from the MR study cannot be acquired via nonionizing means (eg, ultrasonography).
  - (2) The data is needed to potentially affect the care of the patient or fetus *during* the pregnancy.
  - (3) The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain this data.
- b. MR contrast agents should *not* be routinely provided to pregnant patients. This decision, too, is one that must be made on a case-by-case basis by the covering level 2 MR personnel—designated attending radiologist who will assess the risk-benefit ratio for the particular patient.
- c. It is recommended that pregnant patients undergoing an MR examination provide written informed consent to document that they understand the risks and benefits of the MR procedure to be performed, are aware of the alternative diagnostic options available to them (if any), and wish to proceed.

### E. Pediatric MR Safety Concerns

### 1. Sedation and monitoring issues:

Children form the largest group requiring sedation for MRI, largely because of their inability to remain motionless during scans. Sedation protocols may vary from institution to institution according to the procedures performed (diagnostic vs interventional), the complexity of the patient population (healthy preschoolers vs premature infants), the method of sedation (mild sedation vs general anesthesia), and the qualifications of the sedation provider.

Adherence to standards of care mandates following the sedation guidelines developed by the American Academy of Pediatrics, <sup>13,14</sup> the American Society of Anesthesiologists, <sup>15</sup> and the Joint Commission on Accreditation of Healthcare Organizations. <sup>16</sup> In addition, sedation providers must comply with the protocols established by the individual state and the practicing institution. These guidelines require the following provisions:

- a. Preprocedural medical history and examination for each patient
- b. Fasting guidelines appropriate for age
- c. Uniform training and credentialing for sedation providers
- d. Intraprocedural and postprocedural monitors with adapters appropriately sized for children (compatible with the magnetic field)
- e. Method of patient observation (window, camera)
- f. Resuscitation equipment, including oxygen delivery and suction
- g. Uniform system of record keeping and charting (with continuous assessment and recording of vital signs)
- h. Location and protocol for recovery and discharge
- i. Quality assurance program that tracks complications and morbidity

For the neonatal and the young pediatric population, special attention is needed in monitoring body temperature in addition to other vital signs. Temperature monitoring equipment that is approved for use in the MR suite is becoming more readily available. Commercially available, MR-approved neonatal isolation transport units and other warming devices are also available for use during MR scans.

### 2. Pediatric screening issues:

Children may not be reliable historians and, especially for older children and teenagers, should be questioned both in the presence of parents or guardians and separately to maximize the possibility that all potential dangers are disclosed. Therefore, it is recommended that they be gowned before entering Zone IV to help ensure no metallic objects, toys, etc inadvertently find their way into Zone IV. Pillows, stuffed animals, and other comfort items brought from home represent real risks and should be discouraged from entering Zone IV. If unavoidable, each should be carefully checked with the powerful handheld magnet and perhaps again in the MR scanner prior to permitting the patient to enter Zone IV in order to ensure they do not contain any objectionable metallic components.

### 3. MR safety of accompanying family and personnel:

Although any age patient might request that others accompany them for their MR examination, this is far more common in the pediatric population. Those accompanying or remaining with the patient should be screened using the same criteria as anyone else entering Zone IV.

In general, it would be prudent to limit accompanying adults to a single individual. Only a qualified, responsible MR physician should make screening criteria exceptions.

Hearing protection and MR-compatible chairs or stools are recommended for accompanying family members within the MR scan room.

### 4. Fetal MR contrast agent safety concerns:

The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk-benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus outweighing the theoretical but potentially real risks of the long-term exposure of the developing fetus to free gadolinium ions.

Studies have demonstrated that gadolinium-based MR contrast agents pass through the placental barrier and enter the fetal circulation. From here, they are filtered in the fetal kidneys and then excreted into the amniotic fluid. In this location, the gadolinium-chelate molecules are in a relatively protected space and may remain in the amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. As with any equilibrium situation involving any dissociation constant, the longer the chelate molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its chelate molecule. It is unclear what impact such free gadolinium ions might have if they were to be released in any quantity in the amniotic fluid. Certainly, deposition into the developing fetus would raise concerns of possible secondary adverse effects.

As indicated before, but repeated for added emphasis, a documented, in-depth analysis of the potential risks and benefits to the patient and her fetus is necessary in order to arrive at a reasonable conclusion as to the clinical advisability of administering a gadolinium-based MR contrast agent to any pregnant patient.

### F. Time-Varying Gradient Magnetic Field-Related Issues: Induced Voltages

Types of patients needing extra caution:

Patients with implanted or retained wires in anatomically or functionally sensitive areas (eg, myocardium or epicardium, implanted electrodes in the brain) should be considered at higher risk, especially from faster MRI sequences, such as echo planar imaging (which may be used in such sequences as diffusion-weighted imaging, functional imaging, perfusion-weighted imaging, MR angiographic imaging, etc). The decision to limit the dB/dt (rate of magnetic field change) and maximum strength of the magnetic field of the gradient subsystems during the imaging of such patients should be reviewed by the level 2 MR personnel–designated attending radiologist supervising the case or patient.

#### G. Time-Varying Gradient Magnetic Field-Related Issues: Auditory Considerations

- 1. All patients and volunteers should be offered and encouraged to use hearing protection prior to undergoing any imaging in the MR scanners.
- 2. All patients or volunteers in whom research sequences are to be performed (ie, MR scan sequences that have not yet been approved by the Food and Drug Administration) are to have

hearing protective devices *in place* prior to initiating any MR sequences. Without hearing protection in place, MRI sequences that are not FDA approved should not be performed on patients or volunteers.

### H. Time-Varying Radiofrequency Magnetic Field-Related Issues: Thermal

- 1. All unnecessary or unused electrically conductive materials should be removed from the MR system before the onset of imaging. It is not sufficient merely to "unplug" or disconnect unused, unnecessary electrically conductive material and leave it within the MR scanner with the patient during imaging. All electrical connections, such as on-surface coil leads or monitoring devices, must be visually checked by the scanning MR technologist prior to each scan to ensure the integrity of the thermal and electrical insulation.
- 2. Electrical voltages and currents can be induced within electrically conductive materials that are within the bore of the MR imager during the MR imaging process. This might result in the heating of this material by resistive losses. This heat might be of a caliber sufficient to cause injury to human tissue. Among the variables that determine the amount of induced voltage or current is the consideration that the larger the diameter of the conductive loop the greater the potential induced voltages or currents and, thus, the greater the potential for resultant thermal injury to adjacent or contiguous patient tissue.

Therefore, when electrically conductive materials (wires, leads, implants, etc) are required to remain within the bore of the MR scanner with the patient during imaging, care should be taken to ensure no large-caliber, electrically conductive loops (including patient tissue; see section H.5, below) are formed within the MR scanner during imaging. Furthermore, it is possible, with the appropriate configuration, lead length, static magnetic field strength, and other settings, to introduce resonant circuitry between the transmitted RF power and the lead. This could result in very rapid and clinically significant lead heating, especially at the lead tips, in a matter of seconds to a magnitude sufficient to result in tissue thermal injury or burns. This can also theoretically occur with implanted leads or wires even when they are not connected to any other device at either end. Thus, exposure of electrically conductive leads or wires to the RF-transmitted power during MR scanning should only be performed with caution and with appropriate steps taken to ensure significant lead or tissue heating does not result (see section H.9, below).

- 3. When electrically conductive materials are required to be within the bore of the MR scanner with the patient during imaging, care should be taken to place thermal insulation (including air, pads, etc) between the patient and the electrically conductive material while simultaneously attempting to (as much as feasible) keep the electrical conductor from directly contacting the patient during imaging. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of the MR scanner if the body coil is being used for RF transmission. When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of cold compresses or ice packs to such areas.
- 4. Depending on specific magnet designs, care may be needed to ensure that the patient's tissues do not directly come into contact with the inner bore of the MR imager during the MRI process. This care is especially important for several higher-field MR scanners. The manufacturers of these devices provide pads and other insulating devices for this purpose, and manufacturer guidelines should be strictly adhered to for these units.
- 5. It is important to ensure the patient's tissues do not form large conductive loops. Therefore, care should be taken to ensure the patient's arms or legs are not positioned in such a way as to form a large caliber loop within the bore of the MR imager during the imaging process. For this reason, it is preferable that patients be instructed not to cross their arms or legs in the MR scanner.

- 6. Skin staples and superficial metallic sutures: Patients requested to undergo MR studies in whom there are skin staples or superficial metallic sutures (SMS) may be permitted to undergo the MR examination if the skin staples or SMS are not ferromagnetic and are not in the anatomic volume of RF power deposition for the study to be performed. If the nonferromagnetic skin staples or SMS are within the volume to be RF irradiated for the requested MR study, several precautions are recommended:
  - a. Warn the patient and make sure they are especially aware of the possibility that they may experience warmth or even burning along the skin staple or SMS distribution. The patient should be instructed to report immediately if they experience warmth or burning sensations during the study (and not, for example, to wait until the "end of the knocking noise").
  - b. It is recommended that a cold compress or ice pack be placed along the skin staples or SMS if this can be safely clinically accomplished during the MRI examination. This will help to serve as a heat sink for any focal power deposition that may occur, thus decreasing the likelihood of a clinically significant thermal injury or burn to adjacent tissue.
- 7. For patients with extensive or dark tattoos, including tattooed eyeliner, in order to decrease the potential for RF heating of the tattooed tissue, it is recommended that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MRI process if these tattoos are within the volume in which the body coil is being used for RF transmission. This approach is especially appropriate if fast spin echo (or other high-RF-duty cycle) MRI sequences are anticipated in the study. If another coil is being used for RF transmission, a decision must be made if high RF-transmitted power is to be anticipated by the study protocol design. If so, then the above precautions should be followed. Additionally, patients with tattoos that have been placed within 48 hours prior to the pending MR examination should be advised of the potential for smearing or smudging of the edges of the freshly placed tattoo.
- 8. The unconscious or unresponsive patient should have all attached leads covered with a cold compress or ice pack at the lead attachment site for the duration of the MR study prior to the initiation of scanning.
- 9. As noted above, it has been demonstrated that resonant circuitry can be established during MRI between the RF energies being transmitted and specific lengths of long, electrically conductive wires or leads, which can thus act as efficient antennae. This can result in heating of the tips of these wires or leads to temperatures in excess of 90°C in a few seconds. Therefore, patients in whom there are long, electrically conductive leads, such as Swan-Ganz thermodilution cardiac output—capable catheters or Foley catheters with electrically conductive leads, should be considered at risk for MR studies if the body coil is to be used for RF transmission over the region of the electrically conductive lead. This is especially true for higher-field systems and for imaging protocols utilizing fast spin echo or other high-RF-duty cycle MRI sequences. Each such patient should be reviewed and cleared by an attending level 2 radiologist, and a risk-benefit ratio assessment should be performed prior to permitting them access to the MR scanner.

#### I. Drug-Delivery Patches and Pads

Some drug-delivery patches contain metallic foil. Scanning the region of the metallic foil may result in thermal injury. The Since removal or repositioning can result in altering the patient's dose, consultation with the patient's prescribing physician would be indicated in assessing how best to manage the patient. If the metallic foil of the patch delivery system is positioned on the patient so that it is in the volume of excitation of the transmitting RF coil, the case should be specifically reviewed with the radiologist or physician covering the case. Alternative options may include placing an ice pack directly on the patch. This solution may still substantially alter the rate of delivery or absorption

of the medication to the patient (and be less comfortable to the patient, as well). This ramification should therefore not be treated lightly, and a decision to proceed in this manner should only be made by a knowledgeable radiologist attending the patient and with the concurrence of the referring physician, as well.

If the patch is removed, a specific staff member should be given responsibility for ensuring that it is replaced or repositioned.

### J. Cryogen-Related Issues

- 1. For superconducting systems, in the event of a system quench, it is imperative that all personnel and patients be evacuated from the MR scan room as quickly and as safely feasible and that the site access be immediately restricted to all individuals until the arrival of the MR equipment service personnel. This is especially so if cryogenic gases are observed to have vented partially or completely into the scan room, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. As noted in section B.3.n above, it is especially important to ensure all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air canisters, guns, etc) until it can be confirmed that the magnetic field has been successfully dissipated, as there may still be considerable static magnetic field present despite a quench or partial quench of the magnet.
- 2. It should be pointed out that room oxygen monitoring was discussed by the MR Blue Ribbon Panel and rejected at this time because the present oxygen-monitoring technology was considered by industry experts not to be sufficiently reliable to allow for continued operation during situations of power outages, etc.

#### K. Claustrophobia, Anxiety, Sedation, Analgesia, and Anesthesia

Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR, <sup>18,19</sup> American Society of Anesthesiologists, <sup>15,20-22</sup> and JCAHO standards. <sup>23</sup>

### L. Contrast Agent Safety

1. Contrast agent administration issues:

No patient is to be administered prescription MR contrast agents without orders from a duly licensed physician. Intravenous injection—qualified MR technologists may start and attend to peripheral IV access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area. IV-qualified MR technologists may administer FDA-approved gadolinium-based MR contrast agents via peripheral IV routes as a bolus or as a slow or continuous injection, as directed by the orders of a duly licensed site physician.

a. Administration of these agents is to be performed as per the ACR policy: "The ACR approves of the injection of contrast material and diagnostic levels of radiopharamceuticals by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations. There must also be prior written approval by the medical director of the radiology department /service of such individuals; such approval process having followed established policies and procedures, and the radiologic technologists and nurses who have been so approved maintain documentation of continuing medical education related to materials injected and to the procedures being performed." (Res 1-H, 1987, 1997)

### 2. Prior contrast agent reaction issues:

- a. According to the ACR *Manual on Contrast Media*, "Adverse events after intravenous injection of gadolinium seem to be more common in patients who had previous reactions to an MR contrast agent. In one study, 16 (21%) of 75 patients who had previous adverse reactions to MR contrast agents reacted to subsequent injections of gadolinium. Patients with asthma also seem to be more likely to have an adverse reaction to gadolinium. Patients with allergies also seemed to be at increased risk (~2.0-3.7 times, compared with patients without allergies). Patients who have had adverse reactions to iodinated contrast media are more than twice as likely to have an adverse reaction to gadolinium (6.3% of 857 patients).
- b. "At present there are no well-defined policies for patients who are considered to be at increased risk for having adverse reaction to MR contrast agents; however, the following recommendations are suggested: patients who have previously reacted to one MR agent can be injected with another agent, if they are restudied, and at-risk patients can be pre-medicated with corticosteroids and, occasionally, antihistamines."<sup>24</sup>
- c. All patients with asthma, allergic respiratory histories, prior iodinated or gadolinium-based contrast reactions, etc should be followed more closely as they are at a demonstrably higher risk of adverse reaction.

#### M. Patients in Whom There Are or May Be Intracranial Aneurysm Clips

- 1. In the event it is unclear whether a patient does or does not have an aneurysm clip in place, plain films should be obtained. Alternatively, if available, any cranial plain-film, CT, or MR examination that may have been taken in the recent past (ie, subsequent to the suspected surgical date) should be reviewed to assess for a possible intracranial aneurysm clip.
- 2. In the event that a patient is identified to have an intracranial aneurysm clip in place, the MR examination should not be performed until it can be documented that the type of aneurysm clip within that patient is MR safe or compatible. All documentation of types of implanted clips, dates, etc *must* be in writing and signed by a licensed physician. Phone or verbal histories and histories provided by a nonphysician are not acceptable. Faxed copies of operative reports, physician statements, etc are acceptable as long as a legible physician signature accompanies the requisite documentation. A written history of the clip having been appropriately tested for ferromagnetic properties (and a description of the testing methodology used) prior to implantation by the operating surgeon is also considered acceptable if the testing follows the deflection test methodology established by the American Society of Testing and Materials.
- 3. All implanted intracranial aneurysm clips that are documented in writing to be composed of titanium (either the commercially pure or the titanium alloy types) can be accepted for scanning without any other testing.
- 4. All nontitanium intracranial aneurysm clips manufactured 1995 or later for which the manufacturer's product labeling continues to claim MR compatibility may be accepted for MR scanning without further testing.
- 5. Clips manufactured prior to 1995 require either pretesting (per the American Society of Testing and Materials' deflection test methodology) prior to implantation or the individual review of a previous MRI of the clip or brain in that particular case, if available. By assessing the size of the artifact associated with the clip relative to the static field strength on which it was studied, the sequence type, and the MRI parameters selected, an opinion may be issued by one of the site's level 2 MR attending radiologists as to whether the clip demonstrates significant ferromagnetic properties or not. Access to the MR scanner would then be based on that opinion.

- 6. A patient with an aneurysm clip (or other implant) may have safely undergone a prior MR examination at any given static magnetic field strength. This fact in and of itself is *not* sufficient evidence of the implant's MR safety or compatibility and should *not* solely be relied upon to determine the MR safety or compatibility status of the aneurysm clip (or other implant).
  - Variations in static magnetic field strength, static magnetic field spatial gradient, orientation of the aneurysm clip (or other implant) to the static magnetic field or static field gradient, rate of motion through the spatial static field gradient, etc are all variables that are virtually impossible to control or reproduce. These variables may not have resulted in adverse events in one circumstance but may result in significant injury or death on a subsequent exposure. For example, a patient who went blind from interactions between the metallic foreign body in his retina and the spatial static fields of the MR scanner entered the magnet and underwent the entire MR examination without difficulty; he went blind upon exiting the MR scanner at the completion of the examination.
- 7. Barring availability of either pretesting or prior MRI data of the clip in question, a risk-benefit assessment and review must be performed in each case individually. Further, for patients with intracranial clips with no available ferromagnetic or imaging data, should the risk-benefit ratio favor the performance of the MR study, the patient or guardian should provide written informed consent that includes death as a potential risk of the MRI procedure prior to permitting that patient to undergo an MR examination.

# N. Patients in Whom There Are or May Be Cardiac Pacemakers or Implantable Cardioverter Defibrillators

It is recommended that the presence of implanted cardiac pacemakers or implanted cardioverter defibrillators (ICDs) be considered contraindicated for routine MRI. Should an exception be considered, it should be done on a case-by-case and site-by-site basis and only if the site is manned with individuals with the appropriate radiology and cardiology knowledge and expertise on hand. Ideally, the nonemergent patient should be apprised of the risks associated with the procedure and should provide prospective written informed consent prior to its initiation. Further, should any MRI examination be contemplated for a patient with an implanted pacing device, it is recommended that radiology and cardiology personnel and a fully stocked crash cart and defibrillator be on hand throughout the procedure in case a significant arrhythmia develops during the examination and for whatever reason does not terminate with the cessation of the MR study. All such patients should be actively monitored for cardiac and respiratory function throughout the examination. At the conclusion of the examination, the cardiologist or electrophysiologist should interrogate the pacemaker to confirm that the function is consistent with the pre-examination state. The panel is unaware at this time of any ICD devices that are designed to be safely exposed to intentional MR scanning. In fact, there have been reports of ICD device malfunction after inadvertent exposure to MR scanning.

There have been numerous reports of patients with pacemakers who have undergone MR examinations, both intentionally as well as inadvertently, without difficulty or apparent injury. There have also been several patients who were inadvertently exposed to MR studies who have died during the examination or very shortly thereafter. There is an increasing body of evidence documenting the ability of the MRI process to produce, in specific cases and under certain circumstances, direct cardiac stimulation and arrhythmias. It is theorized that such arrhythmogenesis and its severe hypotensive sequelae were the cause of death in at least several of these patients, some of whom were not pacemaker dependent prior to the MR examination. It is also becoming more apparent that the primary cause of such arrhythmias seems to result from interactions between the pacemaker's lead circuitry and the RF power transmitted during the MRI process.

Some have suggested that it might be possible to perform MRI examinations on patients with implanted cardiac pacemakers as long as rigid guidelines were carefully defined and adhered to throughout the imaging process. These include recommendations, among others, that ensure no pacemaker-dependent patient is scanned, that the RF power transmitted during the MRI process is not deposited over the volume that contains the pacemaker or its leads, etc. This guideline makes no attempt to judge the scientific veracity of these observations or claims. However, it clearly recognizes that, even if it is possible to safely perform MRI examinations on cardiac pacemaker patients, the expertise necessary to safely do so is exceedingly rare throughout MR industry today.

The entire field of MR scanning of pacemaker patients is one that is exhibiting tremendous activity, research, and growth of late. Fiber-optic pacemaker devices, coated or shielded leads and pacing devices, and various other designs and configurations of MR pacing devices and leads are being actively investigated in an to attempt to devise MR-safe cardiac pacemakers. It is therefore another area within MR safety that bears close observation and frequent updates over the next few months and years as progress continues to be made toward developing avenues that will enable pacemaker, and eventually perhaps even ICD, patients to have safe access to the powerful diagnostic modality that is MRI.

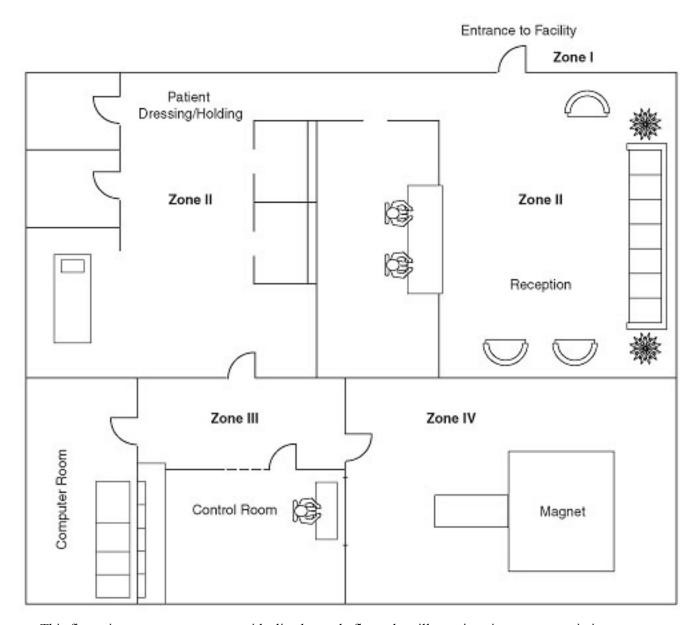
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Figure 1

## **Model MR Facility Zone Configuration**



This figure is meant to represent an idealized sample floor plan, illustrating site access restriction considerations. Other potential MR safety issues, such as magnet site planning related to fringe magnetic field considerations, are not meant to be included herein.

See Appendix 1 for personnel and zone definitions.

Note: In any zone of the facility, there should be compliance with HIPAA regulations in regard to privacy of patient information. However, in Zone III, there should be a privacy barrier so that unauthorized persons cannot view the control panels.

Appendix 1

#### PERSONNEL DEFINITIONS

### **Non-MR Personnel**

Patients, visitors, or facility staff who do not meet the criteria of level 1 or 2 MR personnel will be referred to as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

#### Level 1 MR Personnel

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III will be referred to as level 1 MR personnel (eg, MRI department office staff, patient aides).

#### Level 2 MR Personnel

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to as level 2 MR personnel (eg, MR technologists, radiologists, radiology department nursing staff).

#### **ZONE DEFINITIONS**

#### Zone I

This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.

#### Zone II

This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zone III (see below). Typically, patients are greeted in Zone II and are not free to move throughout Zone II at will, but rather are under the supervision of MR personnel .It is in Zone II that the answers to MR-screening questions, patient histories, medical insurance questions, etc are typically obtained.

### **Zone III**

This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the MR scanner's particular environment. These interactions include, but are not limited to, those involving the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, MR personnel.

#### **Zone IV**

This area is synonymous with the MR scanner magnet room itself. Zone IV, by definition, will always be located within Zone III, as it is the MR magnet and its associated magnetic field, which generates the existence of Zone III.

Non-MR personnel should be accompanied by, or under the immediate supervision of and visual contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or IV.

Level 1 and 2 MR personnel may move freely about all zones.

Appendix 2

### Safety Screening Form for Magnetic Resonance (MR) Procedures

Date: Na	ame (first middle last):			
Female [ ] Male [ ] Age:	Date of birth:	Height:	Weight:	
Why are you having this exam	mination (medical problem)? _			
			Yes	No
Have you ever had an MRI ex	xamination before and had a pr	roblem?		
If yes, please describe:				
Have you ever had a surgical	operation or procedure of any	kind?		
If yes, list all prior surger	ries and approximate dates:			
•	by a metal object or foreign bod		1)?	
Have you ever had an injury shavings, other metal obj	from a metal object in your eye ect)?	e (metal slivers, metal		
If yes, did you seek medi	cal attention?			
If yes, describe what was	found:			
Do you have a history of kidr	ney disease, asthma, or other al	llergic respiratory disease?		
Do you have any drug allergi				
If yes, please list drugs: _				
Have you ever received a cor or study?	ntrast agent or X-ray dye used f	for MRI, CT, or other X-ra		
Have you ever had an X-ray of allergic reaction?	dye or magnetic resonance ima	iging (MRI) contrast agent		
If yes, please describe:				
Are you pregnant or do you s	suspect you may be pregnant?			
Are you breast-feeding?				
Date of last menstrual period	: Are you	postmenopausal?		

Page 2

### **MR Hazard Checklist**

Please mark on the drawings provided the location of any metal inside your body or site of surgical operation.

The following items may be harmful to you during your MR scan or may interfere with the MR examination. You must provide a "yes" or "no" for every item. Please indicate if you have or have had any of the following:

Yes	No	
		Any type of electronic, mechanical, or magnetic implant
		Type:
		Cardiac pacemaker
		Aneurysm clip
		Implanted cardiac defibrillator
		Neurostimulator
		Biostimulator
		Type:
		Any type of internal electrodes or wires
		Cochlear implant
		Hearing aid
		Implanted drug pump (eg, insulin, Baclofen, chemotherapy, pain medicine)
		Halo vest
		Spinal fixation device
		Spinal fusion procedure
		Any type of coil, filter, or stent
		Type:
		Any type of metal object (eg, shrapnel, bullet, BB)
		Artificial heart valve
		Any type of ear implant
		Penile implant
		Artificial eye
		Eyelid spring
		Any type of implant held in place by a magnet
		Type:
		Any type of surgical clip or staple
		Any IV access port (eg, Broviac, Port-a-Cath, Hickman, Picc line)
		Medication patch (eg, nitroglycerine, nicotine)
		Shunt
		Artificial limb or joint
		What and where:
		Tissue expander (eg, breast)
		Removable dentures, false teeth, or partial plate
		Diaphragm, IUD, Pessary
		Type:
		Surgical mesh
		Location:
		Body piercing
		Location:
		Wig, hair implants
		Tattoos or tattooed eyeliner

	*		
	Radiation seeds (eg, cancer treatment) Any implanted items (eg, pins, rods, screws, nails, plates, wires) Any hair accessories (eg, bobby pins, barrettes, clips) Jewelry Any other type of implanted item Type:		
Ins	structions for the Patient		
2. 3. 4. 5. 6. 7.	You are urged to use the earplugs or headphones we supply during your MRI examination since some patients may find the noise levels unacceptable, and the noise levels may affect your hearing. Remove all jewelry (eg, necklaces, pins, rings). Remove all hairpins, bobby pins, barrettes, clips, etc. Remove all dentures, false teeth, and partial dental plates. Remove hearing aides. Remove eyeglasses. Remove your watch, pager, cell phone, credit cards, bankcards, and all other cards with a magnetic strip. Remove body piercing objects. Use gown, if provided, or remove all clothing with metal fasteners, zippers, etc.		
ent this Pat	ttest that the above information is correct to the best of my knowledge. I have read and understand the cire contents of this form, and I have had the opportunity to ask questions regarding the information on s form.  tient signature:		
	D/RN/RT signature: Date:		
РΠ	nt name of MD/RN/RT:		
	For MRI Office Use Only		
Pat	tient name:		
Pat	tient ID number: Referring physician:		
Pro	Procedure: Diagnosis:		
Cli	nical History:		
Ha	zard Checklist for MRI Personnel		
	Endotracheal tube Swan-ganz catheter Extra ventricular device Arterial line transducer Foley catheter with temperature sensor and/or metal clamp Rectal probe Esophageal probe Tracheotomy tube Guidewires		