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American College of Radiology White Paper on MR Safety

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The following is a report of the American College of Radiology Blue Ribbon Panel on MR Safety, chaired by Emanuel Kanal, MD, FACR, to the Task Force on Patient Safety, chaired by James P. Borgstede, MD, FACR. Under the auspices of the Task Force, the panel met in November 2001 consisting 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, RTR, MR; Emanuel Kanal, MD, FACR; Elaine K. Keeler, PhD, (NEMA); James W. Lester, MD; Elizabeth Scoumis, RN, BSN; Loren A. Zaremba, PhD (FDA); and Marie D. Zinninger (American College of Radiology Staff). The following document is intended to be used as a template for MR facilities to follow in the development of an MR safety program.

Recent articles in the medical literature and electronic/print media [1, 2] detailing Magnetic Resonance Imaging (MRI) adverse incidents involving patients, equipment, and personnel spotlighted the need for review. The Panel was charged with reviewing MR safety practices and guidelines and issuing new ones as appropriate for MR examinations and practices today [3–7]. The document restates existing practices and articulates new ones. This document will continue to evolve, as does the MRI field.

There are potential risks in the MR environment, not only for the patient 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. These MR Safe Practices Guidelines have been developed to help guide MR practitioners regarding these issues and 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.

It is the intent of the American College of Radiology (ACR) that these MR Safe Practice Guidelines will be helpful as the field of MR evolves and matures, providing patient 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

A. Establish, Implement, And Maintain Current MR Safety Policies And Procedures

1. All clinical and research magnetic resonance imaging 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 concomitant with the introduction of any significant changes in safety parameters in the MR imaging environment of the site's MR service (e.g., adding faster/stronger gradient capabilities, higher RF duty cycle studies, etc.) 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 to be reported to the Medical Director of the MR site in a timely fashion (e.g., within 24 hours/one business day of their occurrence) and used in continuous quality improvement efforts.

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B. STATIC MAGNETIC FIELD ISSUES: SITE ACCESS RESTRICTION

1. Zoning:
   The MR site is conceptually divided into four Zones (Fig. 1) as follows.
   a. Zone I: This includes all areas that are freely accessible to the general public. This area is typically outside of 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 Zone III and IV (see below). Typically patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather under the supervision of MR Personnel (see Section 2b, 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 and/or ferromagnetic objects and equipment can result in serious injury or death as a result of interactions between the individuals/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 2b, 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 Two–designated (see section 2b, below) physician of the day for the MR site.

      Zone III regions should be physically restricted from general public access—for example, by key locks, pass-key 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 to be discouraged as combinations often tend to become more widely distributed than initially intended, resulting in site restriction violations being more likely with these devices. Only MR Personnel shall be provided with free access, such as the access keys/passkeys, to Zone III regions.

      There should be NO exceptions to this guideline. Specifically, this includes hospital/site administration, physician, security, and other non–MR Personnel (see section 2b, 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 and become MR Personnel themselves. Zone III regions or at the very least the area within them wherein the static magnetic field's strength exceeds 5-gauss should be clearly marked and demarcated as being potentially hazardous.
   d. Zone IV: This area is synonymous with the MR scanner magnet room itself—i.e., the physical confines of the room within which the MR scanner itself 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 itself. Zone IV regions should also be clearly marked and demarcated 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 be installed in such a way as to provide for direct visual observation by Level II MR Personnel to access pathways into Zone IV regions. 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 regions from their normal positions when stationed at their desks in the scan control room.

      Zone IV/MR magnet rooms should be clearly marked with a lighted sign and red light stating, "The Magnet is On." Except for resistive systems, this sign/red light should be illuminated at all times and should be provided with a backup energy source to continue to remain illuminated 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

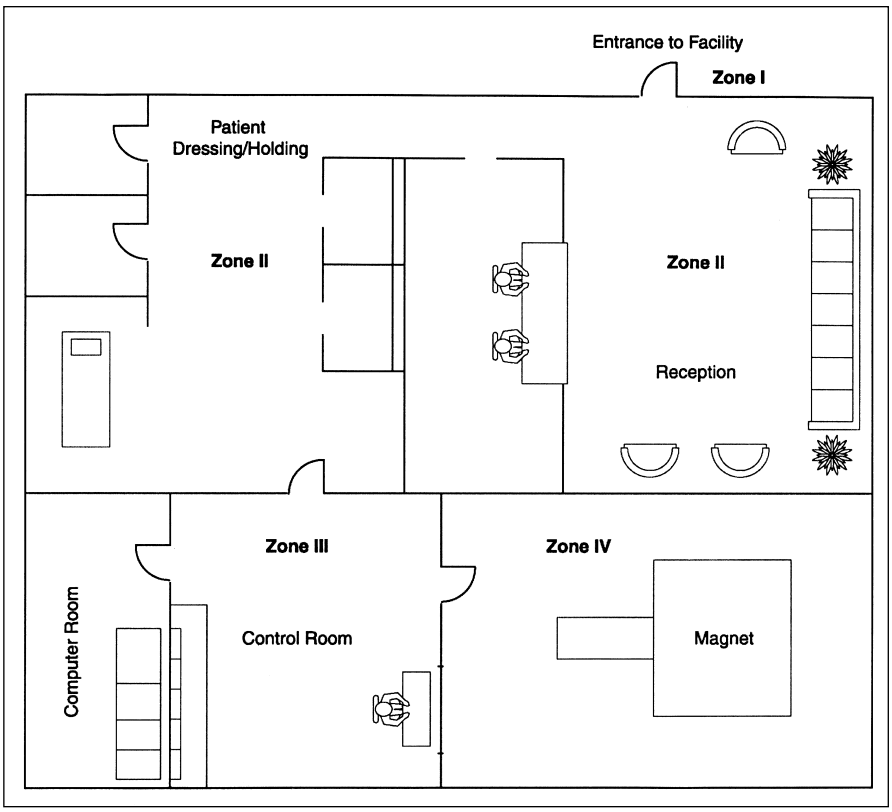

Fig. 1.—MR site floor plan.

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IV for which emergent medical intervention and/or resuscitation is required, appropriately trained and certified MR Personnel should immediately initiate basic life support and/or CPR as required by the situation WHILE the patient is being emergently removed from the MR magnet room/Zone IV to a predetermined magnetically safe location. ALL PRIORITIES SHOULD BE FOCUSED ON STABILIZING (E.G., 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 removed from ZONE IV (the magnet room itself) 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 itself 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 removing the patient from Zone IV/the MR magnet room to a location where the strength of the magnetic field(s) is insufficient to be a medical concern. ZONE III AND ZONE IV SITE ACCESS RESTRICTION MUST BE MAINTAINED DURING RESUSCITATIONS AND/OR OTHER EMERGENT SITUATIONS FOR THE PROTECTION OF ALL INVOLVED.

2. MR Personnel/Non–MR Personnel
   a. All individuals working within at least Zone III of the MR environment should be documented to have completed successfully at least one of the MR site's approved MR safety live lectures or prerecorded presentations as approved by the MR Medical Director. Attendance should be repeated at least annually, and appropriate documentation should be provided. These individuals shall be referred to henceforth as MR Personnel.
   b. There are two levels of MR Personnel.
      1. Level One MR Personnel: Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III regions will be referred to henceforth as Level One MR Personnel.
      2. Level Two MR Personnel: Those who have been more extensively trained and intensively educated in the broader aspects of MR safety issues including, for example, issues related to the potential for thermal loading/burns, direct neuromuscular excitation from rapidly changing gradients, etc., shall be referred to henceforth as Level Two MR Personnel. It is the responsibility of the MR Medical Director of the site not only to identify the necessary training, but also to identify those individuals that qualify as Level Two MR Personnel. It is understood that the Medical Director of the MR site will be one whose education and experience in MR safety qualifies them for designation as Level Two MR Personnel.
   c. All those not having successfully complied with these MR safety instruction guidelines shall be referred to henceforth as Non–MR Personnel.
3. Patient/Non–MR Personnel Screening
   a. ALL Non–MR Personnel wishing to enter Zone III regions of the MR Site must have first successfully passed an MR safety screening process to be performed by authorized MR Personnel. Only MR Personnel are authorized to perform an MR safety screen prior to permitting Non–MR Personnel into Zone III areas.
   b. 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, near the spinal cord, or heart, etc.
      4. Today's metal detectors do not differentiate between ferromagnetic and nonferromagnetic metallic objects/implants/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.
   c. Non–MR Personnel should be accompanied by, or under the immediate supervision and visual/verbal contact with, one specifically identified Level Two MR Person for the entirety of the duration during which the Non–MR Personnel remain within Zone III or Zone IV restricted regions. However, it is acceptable to have them in a changing room or restroom not in visual contact in Zone III as long as personnel and the patient can verbally communicate with each other.

      In the event of a shift change, lunch break, etc., no Level Two MR Personnel shall relinquish their responsibility to supervise the Non–MR Personnel still within Zone III or Zone IV under their charge until such supervision has been formally transferred to another of the Level Two MR Personnel of the MR Site.
   d. Non-emergent patients should be MR safety screened onsite by a minimum of two separate individuals. At least one of these individuals should be one of the Level Two MR Personnel of the MR site. At least one of these two screens should be performed verbally/interactively.

      Emergent patients and their accompanying Non–MR Personnel may be screened only once providing that the screening individual is one of the site's Level Two MR Personnel.

      There should be no exceptions to this.
   e. Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices on or in them (e.g., watches; jewelry; pagers; cell phones; body piercings, if removable; contraceptive diaphragms; metallic drug delivery patches; and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads; cosmetics containing metallic particles, such as eye makeup). It is therefore advisable to require that the patients or research subjects wear a site-supplied gown with no metal fasteners during the MR procedure when feasible.
   f. All patients/Non–MR Personnel with a history of a potential ferromagnetic foreign object penetration must undergo further investigation prior to being per-

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mitted entrance to Zone III of the MR site. Examples of acceptable methods of screening include patient history, plain x-ray films, prior CT or MR of the questioned anatomic area, or access to written documentation as to the type of implant or foreign object that might be present. Once positive identification has been made as to the type of implant/foreign object that is within a patient, best effort assessments should be made to attempt to identify the MR compatibility or MR safety of the implant/object. Efforts at identification might include written testing on the implant prior to implantation (preferred), product labeling regarding the implant/object, peer-reviewed publications regarding MR compatibility, and MR safety testing of the make/model/type of the object, etc. MR safety testing would only be of value assuming that the object/device has 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 (two views) [8, 9] or by a radiologist's review and assessment of contiguous cut prior CT or MR images (obtained since the suspected traumatic event) if available.

g. Conscious, non-emergent patients and research and volunteer subjects are to complete written MR safety screening questionnaires prior to their introduction into Zone III regions. Family/guardians of non-responsive 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 into Zone III regions. These completed questionnaires are then to be reviewed orally with the patient/guardian/research subject in their entirety prior to permitting the patient/research subject to be cleared into Zone III regions.

The patient/guardian/research subject as well as the screening MR staff member must both sign the completed form. This should then become a part of the patient's medical record. No empty responses will be accepted—each question MUST be answered definitively with a "Yes" or "No" or provide specific further information as requested. A sample of a pre–MR screening form is provided (Appendixes 2–5). This is the minimum information to be obtained; more may be added if the site so desires.

h. Screening of the patient/Non–MR Personnel with, or suspected of having, an intracranial aneurysm clip should be performed as per the separate MR Safe Practice Guideline addressing this particular topic (see section K, below).

i. Screening of all unconscious/unresponsive patients and/or patients who cannot provide their own reliable histories, or when the history cannot be reliably obtained from others, regarding prior possible exposures to surgery, trauma, and/or metallic foreign object history/exposure, in whom an MR examination is deemed clinically indicated/necessary:

1. If no reliable patient metal exposure history can be otherwise obtained and if the requested MR examination cannot reasonably wait until such a time that a reliable such history might be obtained, it is recommended that such patients be physically examined by Level Two MR Personnel. All areas of scars or deformities that might be anatomically indicative of an implant such as on the chest or spine region, etc., 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 such recently obtained plain films or computer tomographic or magnetic resonance studies of such areas are not already available). The investigation described above should be made to ensure that there are no potentially harmful embedded/implanted metallic foreign objects or devices. All such patients should also undergo plain film imaging of the skull/orbits and chest to exclude metallic foreign objects (if recently obtained such radiographic and/or MR information is not already available).
2. Monitoring of patients is sometimes necessary in the MR scanner. The potential for thermal injury from possibly excessive radiofrequency power deposition exists. Sedated, anesthetized, and/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 (e.g., 1 Tesla and above). Much patient monitoring information can be satisfactorily acquired via pulse oximetry and/or other means without utilization of electrocardiographic tracing and its inherent thermal injury risks. Patients who require EKG monitoring and who are, unconscious, sedated, and/or anesthetized should be examined with potential repositioning, after each imaging sequence, 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.

j. 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 Two designated attending MR radiologist, or the MR Medical Director, or specifically designated Level Two MR Personnel following criteria for acceptability for MR scanning predetermined by the Medical Director.

k. All Non–MR Personnel (e.g., patients, volunteers, varied site employees and professionals, etc.) with implanted cardiac pacemakers, autodefibrillators, diaphragmatic pacemakers, and/or other electromechanically activated devices on whose function the Non–MR Personnel is dependent should be precluded from the MR magnet room/Zone IV and physically restrained from the 5-gauss line unless specifically cleared in writing by a Level Two MR Personnel–designated radiologist attending physician 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 and/or within the 5-gauss line, and should the attending radiologist deem it medically advisable that they do so (e.g., 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 their undergoing x-ray examination of their orbits.

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l. MR scanning of patients/prisoners/parolees with metallic prisoner restraining devices or radiofrequency ID/tracking bracelets could lead to theoretical potential adverse events including: 1) ferromagnetic attractive effects and resultant patient injury, 2) possible ferromagnetic attractive effects and potential damage to the device and/or its battery pack, 3) radiofrequency (RF) interference with the MR imaging study and secondary image artifact, 4) RF interference with the functionality of the device, 5) RF power deposition and heating of the bracelet 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/parolee wearing radiofrequency tagging bracelets and/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.

m. Firefighter/Police/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/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 onsite prior to the arrival of the firefighters/emergent responders to ensure that they do not have free access to Zone III or Zone 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/firefighters associations and police/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 and/or Zone IV, the magnetic fields may be present and fully operational. Therefore, free access to Zone III or Zone IV by firefighters and/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 Zone III/IV restrictions, all MR sites must have clearly marked MR-compatible fire extinguishing equipment physically stored within and readily accessible to Zone III/IV regions. All Non–MR compatible fire extinguishers and other firefighting equipment should be restricted from being brought into Zone III regions.

For superconducting magnets, the helium (and the nitrogen as well, in the 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 the emergency to ensure that emergency response personnel responding to the fire call are kept out of the MR scanner/magnet room and 5-gauss line, then quenching the magnet during response to an emergency or fire should not be a requirement.

HOWEVER, if the fire is in such a location where Zone III/IV needs to be entered for whatever reason by the firefighting and/or emergency response personnel and their firefighting and emergent equipment such as air canisters, crowbars, axes, defibrillators, etc., a decision to quench a superconducting magnet at that point should be VERY seriously considered to protect the health and lives of the emergent responding personnel in such an emergency situation. Should a quench be performed, appropriately designated MR personnel still need to ensure that ALL non–MR personnel (including and especially emergently responding personnel) continue to be restricted from Zone III/IV regions until the designated MR Personnel have personally verified that the static field is either no longer detectable or at least sufficiently attenuated so as to no longer present a potential hazard to one moving by it with, for example, large ferromagnetic objects such as oxygen tanks, axes, etc.

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 the magnet/Zone IV. For permanent or 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/Zone IV.

4. MR Personnel Screening

All MR Personnel are to undergo an MR screening process as part of their employment interview process to ensure their own 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 that they experience or undergo in which a ferromagnetic metallic object/device may have become introduced within or on them. This will permit an appropriate screening to be performed upon the employee to determine the safety of permitting that MR Personnel–designated employee into the Zone III environment of the MR site.

5. Device/Object Screening

As part of the Zone III site restriction and equipment testing/clearing responsibilities, all sites should have ready access to a strong handheld magnet (≥1000-gauss). 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 (e.g., oxygen cylinders) are to be positively identified in writing as non-ferromagnetic and either MR safe or MR compatible prior to permitting them into Zone III regions. For all device/object screening, all verification and positive identification should be in writing. Examples of such devices that need to be positively identified include fire extinguishers, oxygen tanks, aneurysm clips, etc.

b. If external devices/objects are demonstrated to be ferromagnetic and Non–MR safe/MR compatible, they may

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still, under specific circumstances, be brought into Zone III regions 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 regions if they are under the direct supervision of specifically designated either Level One or Level Two MR Personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction into the Zone III designated region. The safe utilization of these devices at all times while they are present in Zone III will be the responsibility of a specifically named Level One or Two MR Personnel. This device must be appropriately physically secured or restricted at all times during which it is in Zone III regions to ensure that it does not inadvertently become introduced too close to the MR scanner and accidentally become exposed to static magnetic fields/gradients that might result in its becoming either a hazardous projectile 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/devices being considered for introduction beyond Zone II regions should be tested with a strong handheld magnet (≥1000-gauss) for ferromagnetic properties prior to permitting them entry beyond Zone II regions. The results of such testing as well as the date, time, and name of tester, and methodology used for that particular device should be documented in writing. If a device has not been tested and/or its MR compatibility/safety status is unknown, it should NOT be permitted unrestricted access beyond Zone II regions.

d. All portable metallic or partially metallic objects that are to be brought into Zone IV regions (i.e., the MR magnet room itself) must be labeled with either a green "MR Safe" label or a red "Not MR Safe" label. As noted in section 5 introduction above, testing for the purpose of this labeling is to be accomplished by the site's MR personnel by exposing the metallic object to a handheld magnet (≥1000-gauss). 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/object prior to its introduction into 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 Tesla at gradient strengths of 400-gauss/cm," or "MR safe tested up to 1.5 Tesla up to maximum static gradient fields experienced in an unshielded 1.5 Tesla [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/compatible equipment or devices may alter the MR safety and/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 into the MR scanner in that altered manner.

C. MR SAFE PRACTICE GUIDELINES: MR TECHNOLOGIST

1. MR Technologists should be ARRT Registered Technologists (RT). Furthermore, all MR Technologists must be trained as Level Two 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 two MR technologists or one MR Technologist and one other individual with the designation of MR Personnel in the immediate Zone II through Zone IV MR environment. For emergent coverage, the MR Technologist can scan with no other individuals in their Zone II through Zone IV MR environment as long as there is in-house ready emergent coverage by designated Department of Radiology MR Personnel (e.g., radiology house staff, radiology attendings, etc.).

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 [10]. This includes but is not limited to positioning patients, scanning, archiving, injecting contrast, entering the MR scan room in response to an emergency, etc. 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/scanning itself.
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 Two MR Personnel–designated attending radiologist, the risk–benefit ratio to the patient warrants that the study be performed. The radiologist should confer with the referring physician and document this in the radiology report or the patient's medical record that:
      1. The information requested from the MR study cannot be acquired via non-ionizing means (e.g., ultrasonography), and
      2. The data is needed to potentially affect the care of that patient and/or fetus DURING the pregnancy, and
      3. The referring physician does not feel that it is prudent to wait to obtain this data until after the patient is no longer pregnant.
   b. MR contrast agent(s) should NOT be routinely provided to pregnant patients. This, too, is a decision that must be made on a case-by-case basis by the covering Level Two MR Personnel–designated attending radiologist who will assess the risk–benefit ratio for that particular patient.
   c. It is recommended that pregnant patients undergoing an MR examination provide written informed consent to document that they understand the risks/benefits of the MR procedure to be performed, the alternative diagnostic options available to them (if any), and that they wish to proceed.

E. TIME VARYING GRADIENT MAGNETIC FIELD–RELATED ISSUES: INDUCED VOLTAGES

Types of patients needing extra caution: Patients with implanted or retained wires in anatomically and/or functionally sensitive areas (e.g., myocardium or epicardium, implanted electrodes in the brain) should be considered at higher risk especially from faster MR imaging sequences, such as echoplanar imaging (which may be used in such sequences as diffusion weighted imag-

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ing, 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 imaging of such patients should be reviewed by the Level Two MR Personnel–designated attending radiologist supervising the case/patient.

F. TIME VARYING GRADIENT MAGNETIC FIELD–RELATED ISSUES: AUDITORY CONSIDERATIONS

1. All patients/volunteers should be offered and encouraged to use hearing protection prior to their undergoing any imaging in the MR scanners.
2. All patients/volunteers in whom research sequences are to be performed (i.e., MR scan sequences that have not yet been approved by the Food and Drug Administration [FDA]) are to have hearing protective devices IN PLACE prior to initiating any such research MR sequences on these patient/volunteers. Without hearing protection in place, MR imaging sequences that are not FDA approved should not be performed on patients/volunteers.

G. TIME VARYING RADIOFREQUENCY MAGNETIC FIELD–RELATED ISSUES: THERMAL

1. All unnecessary and/or unused electrically conductive materials should be removed from the MR system before the onset of imaging. It is not sufficient to merely "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, monitoring devices, etc., must be visually checked by the scanning MR Technologist prior to each scan to ensure the integrity of the thermal and electrical insulation.
2. For electrically conductive material, wires, leads, implants, etc., that are required to remain within the bore of the MR scanner with the patient during imaging, care should be taken to ensure that no large caliber electrically conducting loops (including patient tissue; see section g, 5, below) are permitted to be formed within the MR scanner.
3. For electrically conductive material, wires, leads, implants, etc., that 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 during imaging, 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/wires as far as possible from the inner walls of the MR scanner if the body coil is being used for radiofrequency transmission. When it is necessary that such 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 tissue(s) do not directly come into contact with the inner bore of the MR imager during the MR imaging process. This care is especially important for several higher field MR scanners. The manufacturers of these devices provide pads and other such insulating devices for this purpose, and manufacturer guidelines should be strictly adhered to for these units.
5. It is also important to ensure that the patient's own tissues do not form large conductive loops. Therefore, care should be taken to ensure that the patient's arms/legs not be 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/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/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/SMS are within the volume to be RF irradiated for the requested MR study several precautions are recommended, as follows:
   a. Warn the patient and make sure that they are especially aware of the possibility that they may experience warmth or even burning along the skin staple/SMS distribution. The patient should be instructed to report immediately if they experience a warmth or burning sensations during the study (and not, for example, wait until the "end of the knocking noise").
   b. It is recommended that a cold compress/ice pack be placed along the skin staples/SMS if this can be safely clinically accomplished during the MR imaging 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/burn to adjacent tissue.
7. For patients with extensive and/or dark tattoos including tattooed eyeliner, in order to decrease the potential for radiofrequency heating of the tattooed tissue it is recommended that cold compresses or ice packs be placed onto the tattooed area(s) and kept in place throughout the MR imaging 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) MR imaging sequences are anticipated to be used 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 in that case as well. Additionally, patients with tattoos that had 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/unresponsive patient should have any/all attached leads covered with a cold compress/ice pack at the lead attachment site for the duration of the MR study prior to the initiation of scanning.
9. Patients in whom there are long electrically conductive leads such as Swan-Ganz thermodilution cardiac output capable catheters, Foley catheters with electrically conductive leads, etc., 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 MR imaging sequences. Each such patient should be reviewed and cleared by an attending Level Two radiologist and a risk benefit ratio assessment performed prior to permitting them access to the MR scanner.

H. CRYOGEN-RELATED ISSUES

1. For superconducting systems, in the event of a system quench it is imperative that all personnel/patients be evacuated from the MR scan room as quickly as safely feasible and the site access be immediately restricted to all individuals until the arrival of the MR equipment

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service personnel. This is especially so if cryogenic gases are observed to have vented partially or completely into the scan room itself, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. As noted in section B.2.m above, it is especially important to ensure that all police/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 magnetic field.

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 to not be sufficiently reliable to allow for continued operation during situations of power outages, etc.

I. CLAUSTROPHOBIA/ANXIETY/SEDATION–ANALGESIA/ANESTHESIA MR SAFE PRACTICE GUIDELINES

Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established American College of Radiology (ACR) [11, 12], American Society of Anesthesiologists (ASA) [13–16], and JCAHO standards [17].

J. CONTRAST AGENT SAFETY MR SAFE PRACTICES

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 intravenous 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 intravenous routes as a bolus or 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 (Res.1-H, 1987, 1997):

      The ACR approves of the injection of contrast material and diagnostic levels of radiopharmaceuticals 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.

2. Prior contrast agent reaction issues [18]:
   a. 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 [18].
   c. All patients with asthma, allergic respiratory histories, prior iodinated and/or gadolinium-based contrast reactions, etc., be followed more closely as they are at a demonstrably higher risk of adverse reaction.

K. MR SAFE PRACTICE GUIDELINES REGARDING MR SCANNING OF PATIENTS IN WHOM THERE ARE/MAY BE INTRACRANIAL ANEURYSM CLIPS

1. In the event that 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 films, CT or MR examination that may have already been taken in the recent past (i.e., 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 magnetic resonance examination should not be performed until it can be documented that the type of aneurysm clip within that patient is MR safe/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 non-physician are not acceptable. Fax 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 itself having been appropriately tested for ferromagnetic properties (and description of the testing methodology used) prior to implantation by the operating surgeon is also considered acceptable if the testing follows the ASTM (American Society of Testing and Materials) established Deflection Test methodology.
3. All implanted intracranial aneurysm clips that are documented in writing to be composed of titanium (either the commercially pure and/or the titanium alloy types) can be accepted for scanning without any other testing necessary.
4. All non-titanium 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 pre-testing (as per the ASTM Deflection Test methodology) prior to implantation or individual review of previous MR imaging of the clip/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 MR imaging parameters selected, an opinion may be issued by one of the site's Level Two MR attending radiologists as to whether the clip(s) demonstrate significant ferromagnetic properties or not. Access to the MR scanner would then be based on that opinion.
6. HAVING SAFELY UNDERGONE A PRIOR MR EXAMINATION (WITH AN ANEURYSM CLIP—OR OTHER IM-

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PLANT—IN PLACE) AT ANY GIVEN STATIC MAGNETIC FIELD STRENGTH IS NOT IN AND OF ITSELF SUFFICIENT EVIDENCE OF ITS MR SAFETY OR COMPATIBILITY, AND SHOULD NOT BE SOLELY RELIED UPON TO DETERMINE THE MR SAFETY OR COMPATIBILITY STATUS OF THAT 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 and/or static field gradient, rate of motion through the spatial static field gradient, etc., are all variables that are virtually impossible to control/reproduce. These variables may well have not resulted in adverse event in one circumstance but may result in significant injury or death on a subsequent exposure. Case in point: A patient who went blind from interactions between the metallic foreign body in the retina and the spatial static fields of the MR scanner entered the magnet and underwent the entire MR examination without difficulty. He only went blind on the way out of the MR scanner at the completion of the examination.

7. Barring availability of either pre-testing or prior MR imaging 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 and/or imaging data, should the risk/benefit ratio favor the performance of the MR study, the patient/guardian should provide written informed consent that includes death as a potential risk of the MR imaging procedure prior to permitting that patient to undergo an MR examination.

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The reader's attention is directed to the commentary on this article, which appears on page 1349.

APPENDIX 1: Personnel and Zone Definitions

Personnel

Non–MR Personnel: Patients, visitors, or facility staff who do not meet the criteria of Level One or Level Two MR Personnel.

Level One MR Personnel:

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III regions will be referred to as Level One MR Personnel (e.g., M.R.I. department office staff, patient aides).

Level Two MR Personnel:

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues including issues related to the potential for thermal loading/burns, direct neuromuscular excitation from rapidly changing gradients, etc., will be referred to as Level Two MR Personnel (e.g., M.R.I. Technologists, Radiologists, Radiology Department nursing staff).

Zones

Zone I: This includes all areas that are freely accessible to the general public. This area is typically outside of 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 the patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather 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 and/or ferromagnetic objects and equipment can result in serious injury or death as a result of interactions between the individuals/equipment and the MR scanner's particular environment. These interactions include but not limited to those with the MR scanner's static and time varying magnetic fields. All access to at least Zone III is to be strictly restricted, with access to regions within it (including Zone IV) 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 itself.

Non–MR Personnel should be accompanied under the immediate supervision and visual contact with one specifically identified Level Two MR Person for the entirety of their duration within Zone III or Zone IV restricted regions.

Level One and Two MR Personnel may move freely about all zones.

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APPENDIX 2: Safety Screening Form for MR Procedures

Date_____ Name_(first middle last) _____
Female [ ] Male [ ] Age_____ Date of Birth_____ Height_____ Weight_____

	YES	NO
1. Why are you having this examination (medical problem)?_____		
2. Have you ever had an MRI examination before and had a problem?----------	____	____
If yes, please describe_____		
3. Have you ever had a surgical operation or procedure of any kind?----------	____	____
If YES, list all prior surgeries and approximate dates: _____		
4. Have you ever been injured by a metal object/foreign body (e.g., bullet, BB, shrapnel)?----------	____	____
If YES, please describe_____		
5. Have you ever had an injury from a metal object in your eye (metal slivers, metal shavings, other metal object)?----------	____	____
If YES, did you seek medical attention? ----------	____	____
Describe what was found _____		
6. Do you have a history of kidney disease, asthma, or other allergic respiratory disease?----------	____	____
7. Do you have any drug allergies?----------	____	____
If Yes, please list drugs _____		
8. Have you ever received a contrast agent/x-ray dye used for MRI, CT, or other x-ray or study?----------	____	____
9. Have you ever had an x-ray dye or magnetic resonance imaging (MRI) contrast agent allergic reaction?----------	____	____
If YES, please describe_____		
10. Are you pregnant or suspect you may be pregnant?----------	____	____
11. Are you breast feeding?----------	____	____
12. Date of last menstrual period_____ Post-menopausal?----------	____	____

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APPENDIX 3: MR Hazard Checklist

THE FOLLOWING ITEMS MAY BE HARMFUL TO YOU DURING YOUR MR SCAN OR MAY INTERFERE WITH THE MR EXAMINATION.

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

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(s)
____ ____ Implanted cardiac defibrillator
____ ____ Neurostimulator
____ ____ Biostimulator (Type _____)
____ ____ Any type of internal electrode(s) or wire(s)
____ ____ Cochlear implant
____ ____ Hearing aid
____ ____ Implanted drug pump (e.g., 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 (e.g., 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 I.V. access port (e.g., Broviac, Port-a-Cath, Hickman, Picc line)
____ ____ Medication patch (e.g., Nitroglycerine, nicotine)
____ ____ Shunt
____ ____ Artificial limb or joint (What and where_____)
____ ____ Tissue expander (e.g., 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 (e.g., cancer treatment)
____ ____ Any implanted items (e.g., pins, rods, screws, nails, plates, wires)
____ ____ Any hair accessories (e.g., bobby pins, barrettes, clips)
____ ____ Jewelry
____ ____ Any other type of implanted item (Type_____)

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and I have had the opportunity to ask questions regarding the information on this form.

Patient signature_____
MD/RN/RT signature_____ Date_____
Print name of MD, RN, RT_____

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APPENDIX 4: Instructions for the Patients

1. You are urged to use the ear plugs or headphones that we supply for use during your MRI examination since some patients may find the noise levels unacceptable and the noise levels may affect your hearing.
2. Remove all jewelry (e.g., necklaces, pins, rings).
3. Remove all hair pins, bobby pins, barrettes, clips, etc.
4. Remove all dentures, false teeth, partial dental plates.
5. Remove hearing aids.
6. Remove eyeglasses.
7. Remove your watch, pager, cell phone, credit and bank cards, and all other cards with a magnetic strip.
8. Remove body piercing objects.
9. Use gown, if provided, or remove all clothing with metal fasteners, zippers.

APPENDIX 5: Hazard Checklist for MRI Personnel

For MRI Office Use Only
Patient Name_____
Patient ID Number_____ Referring Physician_____
Procedure_____ Diagnosis_____
Clinical History_____

Hazard Checklist for MRI Personnel
YES NO
____ ____ Endotracheal tube
____ ____ Swan-Ganz catheter
____ ____ Extraventricular device
____ ____ Arterial line transducer
____ ____ Foley catheter with temperature sensor and/or metal clamp
____ ____ Rectal probe
____ ____ Esophageal probe
____ ____ Tracheotomy tube
____ ____ Guidewires

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