

American College of Radiology White Paper on MR Safety: 2004 Update and Revisions

Emanuel Kanal¹
James P. Borgstede²
A. James Barkovich³
Charlotte Bell⁴
William G. Bradley⁵
Shawn Etheridge⁶
Joel P. Felmlee⁷
Jerry W. Froelich⁸
Jeffrey Hayden⁹
Ellisa M. Kaminski¹⁰
James W. Lester, Jr.¹¹
Elizabeth A. Scoumis¹²
Loren A. Zaremba¹³
Marie D. Zinnering¹⁴

Received March 4, 2004; accepted without revision
March 4, 2004.

¹Department of Radiology, Magnetic Resonance Services,
University of Pittsburgh, 200 Lothrop St., Pittsburgh, PA
15213-2582.

²Penrose-St. Francis Health System, Colorado Springs,
CO 80907.

³Department of Neuroradiology, University of California,
San Francisco, 505 Parnassus Ave., Rm. L371, San
Francisco, CA 94143-0628.

⁴Department of Anesthesiology, New York University
School of Medicine, 550 First Ave., RI-605, New York, NY
10016-4998.

⁵Department of Radiology, University of California, San
Diego, 200 W Arbor Dr., San Diego, CA 92103-8224.

⁶National Electrical Manufacturers Association, Hitachi
Medical Systems America Inc., 1959 Summit Commerce
Park, Twinsburg, OH 44087.

⁷Department of Radiology, Mayo Clinic, 200 1st St., SW,
Rochester, MN 55902-3008.

⁸Department of Radiology, Hennepin County Medical
Center and the University of Minnesota, 701 Park Ave.,
Minneapolis, MN 55415.

⁹American College of Radiology, 1891 Preston White Dr.,
Reston, VA 20191. Address correspondence to J. Hayden.

¹⁰1266 Highland Ave., Ambridge, PA 15033.

¹¹Durham Radiology Associates, 4323 Ben Franklin Blvd.,
Ste. 500, Durham, NC 27704.

¹²6040 Meadow Ln., Bakerstown, PA 15007.

¹³Office of Device Evaluation, Center for Devices and
Radiological Health, United States Food and Drug Administration,
9200 Corporate Blvd., HFZ-470, Rockville, MD 20850.

¹⁴6072 Elston Shore Rd., Neavitt, MD 21652.

AJR 2004;182:1111-1114

0361-803X/04/1825-1111

© American Roentgen Ray Society

There are potential risks in the MR environment not only for the patient, but also for the attending health care professionals, accompanying family members, and others who may find themselves in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, and police. The following is an updated report of the American College of Radiology (ACR) Blue Ribbon Panel on MR Safety, chaired by Emanuel Kanal, MD, FACR [1]. The panel originally 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 Keeler, PhD (National Electrical Manufacturer's Association [NEMA]); James W. Lester, Jr., MD; Elizabeth Scoumis, RN, BSN; Loren A. Zaremba, PhD (United States Food and Drug Administration); Jeffrey Hayden, BS, RT (R) (MR) (ACR staff); and Marie D. Zinnering (ACR staff). Upon Dr. Keeler's retirement, Shawn Etheridge was appointed to represent NEMA.

The original paper was published in the *AJR* in June 2002 [1]. After reviewing feedback from MRI users and other interested parties, as well as changes that had transpired throughout the MR industry in the interim, the panel reconvened in late 2002 and several times in 2003 and agreed on additions and modifications to the document. The following are changes to be made to the original MR Safe Practice Guidelines document published in 2002. The panel intends to post the entire document with these changes as well as an executive summary of the document on the ACR Web site (www.acr.org) following this publication. As was indicated in the original publication, the paper is intended to be used as a template for MR facilities to follow in the development of an MR safety program. These MR Safe Practices Guidelines were 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 as the field of MR safety continues to evolve.

These White Papers do not attempt to deal with all aspects of MR safety, but rather those that apply to already installed, active sites, whether clinical or research. With the increasing advent and use of 3.0-Tesla 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 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 magnetic fields.

Finally, there are a whole host of other issues that should be considered during the site-planning stages that are not dealt with in these articles. These include, among others, cryogen emergency vent locations and pathways, 5-gauss line siting considerations, patient access pathways, considerations regarding fringe field blooming that may result in the event there is a failure of an actively shielded MR imaging system, etc. These issues, and many others, should be reviewed with those experienced with 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 patient services that are among the most powerful, yet safest, of all diagnostic procedures to be developed in the history of modern medicine.

This paper addresses four new topics and then several additions and revisions to the original paper. Changes to the original paper are in Appendix 1.

The four new topics are:

- DRUG DELIVERY PATCHES/PADS
- PEDIATRIC MR SAFETY:

Sedation and monitoring

Pediatric screening issues

MR safety of accompanying family members/personnel

- FETAL MR CONTRAST AGENT SAFETY CONCERNS

- MR SCANNING OF PATIENTS IN WHOM THERE ARE/MAY BE CARDIAC PACEMAKERS and/or IMPLANTED CARDIOVERTER DEFIBRILLATORS (ICDs)

DRUG DELIVERY PATCHES/PADS:

Some drug delivery patches contain metallic foil. Scanning the region of the metallic foil may result in thermal injury [2]. Since removal or repositioning can result in altering of patient dosages, consultation with patient's prescribing physician would be indicated in assessing how to best 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 radiofrequency coil, then the case should be specifically reviewed with the radiologist/physician covering the case. Alternative options may include placing an ice pack directly on the patch. This latter solution may still substantially alter the rate of delivery/absorption of the medication to the patient (and may 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.

PEDIATRIC MR SAFETY CONCERNS:

Sedation and monitoring issues:

Children form the largest group requiring sedation for MR imaging, largely because of their inability to remain motionless during scans. Sedation protocols may vary from institution to institution according to 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 skills and qualifications of the sedation providers.

Adherence to standards of care mandates following sedation guidelines developed by

the American Academy of Pediatrics [3, 4], the American Society of Anesthesiologists [5], and the Joint Commission on Accreditation of Healthcare Organizations [6]. In addition, sedation providers must also comply with protocols established by the individual state and the practicing institution. These guidelines include providing:

- Preprocedure medical history and examination for each patient
- Fasting guidelines appropriate for age
- Uniform training and credentialing for sedation providers
- Intra- and post-procedure monitors with appropriate-sized adapters for children (compatible with the magnetic field)
- Method of patient observation (window, camera)
- Resuscitation equipment including oxygen delivery and suction
- Uniform system of record keeping and charting (with continuous assessment and recording of vital signs)
- Location and protocol for recovery and discharge
- Quality assurance program that tracks complications and morbidity.

For the neonatal and 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.

Pediatric screening issues:

Children may not be reliable historians, and especially for older children and teenagers, the child should be questioned both in the presence of parents or guardian and separately to maximize the possibility that all potential dangers are disclosed. Therefore, it is recommended that they be gownned before entering Zone IV to help ensure that no metallic objects, toys, etc. inadvertently find their way into Zone IV with the patient. Pillows, stuffed animals, or other comfort items brought from home represent real safety 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 itself prior to permitting the patient to enter Zone IV in order to ensure that they do not contain any objectionable metallic components.

MR safety of accompanying family/personnel:

Although any age patient might request that others accompany them for their MR examination, this is far more common in the pediatric patient population. Those accompanying/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 persons to a single individual. Only a qualified, responsible MR physician should make screening criteria exceptions.

Hearing protection and an MR compatible chair or stool are recommended for accompanying family members within the MR scan room.

FETAL MR CONTRAST AGENT SAFETY CONCERNS:

The decision to administer a gadolinium-based MR contrast agent to a pregnant patient should be accompanied by a well-documented and thoughtful risk-benefit analysis. This analysis should be able to defend such a decision to administer the contrast agent based on overwhelming potential benefit to the patient and/or fetus outweighing theoretical but potentially real risks of 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 this amniotic fluid for an indeterminate amount of time until they are finally 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 concern about possible secondary adverse effects to the developing fetus.

As indicated before, but repeated for added emphasis, a documented, in-depth analysis of the potential risks and benefits to that 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.

MR SCANNING OF PATIENTS IN WHOM THERE ARE/MAY BE CARDIAC PACEMAKERS and/or IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDs)

It is recommended that the presence of implanted cardiac pacemakers and/or auto-implanted cardioverter defibrillators (ICD) be considered contraindications for routine MR imaging. 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 non-emergent 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 MR imaging 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 that for whatever reason does not terminate with the cessation of the MR study. All such patients should be monitored for cardiac and respiratory function throughout the examination. At the conclusion of the examination a cardiologist/electrophysiologist should interrogate the pacemaker to confirm that the function is consistent with pre-examination state. We are unaware 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 pa-

tients who were inadvertently exposed to MR imaging studies who have died during the examination and/or very shortly thereafter. There is an increasing body of evidence documenting the ability of the MR imaging 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 implanted pulse generator (a.k.a., cardiac pacemaker)-lead circuitry and the RF power transmitted during the MR imaging process.

It should also be noted that there have not been to date any reports of clinically significant adverse outcomes for any pacemaker patient scanned in an MR imaging unit while appropriately monitored with cardiac supervision.

Some have suggested that it might well be possible to perform MR imaging examinations on patients with implanted cardiac pacemakers as long as rigid guidelines were carefully defined and rigidly adhered to throughout the imaging process. These include recommendations, among others, that ensure that no pacemaker-dependent patient be scanned, that the RF power transmitted during the MR imaging process not be deposited over the volume that contains the pacemaker and/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 MR imaging examinations on cardiac pacemaker patients, the expertise necessary to safely do so is exceedingly rare throughout the 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 and/or shielded leads and pacing devices, and various other designs and configurations of MR pacing devices and leads are being actively investigated 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 access to the powerful diagnostic modality that is magnetic resonance imaging.

References

1. Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology white paper on MR safety. *AJR* 2002;178:1335-1347
2. Shellock FG. *Pocket guide to MR procedures and metallic objects: update 2001*. Philadelphia, PA: Lippincott Williams & Wilkins Healthcare, 2001:147-148
3. [No authors listed] American Academy of Pediatrics Committee on Drugs: guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics* 1992;9:1110-1115
4. [No authors listed] American Academy of Pediatrics Committee on Drugs: guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures—addendum. *Pediatrics* 2002;110:836-838
5. American Society of Anesthesiologists. *Updated practice guidelines for sedation and analgesia by non-anesthesiologists*. Park Ridge, IL: American Society of Anesthesiologists, 2001
6. Joint Commission on Accreditation of Healthcare Organizations. *Standards and intents for sedation and anesthesia care: comprehensive accreditation manual for hospitals*. Chicago, IL: Joint Commission on Accreditation of Healthcare Organizations, 2002: report no. TX2-2

Appendix 1 appears on the next page

APPENDIX I: Additions and Revisions to the Original Paper

The following are the additions and revisions to the original White Paper published in June 2002 using the *AJR* article [1] as the reference point:

Page 1336, Figure 1, MR site floor plan.

Note: All zones in the facility should comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations in regard to patient information privacy. There should be a privacy barrier in Zone III so that unauthorized persons cannot see the control panels.

Page 1337, 2, c. Add–

Specifically, non-MR personnel will be the terminology used to refer to any individual or group who have not within the previous 12 months undergone the designated formal training in MR safety issues as defined by the MR Safety Director of that installation.

Page 1344, Appendix 1,

Add above 2, c, as second sentence to definition for non-MR personnel.

Page 1337, 3, Add new paragraph–

The screening process and screening forms for patients, Non-MR Personnel, and MR Personnel should be identical. Specifically, one should not rely on or assume that the accompanying Non-MR Personnel, health care practitioners, or MR Personnel will not enter the bore of the scanner during the MR imaging process. This might be the case if a pediatric patient cries for his mother and she leans into the bore or the anesthetist might lean into the bore to manually ventilate a patient should a problem arise, etc.

Page 1337, 3, old c. Add a new paragraph 2–

Level One MR Personnel are themselves permitted unaccompanied access throughout Zones III and IV. Level One MR Personnel are also explicitly permitted to be named as responsible for accompanying Non-MR Personnel into and throughout Zone III excluding Zone IV. However it should be noted that Level One MR Personnel are NOT permitted to directly admit into or to be designated as responsible for, Non-MR Personnel in Zone IV.

Page 1341, G, 2. Replace the entire section with the following–

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 heating of this material by resistive losses. This heating might be sufficient to cause injury to human tissue. Among the variables that determine the amount of induced voltage/current is the consideration that the larger the diameter of the conductive loop the greater the potential induced voltages/currents and thus greater potential for resultant thermal injury to adjacent or contiguous patient tissue. Therefore, for electrically conductive material, wires, leads, implants, etc., that are required to remain within the bore with the patient during imaging, care should be taken to ensure that no large-caliber electrically conducting loops (including patient tissue) are permitted to be formed within the MR scanner during imaging.

Furthermore, it is possible with 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/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/wires to the RF transmitted power during MR scanning should only be performed with caution and with appropriate steps taken to ensure that significant lead/tissue heating does not result.

Page 1341, G, 9. 1st sentence should be modified to start–

As noted above, it has been demonstrated that resonant circuitry can be established during MR imaging between the RF energies being transmitted and specific lengths of long electrically conductive wires/leads which can thus act effectively as efficient antennae. This can result in heating of the tips of these wires/leads to in excess of 90 degrees Celsius in a few seconds. Therefore, patients in whom there are long electrically conductive leads such as Swan-Ganz thermodilution cardiac output capable catheters....