

Working Together to Improve MRI Safety

Involving staff from clinical, operational, and facility disciplines

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Nearly everyone who works around magnetic resonance imaging (MRI) has heard the stories and seen the pictures¹ of preventable accidents in the MRI suite: the unscreened patient who made it into the room with a spinal shunt or on a gurney made largely of steel, only to be caught in the magnetic attraction of the MRI and launched into the large electromagnet.

Many experts in the realm of MRI safety believe that a principal factor in the failure to proactively address safety issues in the MR suite is a profound underestimation of the risks. The Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience Database (MAUDE)² catalogues accidents and incidents involving FDA-approved devices. Despite mandatory reporting require-

ments, it is believed that fewer than 10% of MRI accidents are reported (even with a doubling of MRI safety incident reports in the 12 months ending mid-2006 from the previous one-year period). This gross underreporting denies imaging providers the information they need to make effective decisions regarding accident prevention and serves to stigmatize those who admit to having had (or are discovered to have had) MRI safety mishaps.

Upon entering the confines of the MRI suite, rules of safety are imperceptibly changed by the powerful magnetic fields and invisible radiofrequency (RF) waves. Though magnetic energies have not been demonstrated to have adverse biological effects, lifesaving medical devices such as pacemakers and nerve stimulators can malfunction in close proximity to MRI magnets, with potentially fatal results. Ubiquitous health care appliances, such as medical gas cylinders, wheelchairs, or gur-

neys can be launched, homing in on the center of the MRI, attracted by the far-reaching magnetic field.

Safety in the MRI suite is both vitally important and unusually challenging to implement because of the invisibility of the threats coupled with the increasingly common presence of objects that MRIs can act upon with disastrous results.

An Interdisciplinary Approach to MRI Safety

Because of the numerous threats to safety and operations, effective mitigation of hazards in the MRI suite often depends on collaborative problem solving among clinicians, management, and facility designers. By combining the strengths of the varied perspectives, building-in defenses against accidents and supporting best practice procedures are made easier. Problems or solutions readily apparent to one

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discipline may not even occur to another. A well-rounded project team would likely include the organizational and departmental management, MR technologists, radiologists, infection control, anesthesiology, vendor representatives, and experienced MRI design professionals.

TIP When assembling a team to coordinate the installation of new MRI equipment, include internal expertise from radiology management and clinical disciplines. Bring on planning and design expertise as early as possible to inform project development.

Those facilities developed without this sort of interdisciplinary approach—likely a significant proportion of today’s MRI providers—often are frustrated in their attempts to improve any operational parameters, including safety and throughput, because obstacles were unintentionally erected in the path of optimal procedures. Copy-and-paste policies and procedures or suite layouts that do not address the issues unique to a given facility’s MRI equipment, patients, referring physicians, patient load, staffing, and clinical practice further impair an organization’s ability to deliver effective and efficient care.

The hazards in the MRI suite are most accurately divided into three families—operational, clinical, and facility design—though interventions to mitigate any single hazard should include solutions from each group.

Sidebar 1. Descriptions of the American College of Radiology’s Four Zones

ACR Zones	Occupants	Hazards
Zone I	General Public	Negligible MRI hazards
Zone II	Unscreened MRI patients	Immediately outside area(s) of hazard
Zone III	Screened MRI patients/personnel	Potential biostimulation interference, access to magnet room
Zone IV	Screened MRI patients under constant direct supervision of trained MR personnel	Biostimulation interference, RF heating, missile effect, cryogens

Facility Design

An effectively-composed MRI suite provides both a literal and figurative foundation for best practice procedures. As a fundamental starting point for a practice, facilities should be laid out to identify the four zones of successive hazards and access restrictions, as defined in the American College of Radiology’s (ACR’s) *White Paper on MR Safety*. The four-zone model prescribes integrated strategies for screening personnel and objects to control access to those areas with immediate access to the MRI. (See Sidebar 1, above, for a description of the ACR’s four zones.)

TIP Maintain copies of MRI safety reference materials on site to assist in defining best practice procedures for four-zone access and screening protocols.

These access controls are vital even beyond the confines of the magnet room itself. Unlike conventional X-ray or CT scanners, where a lead shield contains the threat within the examination room, magnetism from an MRI machine can penetrate all standard forms of building construction, including concrete, and impose hazards in areas outside the room, the radiology department, and sometimes outside the building. The strength and polar orientation of the magnet used in the MR scanner may project the physical hazards into adjacent spaces, even areas above and below the magnet. In some facilities, rooms outside the MRI suite, even rooftops, may require access restrictions to protect unscreened persons from exposure to the risks.

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TIP Identify the extent of the 5-Gauss magnetic field, including areas above and below the MRI, and control access to these Zone III areas, even outside the confines of the MRI suite.

Contemporary superconducting magnets, the most common type used in clinical MRI equipment, are enabled through the use of liquid helium. This cryogenic liquid, though nontoxic and chemically inert, can present significant hazards that facility design can mitigate. Contained within what amounts to a large thermos bottle surrounding the magnet, the liquid helium is maintained at roughly -450° F. In certain failure modes, the liquid helium can boil off and vent at near-explosive pressure. If the ducting system fails, a room can be flooded with helium gas at hundreds of degrees below zero, potentially entrapping and asphyxiating anyone inside the room. Manufacturers of MRI systems today require both active and passive pressure venting systems to protect against such a risk.

TIP Evaluate current cryogen pressure relief and exhaust requirements from your MRI vendor. In addition, inspect cryogen vent systems, including the quench pipe, at least annually for obstructions or wear.

When informed by the specifics of the practice, suite design and layout significantly contributes to the efficacy of both clinical and operational measures by crystallizing best practice procedures with the spaces, equipment, and accommodations required of each. This can be done through the appropriate design and placement of facilities, such as private HIPAA-compliant patient interview areas for clinical screenings, access controls, and sightlines. Facility planners and clinicians should consider the facility ramifications of such divergent issues as sedation/anesthesia, infection control, image-guided/interventional procedures, emergent scan needs, and bariatric patients early in the process.

Despite what is known about the risks

to patients, staff, and imaging equipment, the invisible nature of the hazards in the MRI suite allows us to slip into complacency far too easily. Many MRI providers believe that they can squeak by with just the special MRI fire extinguisher and the probability that an accident won't happen to them. But surveys of technologists and radiology managers illuminate the dark side of this probability; given enough patient scans over the course of months and years, sooner or later, nearly every MRI facility will have a serious accident if it fails to implement appropriate protections. Those that proactively protect against such an event can greatly diminish their liability exposure and help to assure the safety of patients and staff in the MRI suite.

To ensure that you are effectively evaluating all the MRI safety risks, see page 12 of the online version of this issue for a checklist of questions.

Operational

Frequent injuries in the MRI suite, equipment damage, and interrupted patient throughput are caused by the introduction of ferromagnetic materials into the magnet room. Objects with significant iron or steel content can be sucked into the MRI at speeds of up to 40 miles per hour. Unlike the hazards for CT or conventional X-ray technologies, the magnetic fields for clinical MRI are present for virtually all systems. This means that safety is not only a concern during imaging, but protocols for protecting staff and equipment must be in place and enforced 24 hours a day.

Effective screening protocols should include more than only identifying clinical contraindications; they also should interdict ferromagnetic threats before they approach the MRI room. Recently, the FDA adopted the revised and updated ASTM International testing and labeling criteria for object safety near MRI magnets. Items within the MRI

Sidebar 2. Device-Marking Terminology

MR Safe: The device is safe for use in an MR environment, without exception, regardless of magnet strength and any other field conditions.

MR Conditional: The device is safe for use in a specified MR environment under specified conditions; however, it may not be safe to use in MR environments that don't match the specified conditions.

MR Unsafe: The device is not safe to use in any MR environment.

Source: ECRI: What's new in MR safety: The latest on the safe use of equipment in the magnetic resonance environment. *Health Devices* 34:333-350, Oct. 2005.

suite should be prospectively identified and clearly labeled with the new icons *MR Safe*, *MR Conditional*, or *MR Unsafe* so that there is no ambiguity about an object or device's suitability in (or near) the MRI room. (See Sidebar 2, above, for definitions of *MR Safe*, *MR Conditional*, and *MR Unsafe*.) Facilities with equipment labeled under the previous standards should determine the correct current designation and identify each piece of equipment in the MRI suite using the new nomenclature.

TIP Label all portable equipment and devices within the MRI suite (including those likely to be brought to the suite) using the current ASTM/FDA criteria. Particularly for suites with different magnet types, 'MR Conditional' labeling should include specific parameters for safety.

As an adjunct to conventional screening practices used for identifying potential missile threats, MR safety experts are now recommending the use of ferromagnetic-only detectors specifically developed for use in MRI facilities. These devices identify only ferromag-

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netic objects that can be attracted to MRI machines and, unlike conventional metal detectors, do not alarm on aluminum, titanium, brass, or other metals that aren't magnetically attracted.

TIP MRI facilities may wish to consider siting ferromagnetic detection systems to augment conventional screening. Ferromagnetic detection systems are made available by several manufacturers in the U.S. and pricing varies on the detector size, sensitivity, and format.

Clinical

MRI is touted as a safe modality because magnetism is non-ionizing and does not carry the risks associated with examinations using conventional radiography, computed tomography (CT) scans, or nuclear medicine devices. However, the magnetic energy can present serious risks to persons with implants and medical devices. (See Sidebar 3 on page 12 of the online version

of this issue for a partial list of devices and appliances that should trigger additional safety questions.) Despite recent advances in pacemaker technology, no implanted pacemaker device has yet been approved by the FDA as safe for MR examination. For those implants, prostheses, and devices that have been identified as conditionally safe to be scanned, manufacturer guidelines must be followed precisely for issues such as field strength, gradients, RF deposition, sequences, and coils.

It also is important to note that MRI safety protocols for implants and medical devices are not always linear. Simply because a particular configuration was tested safe under specific conditions at a magnetic field strength of 3.0 Tesla, for example, does not mean that the device or scan is comparably safe under other conditions, including at a lower magnetic field strength. Some scans safe at 3.0 Tesla may be extremely hazardous

when performed at 1.5 Tesla or lower field strengths. It is for this reason that manufacturer guidance is to be followed precisely for scanning patients with conditionally safe devices or implants.

TIP Prospectively identify the safety parameters of every implant, prosthesis, and device before admitting persons into the controlled access portions of the MRI suite. Maintain current reference materials and resources to assess the safety of devices. **PS**

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Checklist for Safety in the MRI Suite

By answering the following questions, you will be able to consider all the safety issues involved in protecting MRI patients, staff, and equipment:

- Does your facility have established procedures for identifying implant/device safety for patients, staff, or guests?
- Do you provide private areas for HIPAA-compliant patient interviews?
- How does your facility provide medical gases in support of anesthetized or emergent patients?
- How comprehensive are your access controls in prohibiting access for unscreened patients and staff?
- How does your facility identify and interdict ferromagnetic materials that may be brought into the suite?
- Do you provide changing areas for patients to gown?
- Has your facility evaluated the use of ferromagnetic detection devices to enhance the screening of patients?
- In the event of a code or another emergent situation in the MRI suite, does the facility have the necessary emergency response materials (that is, oxygen cylinders, resuscitation devices, medications for negative contrast reactions) that are safe in proximity to the MRI machine?
- When was the last time your facility and staff ran a code drill in the MRI suite?
- Do all patient monitoring and clinical support devices used in the MRI suite conform to new ASTM criteria and are they appropriately labeled?
- Are the safety limits clearly identified for any equipment shared between different MRI systems?
- Does your MRI suite comply with your MR manufacturer's current recommendations or requirements for emergency exhaust and pressure equalization?
- Have you conducted and documented annual inspections of cryogen venting/exhaust systems?
- Has your suite been designed and furnished with the appropriate infection control provisions for image-guided biopsies/interventional clinical applications?
- Is there a secured storage area remote from the magnet room to lock away potential missile threats (such as conventional wheelchairs, gurneys, portable cylinders) that may be brought to the outer zones of the MRI suite by patients or transport staff? Does the facility have appropriate "loaner" equipment, safe for use in zone III or zone IV, to support those patients who need portable oxygen, monitoring, or mobility assistance?
- Does the facility comply with the ACR four-zone principle?

Sidebar 3. Devices and Appliances That Trigger Additional Safety Questions

Because of the presence of electronic, electrically conductive, or ferromagnetic components, the following list of devices and appliances should automatically trigger additional safety questions before staff can allow a patient to enter Zone III, or the magnet room:

- Pacemakers, implanted cardiac defibrillators (ICDs), and loop recorders
- Retained leads or pacing wires (even if the device is removed)
- Cochlear implants
- Implanted insulin pumps
- Deep brain/nerve stimulators
- Prostheses
- Pins, screws, and plates
- Shunts
- Transdermal patches
- Aneurism clips
- Tattoos and permanent makeup
- Piercings
- Shrapnel or any metallic foreign body
- Any other implant/onplant or clinical device accompanying the person entering Zone III