Magnetic Resonance Imaging Environment Safety in Ontario

April 2006

Healthcare Human Factors Group
University Health Network
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List of Abbreviations

ACR  American College of Radiology
ASTM American Society for Testing and Materials
ECRI Emergency Care Research Institute
FDA United States Food and Drug Administration
HPFB Health Products and Food Branch of Health Canada
MoHLTC Ontario Ministry of Health and Long Term Care
MRI Magnetic Resonance Imaging
MR Magnetic Resonance
MAUDE FDA Manufacturer and User Device Experience Database
OHTAC Ontario Health Technology Advisory Committee
RF Radiofrequency

List of Units

G  Gauss
kg  Kilogram
T  Tesla
W  Watts
Definitions

dB/dt – Time rate change of magnetic field

Ferromagnetic Materials – Materials that are or can become strongly magnetized in a relatively weak magnetic field. All ferromagnetic materials are susceptible to static magnetic field induced forces.

Level One MR Personnel – Those who have passed minimal safety educational efforts to ensure their own safety as they work in the MR environment. Level One MR Personnel are required to be safety screened for devices and contraindications prior to entering the MR environment.

Level Two MR Personnel – Those who have been more extensively trained and intensively educated in the broader aspects of MR safety issues.

Magnetic Field Strength – The magnetic field measured at the centre of the bore. There are high field strength (greater than 1.0T using superconductive magnets), and mid/low field strength (less than 1.0T using permanent or resistive magnets) systems [1].

Non MR Personnel – Individuals who have not received any MR safety instruction. Non MR Personnel are required to be safety screened for devices and contraindications prior to entering the MR environment.

Radiofrequency (RF) – A frequency band in the electromagnetic spectrum with frequencies in the millions of cycles per second. RF coils transmit RF signals and receive RF signals from the tissues being imaged.

Spatial gradient – The decrease in magnetic field strength over distance. The quicker the magnetic field of an MR system drops off, the higher the spatial gradient. Spatial gradient depends on the form of magnetic field shielding.

Specific Absorption Rate (SAR) – The RF power absorbed per unit of mass of an object, and is measured in W/kg. The SAR describes the potential for heating of the patient's tissue due to the application of the RF energy necessary to produce the MR signal.
Executive Summary

Purpose
In 2005, there were 58 MRI scanners in use at hospitals and private facilities in Ontario. Of these, 53 were high field strength systems. Since then, the MoHLTC has announced funding for nine new MRI scanners for hospitals, and three in the private not-for-profit sector. These new machines are projected to result in more than 53,000 new MRI exams in 2005-2006 [2].

With the increased prevalence of MRI exams in Ontario, the emerging use of MRI for image guided surgery, and the higher field strength MRI machines used for exams, it is important to address the potential risks to patient and staff safety in the MR environment.

The purpose of this study is to investigate the level of safety maintained at MR facilities in Ontario, assess the MR safety literature, and provide recommendations to OHTAC on maintaining a high level of safety at MR sites in Ontario. The scope of this study was focused on the MR environment, including the region from the centre of the magnet bore and extends out to the patient waiting and reception areas. The environment is divided into four zones as defined by the American College of Radiology (ACR) [3, 4]

The Technology

The MR environment
MRI has a number of advantages over other volumetric imaging modalities. Of significance is that MRI does not use ionizing radiation. MRI scanners are classified as high field strength (with magnetic fields greater than 1.0 T) or mid/low field strength (with magnetic fields less than 1.0 T). Within the MR environment, the 5G line (0.0005T) divides the environment into safe and unsafe regions. The environment where the magnetic field strength is less than 5G is generally considered to be safe [3]. Because of the persistent magnetic field, and the hazards associated with magnetic fields, extra care is required in the MR environment to ensure that injury or harm does not come to any personnel while in the environment.

Methods

Literature Review
There is a small body of literature on safety in the MR environment. It is clear that the MR environment is one in which caution is necessary to ensure staff and patient safety. The literature review focused on existing MR safety guidelines, recommendations, and standards. Additionally, the FDA MAUDE database was used to discover adverse incidents associated with the use of MRI.
Field Study
A field study complemented the literature review, and assessed the level of safety maintained at various MRI facilities throughout the province. Sites included teaching hospitals, research facilities, community hospitals, and private-provincially insured facilities. A standard list of questions provided insight into best practices for maintaining a high level of MR safety.

Summary of Findings
The ACR Blue Ribbon Panel for MR safety, chaired by Dr. Emanuel Kanal, published guidelines in 2002 [3] on maintaining safety in the MR environment. In 2004 these guidelines were updated to include new safety concerns [4]. Dr. Kanal has indicated that an update to these guidelines will be published in 2006. The ACR guidelines are well respected throughout the MRI community and are often used as a blueprint for MR policies at individual facilities. The ECRI has published several recommendation documents in their “Health Devices” publication on the topic of MRI safety [5-7]. Health Canada publishes notices to hospitals on safety information for MRI systems [8-10]. Additionally, Dr. Frank Shelley, an MR safety expert, maintains an MR safety website where medical devices and implants are listed according to their level of MR compatibility [11].

Adverse incidents associated with the use of MRI are sparsely documented primarily because only incidents resulting in death are required to be reported to the FDA. Incidents involving injury are reported to manufacturers, a few of which are submitted to the MAUDE database by the manufacturer. The FDA’s MAUDE database [12] reports incidents such as projectiles, burns, and implant and device malfunctions in the MR environment. The most notorious incident occurred in July 2001, when a 6-year-old boy was struck in the head by a ferromagnetic oxygen cylinder that was mistakenly brought into the MR environment while he was undergoing a postoperative scan. The oxygen cylinder was drawn rapidly toward the MRI magnet and became a projectile. The boy died shortly after the incident from his injuries [13].

Following a field study, it was found that not all MR facilities in Ontario follow the ACR guidelines, and there are several inconsistencies in certain MR practices across the province. However there are also several safety tactics successfully employed at facilities that are practiced that do not appear in the literature. In particular the following issues were found:

- The lack of a formal MR Safety Officer position at each hospital or hospital group
- The use of outdated MR equipment categorization
- Not utilizing the four safety zone MR environment architecture
- Not controlling access into the MR environment
- Not indicating the 5 G area through floor demarcation
- Inconsistent MR equipment labels
- The use of unclear MR warning signs
- Inadequate training for Level One MR personnel, and Non-MR Personnel
Conclusions

These recommendations provided for MR safety in Ontario will ensure that facilities throughout the province have access to MR safety information, and that a high level of MR safety is maintained. The primary recommendation is to establish a provincial MRI safety committee to maintain consistent MR safety practices in Ontario.

Recommendations for the MRI Safety Committee’s consideration include:

- Use the updated MRI categorization: MR Safe, MR Conditional, MR Unsafe
- Strictly control access to the MR environment
- Clearly indicate the 5 G perimeter on the floor surrounding the scanner.
- Assign a permanent location for equipment in the magnet room
- Use consistent MR labels on equipment used in the MR environment
- Use consistent MR signs that clearly indicated the hazards of the MR environment
- Require outpatients undergoing MRI scans to change into hospital gowns without metal fasteners
- Provide annual training for personnel working in the MR environment
Issue

MRI has a number of advantages over other volumetric imaging modalities. Of significance is that MRI does not use ionizing radiation. However there are other safety risks related to the use of the strong magnetic fields used in MRI. A MoHLTC Medical Advisory Secretariat Health Technology Review completed in December 2003 addressed Patient Monitoring Systems for MRI [14]. In this review, the safety risks associated with monitoring patients during MRI exams were addressed. In a February 2004 follow-up, the OHTAC provided safety recommendations for patient monitoring systems for MRI [15]. In its recommendations, OHTAC suggested a safety review of Ontario MRI facilities, and alerting MRI facilities of safety hazards to minimize risks to patients and staff.

In addition to safety involving patient monitoring for MRI, there are several other safety issues that must be addressed during each MRI exam. These include the proper screening of patients for implants and contraindications, maintaining a MR environment that is free of ferromagnetic objects, and appropriately communicating MR hazards to staff and patients. The MR environment is highly specialized, and requires a high level of safety. The purpose of this study is to investigate the level of safety maintained at MR facilities in Ontario, assess the MR safety literature, and provide recommendations to OHTAC on maintaining a high level of safety at MR sites in Ontario.

Hazards in the MR environment

The use of medical devices and other equipment requires great care when in proximity to the magnetic field of an MRI unit. There are several types of hazards in the MR environment. Of most concern are [5]:

- Static magnetic field induced forces
- RF heating
- Device malfunctions

Static magnetic field induced forces

Two types of static magnetic field induced forces can create safety problems in the MR environments: torque, and translational force. Torque is a rotational force that causes an object to align parallel to the static magnetic field. Translational force is a linear force that attracts an object into the bore of the magnet.

The closer a ferromagnetic object’s proximity to the MR system’s magnet, the higher the spatial gradient that exists, and the greater the translational force that the object will experience. Therefore there is a greater likelihood that the object will be drawn toward the MR system’s magnet the closer the object is to the magnet.

Static magnetic field induced forces have a significant effect on implanted devices (primarily torque) as well as the projectile effect (primarily translational forces) on unrestrained ferromagnetic objects in the MR environment. Objects such as oxygen
cylinders, IV poles, mop buckets, and patient monitors have all been pulled into the MRI magnetic field with potentially deadly force [5]. An example is shown in Figure 1, where an office chair containing ferromagnetic materials came too close to the system, became a projectile, and got lodged into the bore of the scanner magnet. The static magnetic field is always present, and therefore poses a significant safety risk, such that safety precautions must be taken at all times.

![Office chair wedged into MR scanner](image)

**Figure 1: Office chair wedged into MR scanner [16]**

**RF Heating**

The RF electromagnetic field of an MR system can induce currents in electrically conductive materials present within the bore of the MR system. The induced current can cause heating in the conductor, which can lead to a patient burn if the conductor is in contact with the patient’s body. Patients have received burns from contact with
conductive medical equipment cables (e.g. ECG leads), at the site of pulse oximeter sensors, and from tattoos (heating of iron in the tattoo ink) [5].

**Device Malfunctions**
The static magnetic field can affect devices such as infusion pumps and ventilators, which have ferromagnetic materials in their internal components. The magnetic field can cause the components to malfunction or to cease functioning completely. As a result, there are many devices that are contraindicated for use in proximity to an MRI scanner because their functionality can be affected by the magnetic field.

In one example, a patient-controlled analgesic infusion pump malfunctioned due to the static magnetic field causing the pump’s motor to operate in reverse. The pump’s display gave no indication of a problem to the user [5].

Other incidents of insulin infusion pumps and ventilator malfunctions have been reported [5, 12]. Medical device transducer leads can act as antennae for RF energy, which can lead to device malfunctions and possible heat-related injury to the patient. Additionally, the gradient magnetic field of many new MR systems generate signals that appear similar to physiologic signals in the frequency spectrum, and therefore can interfere with the interpretation of ECG signals.

**Existing Safety Guidelines**

**ACR Guidelines**
In November 2001, the ACR formed a Blue Ribbon Panel, chaired by Dr. Emanuel Kanal to develop a document “intended to be used as a template for MR facilities to follow in the development of an MR safety program” [3]. Based on adverse incidents detailed in medical literature and in the media, the panel indicated that potential risks exist in the MR environment for patients, accompanying family members, attending healthcare professionals, and those who are in the MR environment on rare occasions (such as security guards and firefighters). The recommendations were aimed at maintaining safety for all individuals who find themselves in the MR environment at any time. The ACR White Paper on MR Safety was published in June 2002. The Canadian Association of Radiologists, a chapter of the ACR, and has adopted the same standards and guidelines.

In 2004, the 2002 White Paper was updated to include new MR safety issues [4]. The panel continues to revise and update the white paper. An updated version of the White Paper is scheduled to be available later in 2006.
The 2004 White Paper includes MR safety guidance on the following topics:

- Establishing, implementing, and maintaining current MR safety policies and procedures
- MR Site access restriction
  - MR environment zoning
  - MR and non-MR personnel
  - Personnel and patient screening
  - Device and object screening
- MR Technologists
- Pregnancy related issues
- Pediatric MR safety concerns
- Time varying gradient magnetic field related issues
  - Induced voltages
  - Auditory considerations
  - Thermal
- Drug delivery patches and pads
- Cryogen related issues
- Claustrophobia, anxiety, sedation, analgesia, and anesthesia
- Contrast agent safety
- Patients with intracranial aneurysm clips
- Patients with cardiac pacemakers or implantable cardioverter defibrillators

Dr. Kanal recommends that individual MR sites use the White Paper as a blueprint for establishing MR safety policies at individual sites.

**ECRI Recommendations and Alerts**

The ECRI has published several recommendation documents in their “Health Devices” publication on the topic of MR safety. In 2001, the ECRI published preliminary guidelines on ensuring the safe use of equipment in the MR environment [5]. Since then, the ECRI has summarized important information on MR safety, and published guidance articles and alerts on the latest in MR safety news [6, 7].

**FDA Equipment Categorization**

Medical device vendors are required to communicate MR safety information regarding devices (i.e. safety with respect to spatial gradient, SAR, etc.) in the MR environment. In 1997 the United States Food and Drug Administration (FDA) defined two terms categorizing devices that have been shown to be useful in the MR environment [5].

**MR Safe** – “The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of the diagnostic information”

**MR Compatible** – “The device, when used in the MR environment, is MR Safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device”
As this terminology came to be used in practice, it was found that the terms were being used incorrectly or interchangeably. There were incorrect assumptions that MR Safe devices were also MR Compatible, which is not the case. MR Safe and MR Compatible are not mutually exclusive. Additionally, sometimes the incorrect assumption was made that if the device is deemed MR safe or compatible, it is safe or compatible in any situation, in any MR environment.

In 2005, the ASTM International issued a “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic resonance Environment” [17]. This standard was developed and endorsed by the FDA as the new standard for MR device categorization and marking. It removes the confusion from the previous categorization, and no longer considers image quality, and primarily focuses on safety in the MR environment.

In this standard, there are new categories for the marking and categorization of medical devices used in the MR environment. Along with these categories, new icons for labels are issued for ease of identifying the device and its safety rating.

<table>
<thead>
<tr>
<th>MR Safe: “An item that poses no known hazards in all MR environments.” (e.g. a plastic Petri dish)</th>
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<tbody>
<tr>
<td>MR Conditional: “An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency fields, and specific absorption rate. Additional conditions, including specific configurations of the item, may be required.” (e.g. a Patient Monitor)</td>
</tr>
<tr>
<td>MR Unsafe: “An item that is known to pose hazards in all MR environments.” (e.g. Floor Buffer)</td>
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**Health Canada Notice to Hospitals**

The HPFB of Health Canada posts safety alerts, public health advisories, press releases and other notices on the Health Canada web site. These are a service to health professionals, consumers, and other interested parties. In 2005, the HPFB published two Notices to Hospitals on safety information for MRI systems. The notices included safety information on transdermal drug patches [8], and safety information on active implantable medical devices and systems [9, 10].
MRI Safety Experts

Dr. Emanuel Kanal is the director of MR services and Professor of Radiology and Neuroradiology at the University of Pittsburgh Medical Center. He is the chair of the American College of Radiology Blue Ribbon Panel on MR safety programs.

Dr. Frank Shellock is an Adjunct Clinical Professor of Radiology and Medicine at the Keck School of Medicine at the University of Southern California. He is also the chair of the Institute for Magnetic Resonance Safety, Education, and Research. His publications (including his book and website) are used by almost all MR facilities for the verification of devices and implants in the MR environment [1, 11].

Dr. Kanal and Dr. Shellock are well-respected MR safety experts. Their publications and websites are widely used in the MR community for establishing safety policies and verifying MR devices. Dr. Kanal and Dr. Shellock are active contributors to various MR safety periodicals, websites, and email listings. They both were consulted for their expertise for this project.
**FDA MAUDE Database**

In the September 21, 2005 ECRI Audio Conference on MRI Safety and Medical Devices [18], Mr. Jason Launders of the ECRI presented an analysis of the FDA MAUDE database from 1995 to May 2005 [19]. He searched all reports for MRI device codes, electrode burns, implants, aneurysm clips, pacemakers, and deaths associated with MRI.

The search found 389 unique and relevant reports. In these there were nine reported deaths, and 302 incidents attributable to MRI technology. Of the MRI injuries, 71% involved burns (coils, leads connected to monitoring equipment, or body loops), 10% involved other items (e.g. implants), 10% were caused by projectiles, 4% were acoustic injury (e.g. temporary hearing loss), 4% were fire related injuries, and 2% were caused by internal heating (implanted leads). Metallic implant failures/burns, infusion pump failure, pacemaker failure, aneurysm clip failure, and neurostimulator failure were represented in the “other item” category of MRI device incidents.

While the MAUDE database cites many MRI incidents, the data are unreliable due to a large number of unreported events. Dr. Emanuel Kanal of the ACR stated, “the percentage of accidents reported to the FDA is well, well below 10%” [18]. However the MAUDE database can provide insight into the types of injuries and hazards in the MR environment.
Field Study
A field study of eleven hospitals and one private MR clinic was conducted to assess the level of safety maintained in MR environments around the province, as well as to learn of best practices for MR safety. This sample represents approximately 25% of the facilities in Ontario that have MRI scanners [20]. A standard list of questions and points of inquiry was used in this field study (Appendix A). Points of interest included equipment categorization (i.e. MR Compatible, MR Safe), infrastructure within the MR environment (i.e. signs, labels, floor markings), policies on patient care, and the training provided to personnel.

Results

MR Safety Officer
Most sites do not have a formal MR Safety Officer position. Usually the charge technologist and/or the chief MR Radiologist is responsible for the MR safety policies at the sites. As part of the recommendations on establishing, implementing, and maintaining current MR safety policies and procedures, the ACR recommends appointing an MR safety officer who is responsible for ensuring that MR safe practice guidelines are implemented and adhered to at all times.

Equipment Categorization
The use of MR safety categorization prior to August 2005, MR Safe and MR Compatible, was assessed at each site. All sites are correctly using the MR equipment categorization. Nearly all sites only make use of “MR Compatible” equipment to avoid confusion between MR Safe and MR Compatible. Additionally, consistency is being maintained in using the categorization to identify MR equipment.

Sites were unaware of the new MR Safety categories, and therefore were still using the 1997 FDA categorization. The new categorization standards for MR equipment (MR Safe, MR Conditional, and MR Unsafe) are recommended for use by the FDA to maintain consistency with the standards that are now being used by equipment manufacturers [17].

Environment Architecture
The ACR recommends dividing the MR environment into four zones [4]. These zones are shown in Figure 2 and are described as follows:

- Zone 1 is the area outside the MR environment that is accessible to the general public.
- Zone 2 is the interface between the public Zone 1 and the controlled Zone 3 and Zone 4. In Zone 2, patients are under the supervision of MR personnel.
• Zone 3 is the area where only screened personnel and objects are permitted. MR Unsafe equipment is exchanged with MR Conditional or MR Safe equipment in Zone 3. Access to Zone 3 is strictly restricted and should be physically controlled from general public access.

• Zone 4 is the MR scanner room and appropriate signs should be used to communicate this.

Figure 2: Four-zone MR environment, adapted from [4]

For sites that were visited, the patient flow from the reception area (Zone 1) to the magnet room (Zone 4) was assessed. Controlled access beyond the reception area was verified. Additionally, the types of controls used to prevent prohibited entry into the MR area were noted.

There is no consistent MR suite layout primarily because of the architecture of the space in which the MR environment is installed. The ACR recommendation of the four safety zones is not followed across all sites. Half of the sites used only three zones. Additionally, only a few sites control the access of non-MR personnel in the MR
environment. Other sites have no controlled access. As such, anyone could walk through the hospital, into the MR environment, and directly into the magnet room. The ACR recommends that beyond the reception desk in the MR environment, MR personnel should escort all non-MR personnel.

**Magnet room door**

Zone 4 of the MR environment is typically designed with a door that swing inward to the magnet room. If the magnet in the MR scanner is quenched, there is a positive pressure buildup in the magnet room. This positive pressure pushes a closed door against the stops and makes the door nearly impossible to open until the pressure on the inside of the room is equalized with the pressure outside the room. The MAUDE database [12] lists one asphyxiation death of a service person caused by breathing the ultracold vaporized helium. This is also a risk for patients who are in the room when the magnet is quenched. The positive pressure buildup may prevent technologists from attending to the patient during an emergency situation. During the field study two technologists from different sites mentioned that they were told by the scanner manufacturer to break the window between Zone 3 and Zone 4 to equalize the pressure if this occurred. To prevent such incidents and to provide the safest possible environment for patients, technologists, and other MR personnel, the magnet room door should swing outward from the magnet room, but should not obscure the technologists view as to who, or what, is entering the magnet room [21]. An MR hazard sign should therefore be placed both on the inside and outside of the magnet room door.

**Floor markings**

In its guidelines, the ACR recommends that where the static magnetic field strength exceeds 5 G, the area should be clearly demarcated as being potentially hazardous [4]. Below 5 G, the static magnetic field has diminished sufficiently to pose no physical threat to staff or patients [5].

An assessment was done as to whether sites marked the 5 G line out in the room. The method and location of markings was noted and compared across the sites. Any other floor markings used for safety purposes were also noted.

Two-thirds of the sites assessed included the demarcation of 5 G in the MR environment. The method differed from site to site. These include the use of adhesive tape, and contrasting coloured floor tiles. Some sites had an additional demarcation indicating the proximity limit for certain equipment (e.g. an anesthesia machine that is MR Compatible to 300 mT, or 3000 G).

**Equipment Location**

Occasionally MRI scans are performed on patients who require specialized monitoring equipment [14]. This equipment can be potentially hazardous in the MR environment. An assessment was made as to whether sites had a designated area for potentially MR Unsafe equipment. While this is not part of the ACR guideline, it appears to be a good strategy for ensuring potentially unsafe equipment does not come too close to the
scanner. This also would make MR personnel cognizant of the equipment in the MR environment so that extra care is exercised with potentially unsafe equipment.

Very few sites were found to have dedicated space for equipment that is unsafe within the 5 G line. A few sites make use of a pole onto which the equipment can be fastened or tethered, or a table designated for MR equipment.

**Safety Labels**
The ACR recommends that all metallic or partially metallic objects that are to be brought into Zone 4 be labeled for MR safety [4].

The use of labels on MR equipment was assessed. If labels were being used, the text or icons on the labels was noted.

![Figure 3: MRI Safety Labels used in Ontario](image)

Approximately one-third of sites do not label their MR equipment. Sites that do use labels use various forms including: manufacturer-provided labels, label-maker labels, purchased labels, and copper tape. There is no consistency in the text or icons used on the labels. Additionally, there is no consistency in label placement on the devices.

The FDA has created a preliminary draft labeling recommendation for device manufacturers. This recommendation is still under discussion and will likely not be finalized for another year. The FDA Center for Devices and Radiological Health indicated that manufacturers are opting to use the icons from the ASTM 2503 standard [22]. In addition to manufacturers making use of the new icons, individual sites are encouraged to make use of the icons on their own labels for identifying MR Safe, MR Conditional, and MR Unsafe items. Consistent labels and label placement make it easier for MR personnel to verify the safety of MR equipment. This reduces ambiguity and clearly communicates the safety of the equipment. A template for these labels is provided in Appendix B.

**Safety Signs**
The ACR suggests that the door to Zone 4 be clearly marked with a sign indicating that a strong magnetic field is always present [4].
An assessment was made of the number and types of safety signs used in the MR environment. The text and images on the signs were noted and compared across the sites.

There was no consistency in the signs used in MR suites across the province. While all sites make use of safety signs, some sites make their own signs, others use purchased signs or signs provided by the scanner manufacturer. Some signs are difficult to read, using languages and icons that are difficult to understand. These signs are more difficult to interpret. Examples of these signs are shown in Figure 4 and Figure 5.

![Image of MRI Safety Warning Signs used in Ontario](image-url)

**Figure 4: MRI Safety Warning Signs used in Ontario**
Product Procurement

ASTM F2503-05 standard [17] indicates that safety testing for items that may be placed in the MRI environment should address magnetically induced displacement force (Test Method F 2052) [23], magnetically induced torque (Test Method F 2213) [24], and RF heating (Test Method F 2182) [25]. Manufacturers should perform these tests and include the results to verify the MR Safe, MR Conditional, or MR Unsafe categorization according to the results from the testing. During device procurement, it should be verified that the device has passed each of the three test methods, and is tagged with a label that follows ASTM Standard F2503 and the FDA Preliminary Draft Labeling [17].

MRI Sites in Ontario follow a number of different processes when purchasing equipment to be used in the MR environment. Equipment purchases include patient monitors and accessories, anesthesia machines, ventilators, IV poles, and wheelchairs. Some sites purchase MR Compatible equipment from the MR scanner manufacturer. Other sites purchase MR Compatible equipment from the manufacturer and then verify its compatibility with a handheld magnet.
**Implants and Contraindications**

The methods used for screening patients for implants or other contraindications were assessed. Additionally, the method of verifying implant safety was assessed for best practice.

All sites essentially follow the same procedure for assessing patient implants. They obtain information on the implant from the patient, hospital records, or surgical notes. Next, the MRISafety.com website, or “Reference Manual for Magnetic Resonance Safety, Implants, and Devices” [1] is consulted to determine MR compatibility. If compatibility cannot be verified, the manufacturer is contacted and information is obtained. If the implant or contraindication cannot be assessed, the patient is not scanned.

This procedure for verifying the compatibility of implants was found to be the preferred practice. In addition to the MRISafety.com website and reference manual, the notices issued by the HPFB should be used to identify implants and devices that are contraindicated for MR use by Health Canada.

**Thermal Issues**

Patient burns are a serious hazard in the MR environment. Sites were asked about the methods used to counteract patient burns while being scanned. This included policies regarding scanning patients in their own clothing. Additionally, technologists were asked about the incidence of patient burns at their sites.

Because of the heterogeneous materials used in patient clothing, the ACR recommends that patients wear a “site-supplied gown with no metal fasteners” during the MR procedure [4]. When there is the potential for a patient burn, such as with ECG electrodes or tattoos, the ACR recommends reducing the temperature of the area through the use of ice packs or cold compresses for the duration of the MR scan [4].

The sites visited recorded very few instances of patient burns. A few patients reported heating in the areas where they had tattoos. To counteract heating caused by tattoos, leads, wires, or the magnet, linens and cold compresses are used for protecting the patient. Linens are used as a thermal insulator between limbs and the sides of the magnet. Cold compresses are used on external wires, leads and tattoos to cool the area during the scan. Not all sites require patients to change into hospital gowns during the scan. One instance was reported of a patient burn as a result of conductive threading in the patient’s clothing.

**Metal and Ferromagnetic Detectors**

No sites included in this study make use of metal or ferromagnetic detectors. The ACR and ECRI do not recommend the use of metal detectors in the MR environment. Metal detectors cannot differentiate between ferromagnetic materials and non-ferromagnetic materials. The use of metal detectors leads to decreased vigilance because of the constant “false positive” alarms, and could provide a false sense of security by failing to detect small implanted devices.
Ferromagnetic detectors are just now becoming available. In a conversation with Mr. Kemp Massengill, President and CEO of Mednovus Inc. [26], it was found that several designs of passageway ferromagnetic detectors exist; however, each has its own drawbacks. They are heavy, expensive, and not very sensitive in the centre of the passageway. Handheld ferromagnetic detectors will soon become available for use as well. They have a depth of sensitivity of one inch and therefore can detect small objects on a patient. However this depth of one inch may not be adequate to detect implanted devices (e.g. aneurism clips or shrapnel). Additionally they are not recommended for use around the eyes because they may dislodge ferromagnetic debris in the orbits and cause damage to a patient’s eyes. At the time of writing, further studies are being conducted on ferromagnetic detectors. This is an evolving field, and attention should be directed toward the results of these studies. Ferromagnetic detectors could potentially be used in the MR environment in the future. The ACR will address ferromagnetic detectors in the 2006 version of the White Paper on MR Safety. The ECRI has not yet tested ferromagnetic detectors, and therefore cannot approve or disapprove of their use.

Training
Two types of MR personnel are identified by the ACR [4]. Level One MR personnel are “individuals that have passed minimal safety educational efforts to ensure their own safety as they work within Zone 3”. Level Two MR personnel are individuals “who have been intensively educated in the broader aspects of MR safety issues” and can work in any of the four MR zones. Non-MR personnel are those who have not received any formal MR safety instruction.

Each site described the types of personnel allowed into the MR environment. This included technologists, radiologists, nurses, respiratory therapists, housekeeping staff, and security guards. The personnel that are allowed to enter the MR environment depend on the type of patients being scanned, and the policies of individual MR sites. When pediatric or critical care patients are being scanned, more personnel (e.g. parents, nurses, and respiratory therapists) are present in the MR environment. Security and housekeeping personnel only enter the MR suite if the individual site permits their entry. Certain sites do not permit housekeeping and security staff to enter the MR environment. At these sites, technologists take over the housekeeping and security responsibilities.

For Level One MR personnel that were permitted entry into the MR environment, the type of training provided was assessed. The Level One MR personnel method of screening for devices and contraindications was noted. Finally, the techniques for orienting newly trained MR technologists to the specific MR site were gathered and compared across the sites.

At approximately one-third of the facilities, Level One MR personnel are permitted entry into Zone 4 of the MR environment. Primary caregivers often accompany patients, particularly those that are critically ill. Housekeeping and maintenance personnel visit the MR environment for their scheduled duties.
Some sites provide one-time training for individuals to be designated as Level One MR personnel. The training includes safety screening of devices, implants and other contraindications. Technologists noted that it often difficult to schedule training time for staff. Typically, there is no follow-up training.

There are inconsistencies in screening Level One MR personnel for devices and contraindications. Certain sites keep the screening forms on file and simply review the information with the individual each time they visit the MR environment. Other sites require the individual to fill out a new screening form each time they visit the MR environment.

Newly trained MR technologists are often paired with an experienced technologist to orient them to the MR environment of the specific site. Most sites have an orientation checklist that highlights the equipment, safety measures, policies and procedures for the MR environment.

One useful practice was observed that could benefit other MR sites in Ontario. New technologists spend the first few weeks primarily screening patients and verifying their conclusions with an experienced technologist. This way, the technologist can practice the essential skill of screening for contraindications and unsafe devices.

MR technologists suggested that an annual online training program would help maintain a high level of MR safety, as it would remind individuals of the risks and hazards in the MR environment. Following the initial training, an annual self-directed computer based training program, followed by a self-graded interactive questionnaire is recommended as annual training and certification for all individuals that interact with the MR environment as part of their job.

Communication
The MR technologist community in Ontario is a fairly close-knit group. Across sites, several technologists have worked together in the past. Technologists were asked about the necessity and desire to communicate with other sites regarding MR safety issues.

Technologists who have worked at other sites often communicate and share ideas through personal discussions, or an electronic bulletin board. These technologists view this as an effective activity, and suggested that some structured means of sharing information across the province would be very useful.

Interventional MR Safety
Most interventional MRI procedures have been in the field of neurosurgery [27-30]. MRI is often used to monitor the progress and results of a procedure. Neurosurgeons have documented their processes for MR safety when performing the procedures. Because interventional MRI is not very common, there are very few guidelines for surgical procedures that occur within the MR environment.
Surgeons have noted that they have made use of disposable and non-ferromagnetic (primarily titanium) instrumentation while performing procedures [27]. If standard surgical instrumentation is utilized, procedures are performed outside of the 5G line, and the patient is moved back into the MR scanner for periodic imaging.

As with all MR procedures, large equipment used during interventional procedures such as trolleys, linen hampers and anesthetic equipment should be made with non-ferromagnetic materials wherever possible, such as non-magnetic grade of stainless steel. The obvious risk of using ferromagnetic instrumentation and equipment is that it can inadvertently come too close to the magnet and become a projectile. Because of this serious risk the use of non-ferromagnetic instrumentation and specialized equipment for interventional MRI procedures is recommended. If equipment is made of ferromagnetic materials, it should be kept beyond the 5 G line in an area designated for potentially unsafe equipment.

**Summary of Results**

The results of the field study are summarized in Table 1. It is evident from these results that there are inconsistencies in MR safety practices throughout the province. The inconsistency in MR safety practices could potentially lead to adverse MR incidents in Ontario.
<table>
<thead>
<tr>
<th>Inquiry</th>
<th>Yes</th>
<th>No</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do sites have an MR Safety Officer?</td>
<td>0</td>
<td>12</td>
<td>No sites have appointed an MR Safety Officer</td>
</tr>
<tr>
<td>Do sites use the 1997 FDA MR equipment categorization?</td>
<td>12</td>
<td>0</td>
<td>All sites use MR Compatible equipment</td>
</tr>
<tr>
<td>Do sites use the 2005 FDA/ASTM MR equipment categorization?</td>
<td>0</td>
<td>12</td>
<td>No sites had heard of the updated categorization</td>
</tr>
<tr>
<td>Do sites follow the 4-zone MR environment architecture?</td>
<td>6</td>
<td>6</td>
<td>MR environment architecture was dependent on the configuration of the space allotted for the MR environment</td>
</tr>
<tr>
<td>Does the magnet room door (to Zone 4) swing outward?</td>
<td>0</td>
<td>12</td>
<td>All doors to Zone 4 swing inward</td>
</tr>
<tr>
<td>Do sites mark the 5G line on the floor of Zone 4?</td>
<td>8</td>
<td>4</td>
<td>Not all sites with 5G line have it marked in a permanent manner</td>
</tr>
<tr>
<td>Do sites have a location in Zone 4 for MR Conditional equipment?</td>
<td>3</td>
<td>9</td>
<td>Tables, poles, and floor markings used to indicate the location for MR Conditional equipment</td>
</tr>
<tr>
<td>How many sites reported accidental projectiles in the MR suite?</td>
<td>2</td>
<td>10</td>
<td>Patient monitors, sand bag, ventilator</td>
</tr>
<tr>
<td>Do sites use MR safety labels on all MR equipment?</td>
<td>5</td>
<td>7</td>
<td>Different types of labels are used, depending on the site, and the equipment</td>
</tr>
<tr>
<td>Do sites use multiple MR safety signs?</td>
<td>9</td>
<td>3</td>
<td>Different signs used depending on the MR site, and the brand of scanner</td>
</tr>
<tr>
<td>Do sites require outpatients to change into gowns?</td>
<td>3</td>
<td>9</td>
<td>Patients are often scanned in their own clothing</td>
</tr>
<tr>
<td>How many sites reported patient burns while being scanned?</td>
<td>2</td>
<td>10</td>
<td>Burns from conductive material in clothing, tattoos, body parts forming loops</td>
</tr>
<tr>
<td>Do sites use metal detectors?</td>
<td>0</td>
<td>12</td>
<td>Metal detectors cause too many false positives</td>
</tr>
<tr>
<td>Do sites use ferromagnetic detectors?</td>
<td>0</td>
<td>12</td>
<td>Ferromagnetic detectors are very new, untested technology and not widely available</td>
</tr>
<tr>
<td>Do sites offer safety training for staff?</td>
<td>12</td>
<td>0</td>
<td>All sites provide a one time in-service</td>
</tr>
</tbody>
</table>

**Table 1: Summary of Field Study**
Conclusions and Recommendations

It is important that Ontario be proactive in promoting MR Safety at all MR sites in the province. Reviewing the findings of the field study and the existing published MR safety guidelines provides a number of recommendations for Ontario MR sites. The recommendations in this section are based on the findings from the existing guidelines and the field study of safety practice in MRI sites across Ontario. These recommendations also include best practices found during the field study.

 Provincial MRI Safety Committee

A provincial MRI safety committee should be formed to promote consistent MR safety practices in Ontario. It should represent MRI facilities around the province, including large research facilities, community hospitals, and independent MRI centres. The committee should be charged with:

• Gathering and disseminating new MR safety information through the province
• Creating an annual staff training program
• Facilitating communication among MR technologists around the province
• Recording MR safety incidents, and creating a database of near-misses and adverse MRI incidents
• Developing consistent practices to prevent MR incidents in Ontario
• Develop a consistent screening form to be used in all MR facilities in Ontario

As part of its mandate to promote MR safety in Ontario, the remaining recommendations should be considered by the MRI Safety Committee for implementation at all MRI sites in Ontario.

MR Safety Officer

Appoint an MR safety officer at each site or hospital group. The MR safety officer is responsible for the regular maintenance, review, and updating of policies and procedures, overseeing staff screening and training, as well as educating non-MR personnel on MR safety. This responsibility should be added to a current MR technologist or radiologist position and does not need to be a position on its own.

Equipment Categorization

Adopt the use the 2005 ASTM [17] and FDA MR equipment categorization standards (MR Safe, MR Conditional, and MR Unsafe) to maintain consistency with the standards that will be used by equipment manufacturers. All equipment that is used in Zone 4 should have proper MR safety labels.

All sites should make use of labels that follow the ASTM standard [17] for MR labels. Permanent labels with the appropriate ASTM icon should be placed on all new and existing equipment used in the MR environment.
Environment Architecture
The MR environment should follow the four-zone architecture outlined by the ACR [4] for all new suites.

Controlled entry in the MR environment
Doors to Zone 2 and Zone 3 should be locked with an electronic lock. The doors to Zone 4 can be key locked, and remain unlocked while the technologist is present in Zone 3. Technologists should act as a “gate keepers” to Zone 4 and regulate the passage of all personnel, patients and equipment at all times.

Magnet Room Door
The magnet room door should swing outward from the magnet room, and should not obstruct the technologist’s view of who or what is entering the magnet room. An MR hazard safety sign should be placed on both sides of the door.

Floor Markings
The 5 G perimeter line should be marked on the floor of the magnet room in a permanent manner, and should contrast the colour of the flooring.

Equipment Location
A clearly designated space should be dedicated to unsafe equipment in the MR environment. The equipment should remain beyond the 5 G line when being brought into the MR environment, and at all times while being used in the scanner room. The space should be identified by permanent markings on the floor. This equipment should also be physically restrained by non-ferrous means (e.g. brass chains or nylon rope).

Safety Signs
A standard MR hazard sign should be used at MR facilities across the province. The sign developed by Dr. Frank Shellcock, and available for purchase from Magmedix, Inc. [31] was found to be the best sign in use (Appendix C). It clearly communicates the hazards of MR by using understandable icons and language.

Product Procurement for use in the MRI Suite
During device procurement, it should be verified that the device has passed each of the three ASTM test methods, and is tagged with a label that follows ASTM Standard F2503 and the FDA Preliminary Draft Labeling [17].

Thermal Issues
All sites should require patients to change into hospital gowns (whenever possible) without metal fasteners, to ensure ferromagnetic or conductive items do not come into the magnet room in error.

Metal and Ferromagnetic Detectors
The use of metal detectors in the MR environment is not recommended.
The use of ferromagnetic detectors is not recommended, however progress is being made in this area and should be reconsidered in the future.

**MR Safe Fire Extinguishers**

Use MR safe carbon dioxide fire extinguishers in the MR environment. These are recommended for use by the ECRI [7] for fighting small fires involving common combustibles.

**Screening Forms**

The MR Safety Committee should use Dr. Frank Shellock’s screening form [11] as a blueprint for a screening form that is used throughout Ontario. A single, comprehensive screening form will ensure that the highest level of safety screening be observed at all MRI facilities in the province. A copy of this form can be found in Appendix D.

**Implants**

Upon notification that a patient has an implanted medical device, the MR conditions of the implant should be verified from the information provided by the implant manufacturer, MRISafety.com, the “Reference Manual for Magnetic Resonance Safety: Implants and Devices”, and the notices issued by HPFB of Health Canada.

**Training**

One-time live training should be provided to all MR personnel at each site. Following this, MR safety training should be available for all MR personnel to complete on an annual basis. MR Site should submit lists of individuals that have completed the annual MR training as proof of compliance with the training process.

Sample training and testing programs are available online [32, 33] where individuals are reminded of the hazards of their workplace and quizzed on their knowledge of these risks. Individuals are also required to fill out a screening form at this time.

**Interventional MR Safety**

Use of non-ferromagnetic instrumentation and specialized equipment for interventional MRI procedures is recommended. Electronic-based equipment such as patient monitors and anaesthesia machines should be MR Conditional to the environment in which they are to be used. For safety, they should be kept beyond the 5 G line, in a clearly designated area of the MR environment.

**Checklist for MR Safety**

A checklist for MR safety should be developed and provided to MR facilities around the province. The information provided in this report along with the recommendations from the ACR, ECRI, and Health Canada should be condensed into a checklist. An outline of the topics that should be considered in the MR Safety checklist can be found in Appendix E.
References


[12] "FDA Manufacturer and User Device Experience Database MAUDE."


[16] "Simply Physics. simplyphysics.com."


Appendix A: Field Study Questionnaire

MRI Safety Questions

SITE:
DATE:
TECH NAME:

TYPE OF MRI SCANNER (Manufacturer and strength):
DO YOU HAVE CRITICALLY ILL PATIENTS? Yes/No

1. Labels

- Do you make use of labels to identify if something is MRI Safe, MRI Compatible, or Not MRI Safe?
- Any thoughts on what we should be included on the ideal safety labels? Logos, icons, text, etc?

2. Infrastructure

- Do you deploy the 4 zones for the MRI environment (as suggested by Kannal and the ACR)?
- Do you mark the 5G line out in the environment? If so, is it permanent (e.g. different color tiles) or moveable (e.g. masking tape)
- What type of safety signs do you use? What is the text on them? Where were they purchased or are they made in house?
- Do you tether any monitoring equipment in the environment to ensure it doesn’t come too close to the magnet
- Are there any improvements that could be made to the suite you work in to make the suite safer?
- Do you have any ideas on how to improve suite safety? Eg. Docking monitors to the ground, using ceiling tracks, etc.

3. Training and Communication

- What are your thoughts on annual certification (like WHIMIS) for anyone entering the MRI suites (including techs, cleaning staff, physicians, maintenance, etc.)
- How do you currently train non-MR professionals on the dangers of MR
- Do you ever call other MR sites to ask for input into implants, contraindications, etc? i.e. Do you communicate with other sites on MR related matters?
4. Implants
   - Currently what is your policy on scanning patient with implants?
   - How do you verify implants?
   - May I have a copy of your screening form?

5. Burns
   - Have you had any instances of patients being burned while in the being scanned?
     And what were they caused by?
   - What techniques do you use to counteract patient burns?

6. Pregnancy
   - What is your policy on scanning patients that are pregnant?

7. Other policies
   - What is your policy on scanning patients that may have metal in the eye?
   - Do you always require the use of earplugs? What if a patient refuses to wear them?
   - Do you require patients to change into gowns?
   - What MR safe equipment do you have at your facility? (e.g. fire extinguishers, mop buckets, etc).
Appendix B: Sample Safety Labels

<table>
<thead>
<tr>
<th>MR SAFE</th>
<th>MR SAFE 3T</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR UNSAFE</td>
<td>MR SAFE 3T</td>
</tr>
<tr>
<td>MR Conditional 1.5 T</td>
<td>MR</td>
</tr>
</tbody>
</table>
Appendix C: MRI Safety Sign
# Appendix D: MRI Screening Form

## Magnetic Resonance (MR) Procedure Screening Form for Patients

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Last name</td>
</tr>
<tr>
<td>Age</td>
<td>Height</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>Male</td>
</tr>
<tr>
<td>Address</td>
<td>Telephone (home)</td>
</tr>
<tr>
<td>City</td>
<td>Telephone (work)</td>
</tr>
<tr>
<td>State</td>
<td>Zip Code</td>
</tr>
<tr>
<td>Reason for MRI and/or Symptoms</td>
<td></td>
</tr>
<tr>
<td>Referring Physician</td>
<td>Telephone</td>
</tr>
</tbody>
</table>

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind?  ☐ No ☐ Yes

If yes, please indicate the date and type of surgery:

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of surgery</th>
</tr>
</thead>
</table>

2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)?  ☐ No ☐ Yes

If yes, please list:

<table>
<thead>
<tr>
<th>Body part</th>
<th>Date</th>
<th>Facility</th>
</tr>
</thead>
</table>

3. Have you experienced any problem related to a previous MRI examination or MR procedure?  ☐ No ☐ Yes

If yes, please describe:

4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)?  ☐ No ☐ Yes

If yes, please describe:

5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)?  ☐ No ☐ Yes

If yes, please describe:

6. Are you currently taking or have you recently taken any medication or drug?  ☐ No ☐ Yes

If yes, please list:

7. Are you allergic to any medication?  ☐ No ☐ Yes

If yes, please list:

8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination?  ☐ No ☐ Yes

9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, or seizures?  ☐ No ☐ Yes

If yes, please describe:

For female patients:

10. Date of last menstrual period | Post menopausal?  ☐ No ☐ Yes

11. Are you pregnant or experiencing a late menstrual period?  ☐ No ☐ Yes

12. Are you taking oral contraceptives or receiving hormonal treatment?  ☐ No ☐ Yes

13. Are you taking any type of fertility medication or having fertility treatments?  ☐ No ☐ Yes

If yes, please describe:

14. Are you currently breastfeeding?  ☐ No ☐ Yes

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Please indicate if you have any of the following:

☑ Yes ☐ No Aneurysm clips
☑ Yes ☐ No Cardiac pacemaker
☑ Yes ☐ No Implanted cardioverter defibrillator (ICD)
☑ Yes ☐ No Electronic implant or device
☑ Yes ☐ No Magnetically-activated implant or device
☑ Yes ☐ No Neurostimulation system
☑ Yes ☐ No Spinal cord stimulator
☑ Yes ☐ No Internal electrodes or wires
☑ Yes ☐ No Bone growth/bone fusion stimulator
☑ Yes ☐ No Cochlear, otologic, or other ear implant
☑ Yes ☐ No Insulin or other infusion pump
☑ Yes ☐ No Implanted drug infusion device
☑ Yes ☐ No Any type of prosthesis (eye, penis, etc.)
☑ Yes ☐ No Heart valve prosthesis
☑ Yes ☐ No Eyelid spring or wire
☑ Yes ☐ No Artificial or prosthetic limb
☑ Yes ☐ No Metallic stent, filter, or coil
☑ Yes ☐ No Shunt (spinal or intraventricular)
☑ Yes ☐ No Vascular access port and/or catheter
☑ Yes ☐ No Radiation seeds or implants
☑ Yes ☐ No Swan-Ganz or thermodeflection catheter
☑ Yes ☐ No Medication patch (Nicotine, Nitroglycerine)
☑ Yes ☐ No Any metallic fragment or foreign body
☑ Yes ☐ No Wire mesh implant
☑ Yes ☐ No Tissue expander (e.g., breast)
☑ Yes ☐ No Surgical staples, clips, or metallic sutures
☑ Yes ☐ No Joint replacement (hip, knee, etc.)
☑ Yes ☐ No Bone/plate pin, screw, nail, wire, plate, etc.
☑ Yes ☐ No IUD, diaphragm, or pessary
☑ Yes ☐ No Dentures or partial plates
☑ Yes ☐ No Tattoo or permanent makeup
☑ Yes ☐ No Body piercing jewelry
☑ Yes ☐ No Hearing aid

☐ Yes ☐ No Other implant
☐ Yes ☐ No Breathing problem or motion disorder
☐ Yes ☐ No Claustrophobia

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.

IMPORTANT INSTRUCTIONS

Before entering the MR environment or MR system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clippers, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Signature of Person Completing Form: __________________________________________ Signature: __________________________ Date __________ / __________ / __________

Form Completed By: ☑ Patient ☐ Relative ☐ Nurse: __________________________ Print name: __________________________ Relationship to patient: __________________________

Form Information Reviewed By: __________________________________________ Print name: __________________________ Signature: __________________________

☒ MRI Technologist ☐ Nurse ☐ Radiologist ☐ Other: __________________________

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MAGNETIC RESONANCE (MR) ENVIRONMENT SCREENING FORM FOR INDIVIDUALS*

The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on.

*NOTE: If you are a patient preparing to undergo an MR examination, you are required to fill out a different form.

Date __/__/____ Name ____________________________ Age ______

Address ____________________________ Telephone (home) (____)____.

City ____________________________ Telephone (work) (____)____.

State ____________________________ Zip Code ____________

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? [ ] No [ ] Yes
   If yes, please indicate date and type of surgery: Date __/__/____ Type of surgery ____________________________

2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? [ ] No [ ] Yes
   If yes, please describe: ____________________________

3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? [ ] No [ ] Yes
   If yes, please describe: ____________________________

4. Are you pregnant or suspect that you are pregnant? [ ] No [ ] Yes

WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. Do not enter the MR environment or MR system room if you have any question or concern regarding an implant, device, or object.

Please indicate if you have any of the following:

[ ] Yes [ ] No Anorectal clips
[ ] Yes [ ] No Cardiac pacemaker
[ ] Yes [ ] No Implanted cardioverter defibrillator (ICD)
[ ] Yes [ ] No Electronic implant or device
[ ] Yes [ ] No Magnetically-activated implant or device
[ ] Yes [ ] No Neurostimulation system
[ ] Yes [ ] No Spinal cord stimulator
[ ] Yes [ ] No Cochlear implant or implanted hearing aid
[ ] Yes [ ] No Implant or infusion pump
[ ] Yes [ ] No Implanted drug infusion device
[ ] Yes [ ] No Any type of prosthesis or implant
[ ] Yes [ ] No Artificial or prosthetic limb
[ ] Yes [ ] No Any metallic fragment or foreign body
[ ] Yes [ ] No Any external or internal metallic object
[ ] Yes [ ] No Hearing aid (Remove before entering the MR system room)
[ ] Yes [ ] No Other implant ____________________________

IMPORTANT INSTRUCTIONS

Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

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 have had the opportunity to ask questions regarding the information on this form.

Signature of Person Completing Form: ____________________________ Date __/__/____

Form Information Reviewed By: ____________________________ Signature ____________________________

[ ] MRI Technologist [ ] Radiologist [ ] Other ____________________________

Appendix E: Checklist for MR Safety

Below is an outline of the topics that should be considered in the MR Safety checklist.

A. Establish, implement, and maintain current MR safety policies and procedures
   B. Static magnetic field issues: site access restrictions
      a. Zoning
      b. Safety infrastructure
         i. Signs
         ii. Labels
         iii. Floor markings
      c. MR and Non-MR Personnel
     d. Screening
        i. Patients
        ii. MR personnel
        iii. Devices and objects
C. MR safe practice guidelines for MR technologists
   a. Certification
   b. Training
D. Pregnancy related issues
E. Pediatric MR safety concerns
F. Time varying gradient magnetic field issues
   a. Induced voltages
   b. Auditory considerations
   c. Thermal considerations
G. Drug delivery patches and pads
H. Cryogen related issues
I. Claustrophobia, anxiety, sedation-analgesia, anesthesia MR safe practice guidelines
J. Contrast agent MR safe practices
K. MR safe practice guidelines regarding MR scanning of patients with intracranial aneurysm clips
L. MR safe practice guidelines regarding MR scanning of patients with cardiac pacemakers or implantable cardioverter defibrillators
M. Purchase and installation of MR Conditional equipment
   a. Patient monitors
   b. Ventilators
   c. Anesthesia machines