

**REPORT
OF THE DIAGNOSTIC
IMAGING SAFETY COMMITTEE FOR
MAGNETIC RESONANCE IMAGING
(MRI)**

February 2007

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EXECUTIVE SUMMARY

Magnetic Resonance Imaging (MRI) is extremely safe when used by trained professionals. Adverse effects and accidents related to MRI occur very rarely, yet MRI still poses certain safety hazards that are not obvious or intuitive, especially to those who are not familiar with MR technology. MRI adverse effects are immediate, and in the rare instances when they have occurred, some have resulted in serious physical injury or even death. This document is intended to provide guidance on the safe operation of MRI facilities in Ontario and should be reviewed and updated on a regular basis.

The objectives of this report are to describe how:

1. MRI facilities in Ontario will be *designed and constructed* in a manner that is conducive to the safe operation of the facilities, and that will reduce the risk of safety hazards to MR personnel, other health care workers, patients, and the general public;
2. MRI facilities in Ontario will be *operated, maintained and inspected* in a manner that will reduce the risk of safety hazards to MR personnel, other health care workers, patients, and the general public.

RECOMMENDATIONS

The Committee recommends that the province of Ontario put in place regulations and/or legislation as follows:

Design and construction

1. All MRI facilities shall be designed and constructed in a manner that recognizes the potential safety hazards associated with the area around an MR scanner. In particular, all MRI facilities shall restrict access to MR safety zones (Zones III and IV) to only MR personnel, patients and research subjects under the direct supervision of MR personnel, and appropriately trained MR research personnel. (See pages 9-10)
2. All proposals for new MRI facilities should be reviewed by the province of Ontario to ensure that their design and operation plans meet the criteria set out in this report, prior to receiving approval and licensing from the province.

Inspection

3. Upon completion of construction, the province should inspect the MRI facilities to ensure that they meet the criteria set out in this report, prior to approving the start of operations.
4. All MRI facilities shall be inspected for adherence to the policies and practices described in this report as soon as is possible after acceptance of this report, and then no less frequently than every five years thereafter. If a facility does not satisfy the policies and practices set forth in this report, the facility should be advised by the province to remedy its deficiencies or risk losing its MRI facility license.

Policies and procedures

5. Each MRI facility shall have an **MR Safety Officer** whose responsibilities will include ensuring that MR safe practice guidelines are established, implemented, maintained, and routinely reviewed and updated as necessary. (See pages 11-12)

6. The level of **compliance** of an MRI facility's staff to its MR safety policies and procedures shall be assessed and documented annually. This will be the responsibility of the facility's MR Safety Officer. The policies and procedures manual should be on site and readily available to MR professionals and to agents of the Ministry of Health and Long-Term Care or of other regulatory bodies at all times of operation.

7. MR safety policies and procedures shall be reviewed concurrently with the introduction of any significant changes to the safety parameters of the MR environment of the site and modified as needed. (See page 12)

8. Each MRI facility shall develop a **screening** process and a screening form for the purpose of ascertaining which workers, patients, or other members of the public are at risk from being in or near the MRI facility. (See pages 12-13)

9. Each MRI facility shall have procedures in place to ensure that any and all **adverse events** or MR safety incidents (or "near incidents") that occur in the facility are reported to the MR Medical Director or MR Safety Officer in a timely manner. (See page 13)

10. The province should develop a process to gather reports of adverse events and “near misses” from all MRI facilities in the province, and make these known on a regular basis across all Ontario MRI facilities. (See page 13)

Certification

11. MR scans of human patients and human research subjects shall be performed only by CMRTO registered MR technologists or by medical doctors with specific training in MR. If the latter, the medical doctor shall have training in MR safety that is at least equal to the MR safety training received by Level 2 MR personnel. Students in an accredited program may perform MR scans if they are under the supervision of a CMRTO registered MR technologist. MR scans of animals and/or inanimate objects may be performed by CMRTO registered MR technologists or by other appropriate medical, scientific, or service personnel, provided they have been adequately trained in MR safety.

MR safety zones

12. Each MRI facility shall have well demarcated MR safety zones (Zones III and IV) in and around the MR scanner room, wherein access by non-MR personnel is to be restricted by physical barriers. (See pages 14-17)

MR personnel

13. Each MRI facility shall train and designate Level 1 and Level 2 MR personnel. All other persons shall be designated as non-MR personnel. Non-MR personnel will be prohibited from gaining access to MR safety zones unless accompanied by MR personnel. (See pages 17-19)

Screening: humans

14. Each MRI facility shall develop and implement a screening process and screening form for patients and other non-MR personnel. In particular, policies and procedures must exist and be followed for: emergency response personnel such as police and firefighters; objects carried on or in the bodies of non-MR personnel; and the monitoring of patients' vital signs while they are in the MR scanner. (See pages 19-24)

Screening: devices and objects

15. Each MRI facility shall develop and implement a screening process for all devices and objects that may be introduced into MR safety zones. The MR safety or MR compatibility of any device or object must never be assumed. All unknown, external objects and devices must be tested and labelled before being brought into an MR safety zone. (See pages 24-27)

Other safety issues

16. Each MRI facility shall develop and implement policies concerning the following: pregnancy-related issues; time-varying gradient magnetic field-related issues; and cryogen-related issues. (See pages 27-29)

Public education

17. The province should produce public education materials that explain the basic function and design of MR scanners and the risks posed to those who are in or near such scanners, whether as patients, accompanying persons, or personnel. (See pages 29-30)

Standing committee

- 18.** The province should establish a standing committee comprising of MR experts such as doctors and technologists, as well as other stakeholders such as patients and policy makers, to examine periodically the evolution of MR technology and application, in order to advise and modify as necessary the recommendations in this report.

FULL REPORT

BACKGROUND

The Ontario Health Technology Advisory Committee (OHTAC) recommended that a study of the safety aspects of computed tomography (CT) and magnetic resonance imaging (MRI) be conducted. The Ministry of Health and Long-Term Care (MOHLTC) provided a research grant to the Healthcare Human Factors Group at the University Health Network (UHN) to investigate and provide safety recommendations on CT and MRI for OHTAC's consideration. Recommendations from the resulting two reports, covering CT and MRI safety, were endorsed by OHTAC. One of the recommendations was for MOHLTC to create a Diagnostic Imaging Safety Committee (DISC) for CT and MRI. The MR Safety Committee would be responsible for developing recommendations concerning standards and best practices for MR, including facilities' physical requirements, testing and inspection of MR scanners and facilities in Ontario, and education and training of relevant health care workers.

INTRODUCTION

Magnetic Resonance Imaging (MRI) is an established and very important diagnostic imaging method. MRI is widely used in Ontario, with approximately one hundred MRI facilities in the province. Several hundreds of health care professionals, scientists, engineers, and related health care personnel work in or near MRI systems in Ontario every day. Hundreds of thousands of

patients are examined with MRI in Ontario every year. Although MRI is extremely safe when used by trained professionals, and although adverse effects and accidents related to MRI facilities are very rare, MRI poses several safety hazards to workers and patients that are not obvious or intuitive, especially to those who are not familiar with MR technology.¹ This document is intended to provide guidance on the safe operation of MRI facilities in Ontario. It is also intended to be reviewed and updated on a regular basis as knowledge about MR safety continues to evolve and improve.

Adverse effects or accidents can occur with any medical imaging test. In radiology and medical imaging departments, the adverse effects that have attracted the most attention and regulation have been those related to cumulative and long-term exposure to ionizing radiation from tests such as radiographs, computed tomography (CT) scans, and radio-isotope scans (“nuclear medicine”). It is known that excessive doses of ionizing radiation are associated with an increased risk of developing cancer, which can occur many years after the exposure to the ionizing radiation. MRI does not use any ionizing radiation; hence, these same concerns do not apply to MRI. Indeed, the lack of ionizing radiation is one of several advantages of MRI over techniques such as CT scanning. However, the very strong magnetic fields that are an integral part of all MRI systems pose their own safety hazards. In contrast to the safety hazards associated with CT, which occur many years after the test is done, MRI adverse events are immediate. In the rare instances when they have occurred, some have resulted in serious physical injury or even death.

¹ The abbreviations MR and MRI mean Magnetic Resonance and Magnetic Resonance Imaging, respectively. MR is usually taken to encompass both Magnetic Resonance Imaging and Magnetic Resonance Spectroscopy (MRS), but in day-to-day use, and in this report, MR is used interchangeably with either of the terms MRI or MRS. This is common practice unless an important distinction is required, which is not the case in this report.

This report is not intended to be a comprehensive MR safety document. Rather, it is confined to an analysis of the immediate physical risks to workers and patients that are associated with the operation of MRI facilities, and to recommendations on the design and operation of MRI facilities to minimize these risks. The Committee recognizes there are concerns about possible long-term adverse effects related to exposure to MRI systems, but at the time of this report, no such long-term effects are known, and thus, the possibility of delayed, long-term adverse effects is not addressed. New knowledge may come to light in the future and the Committee reiterates that the recommendations in this report must be reviewed periodically. Furthermore, this report does not address the use of drugs, such as contrast agents, used in conjunction with MRI examinations. Like all pharmaceuticals, these drugs have their own adverse effects, which are usually independent of the MRI facility and the MRI scanning process. Recommendations for the safe use of such drugs and for the treatment of any adverse events related to their use are dealt with elsewhere in the medical and pharmaceutical literature.

This report refers extensively to the recommendations of the American College of Radiology (ACR) Guidance Document for Safe MR Practices, 2007 (also known as the ACR White Papers on MR Safety). The ACR White Papers are the result of extensive literature reviews and constitute the consensus opinion of a large group of respected MR safety experts. (insert footnote: ACR papers are in Appendix E?) This report differs from the ACR White Papers in that it is not as comprehensive in dealing with as many issues (e.g., the use of MRI contrast agents) and in that it is less prescriptive in its recommendations for the physical siting requirements for MRI facilities. This is intentional. The ACR document addresses a much wider readership and covers a wider range of facilities. There are over five thousand MRI facilities in the United States, situated in much more

diverse circumstances than what currently exists in the province of Ontario. Ontario has far fewer MRI facilities, which are much more uniform in their physical characteristics. In particular, the boundary line that is generally accepted as the one delimiting the potential risk of being too close to an MR scanner (the “5 Gauss line”) is inside the actual scanner room in almost all existing facilities in Ontario. Hence, the extensive discussion in the ACR White Papers devoted to defining MR safety zones outside the scanner room has little applicability to Ontario’s MRI facilities, and is therefore dealt with much more succinctly in this report.

OBJECTIVES

The objectives of this report are to describe how:

1. MRI facilities in Ontario will be *designed and built* in a manner that is conducive to the safe operation of the facilities, and that will reduce the risk of safety hazards to MR personnel, other health care workers, patients, and the general public;
2. MRI facilities in Ontario will be *operated, maintained and inspected* in a manner that will reduce the risk of safety hazards to MR personnel, other health care workers, patients, and the general public.

RECOMMENDATIONS

For the purposes of this report, it is intended that recommendations made to “Ontario” or to “the province of Ontario” be understood as being made to Ontario’s Ministry of Health and Long-Term Care or any other provincial body responsible for governing MRI facilities.

The Committee recommends that the province of Ontario put in place regulations and/or legislation as follows:

DESIGN AND CONSTRUCTION OF MRI FACILITIES

1. All MRI facilities (as defined in Appendix A) shall be designed and constructed in a manner that recognizes the potential safety hazards associated with the area around an MR scanner. In particular, all MRI facilities shall be designed in a manner that restricts access to MR safety zones to only MR personnel, patients and research subjects under the direct supervision of MR personnel, and appropriately trained MR research personnel.

The main physical risks near an MR scanner are twofold: 1) the risk of physical attraction of certain objects into the MR scanner; and 2) the risk of malfunction of certain biomedical devices that are sensitive to magnetic fields, such as pacemakers. The first situation can occur only in immediate proximity to an MRI magnet while the second can occur in the “fringe” field at some distance from the magnet. Consequently, a fringe field threshold of 0.5mT

[0.5milliTesla = 5 Gauss (G)] was established about 25 years ago as a conservative limit, several times smaller than the lowest magnetic field that could affect the most sensitive cardiac pacemaker. In the intervening years, biomedical instrumentation has generally become less sensitive to magnetic fields, but the 0.5mT (5 Gauss) threshold persists as a useful guideline for designing and constructing MRI facilities. Most existing facilities in Ontario contain the 0.5mT fringe field within the MR scanner room and this is the recommended practice. In some designs, it may be necessary that the fringe field outside the magnet room slightly exceed 0.5mT (up to 1mT), which is acceptable, provided that such facilities have appropriate precautions in place to limit the access of non-MR personnel to these fringe field areas.

Good design practice is to provide lockable physical barriers that prevent inappropriate access of hospital personnel, patients, and members of the public to all areas where the fringe magnetic field exceeds 0.5mT. Ideally, this objective would be achieved by shielding the MR scanner, the MRI room, or both, to ensure the 0.5mT fringe field is contained within the MR scanner room. In those circumstances where this cannot be achieved, physical barriers must be in place to prevent access to fringe field areas in the same manner as to the MR scanner room. All new MRI facilities should have the fringe field surveyed to ensure there is no risk of adverse events for the most susceptible biomedical devices.

APPROVAL, INSPECTION, AND ACCREDITATION OF NEW AND EXISTING MRI FACILITIES

2. The Committee recommends that all proposals for new MRI facilities be reviewed by the province of Ontario to ensure that their design and operation plans meet the criteria set out in this report, prior to receiving approval and licensing from the province.

3. Upon completion of construction, the Committee recommends that the province inspect the facilities to ensure that they meet the criteria set out in this report, prior to approving the start of operations.

4. The Committee recommends that every MRI facility in Ontario be inspected for adherence to the policies and practices described in this report as soon as is possible after acceptance of this report, and then no less frequently than every five years thereafter. If a facility does not satisfy the policies and practices set forth in this report, the facility should be advised by the province to remedy its deficiencies or risk losing its MRI facility license.

ESTABLISHMENT, IMPLEMENTATION, AND MAINTENANCE OF MR SAFETY POLICIES AND PROCEDURES

5. Each MRI facility shall have an MR Safety Officer whose responsibilities will include ensuring that MR safe practice guidelines are established, implemented, maintained, and routinely

reviewed and updated as necessary. It is also the responsibility of the MR Safety Officer, together with the site's administration, to ensure that the policies and procedures resulting from these MR safe practice guidelines are adhered to at all times by the site's personnel. The MR Safety Officer may be the same person as the facility's MR Medical Director, or these responsibilities may be carried out by two different people.

6. The level of compliance of an MRI facility's staff to its MR safety policies and procedures shall be assessed and documented annually. This will be the responsibility of the facility's MR Safety Officer. The policies and procedures manual should be on site and readily available to MR professionals and to agents of the Ministry of Health and Long-Term Care or of other regulatory bodies at all times of operation.
7. MR safety policies and procedures shall be reviewed concurrently with the introduction of any significant changes to the safety parameters of the MR environment of the site (e.g., an increase in MR scanner field strength; the placement of the MR scanner in a different location; modifications to the size or geometry of the scanner room) and modified as needed. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing local guidelines, policies, and procedures.
8. Each MRI facility shall develop a screening process and a screening form for the purpose of ascertaining which patients, workers, or other members of the public are at risk from being in or near the MRI facility. It is not the purpose of this report to prescribe the exact process for developing the screening form or its content. However, the Committee recommends that MRI

facilities use a standard screening process and screening form from a trusted, expert source, such as the ACR White Papers on MR Safety. (The ACR's screening form can be found in Appendix B.) The Committee advises that each facility consider making modifications to the standard screening process for each of the following types of persons ("special cases"):

- a. Children;
- b. Unconscious and other non-communicative persons;
- c. Persons who do not understand English (or the language in use at the MRI facility);
- d. Patients, accompanying persons, or health care workers who are pregnant; and
- e. MR personnel.

The development of the screening process and the screening form should be done under the direction of the MR Medical Director and MR Safety Officer. It is their responsibility to stay current with the MR safety literature, including but not limited to, safety alerts from Health Canada and the Federal Drug Administration (FDA).

9. Each MRI facility shall have procedures in place to ensure that any and all adverse events or MR safety incidents (or "near incidents") that occur in the facility are reported to the MR Medical Director or MR Safety Officer in a timely manner (e.g., within 24 hours or one business day of their occurrence). These reports are to be used in a continuous effort to improve quality *within institutions*.

10. With the intent of continuous quality improvement *across institutions*, Ontario should develop a process to gather reports of adverse events and “near misses” from all MRI facilities in the province, and make these known on a regular basis across all Ontario MRI facilities.

11. MR scans of human patients and human research subjects shall be performed only by College of Medical Radiation Technologists of Ontario (CMRTO) registered MR technologists or by medical doctors with specific training in MR. If the latter, the medical doctor shall have training in MR safety that is at least equal to the MR safety training received by Level 2 MR personnel. Students in an accredited program may perform MR scans if they are under the supervision of a CMRTO registered MR technologist. MR scans of animals and/or inanimate objects may be performed by CMRTO registered MR technologists or other appropriate medical, scientific, or service personnel, provided they have been adequately trained in MR safety.

MR SAFETY ZONES

12. Each MRI facility shall have well demarcated MR safety zones in and around the MR scanner room, wherein access by non-MR personnel is to be restricted by physical barriers.

The concept of MR safety zones is derived from the ACR White Papers. However, rather than defining four MR safety zones as the ACR document does, this report simplifies the concept and defines only two MR safety zones. In the interests of congruence with the ACR White Papers, the nomenclature for these two zones is retained as “Zone III” and “Zone IV”. Areas

that are not designated as Zone III or Zone IV equate with areas that have no barriers to physical access (i.e., general public areas).

Zone IV:

Zone IV is the MR scanner room itself. Zone IV must be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. Zone IV must be clearly marked with signage that indicates: “The magnet is on.”

Zone IV must always be in a fully enclosed space. All doors into Zone IV must have locks and must be locked any time Zone IV is not under the direct supervision of MR personnel.

In all MRI facilities, Level 2 MR personnel should have direct visual observation of access pathways into Zone IV. For example, MR technologists should be able to directly observe and control, via line-of-sight or via video monitors, the entrances or access corridors into Zone IV from their normal positions when stationed at their desks in the scan control room.

In the case of cardiac or respiratory arrest or of any other medical emergency arising within Zone IV for which emergent medical intervention or resuscitation is required, MR personnel should immediately remove the patient from the MR scanner room to a predetermined, magnetically safe location, prior to initiating any attempt at resuscitation. This is imperative because the magnetic environment in Zone IV may hinder safe resuscitative efforts. Once in a magnetically safe location, appropriately trained and certified MR personnel should initiate basic life support or CPR as required by the situation *and* call the arrest team. Zone III and IV

access restrictions *must* be maintained during resuscitations and other emergent situations for the safety of all involved.

Zone III:

Zone III is the area outside the actual MR scanner room in which free access by unscreened, non-MR personnel or by ferromagnetic objects or equipment can result in serious injury or death, as a result of interactions between the individuals or equipment and the MR scanner's particular environment. These interactions include, but are not limited to, those involving the MR scanner's static and time-varying magnetic fields.

For all intents and purposes, Zone III equates to the area within the 5 Gauss (5 G) perimeter line, because no harmful effects related to MRI have occurred outside the 5 G line. Almost all existing Ontario MRI facilities have the 5 G line contained within the MR scanner room itself, thus, under current Ontario conditions, the concept of Zone III as a potentially unsafe area outside the scanner room applies to only a few facilities. In these facilities, it is imperative that all access to Zone III be strictly restricted — with access controlled by, and entirely under the supervision of — MR personnel.

However, the fact that currently, most Ontario MRI facilities have Zones III and IV contained in the same physical parameters poses its own potential dangers. For example, it has come to pass that unaccompanied non-MR personnel have directly entered Zone IV (e.g., a patient who has just been scanned comes back into the MR scanner room to ask a question to the MR technologist still in the room) because the “buffer zone” of Zone III does not physically exist.

Therefore, the Committee recommends that all new MRI facilities be constructed with clearly delineated and restricted Zones III *and* IV.

Access to Zone III must be physically restricted from the general public by key locks, passkey locking systems, or any other reliable, physically restricting method that allows differentiation between MR personnel and non-MR personnel. The use of combination locks is discouraged due to combinations often becoming more widely distributed than initially intended, resulting in a greater likelihood of site restriction violations. Only MR personnel will be allowed free access and given access keys or passkeys to Zone III. There should be *no* exceptions to this guideline. Specifically, exceptions *should not* be made for hospital or site administration, or for medical, security, or other non-MR personnel.

Non-MR personnel are not to be allowed independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves. Zone III, or at least the area within it wherein the static magnetic field's strength exceeds 5 G, should be demarcated and clearly marked as being potentially hazardous.

Specifically identified MR personnel (typically, but not necessarily only, MR technologists) are responsible for ensuring that this MR safe practice guideline is strictly followed for the safety of patients and other non-MR personnel, of health care personnel, and of the MR equipment itself. This function of MR personnel is directly under the authority and responsibility of the MR Medical Director or of his/her delegate for the MRI facility.

MR PERSONNEL AND NON-MR PERSONNEL

13. Each MRI facility shall train and designate Level 1 and Level 2 MR personnel. All other persons shall be designated as non-MR personnel. Non-MR personnel will be prohibited from gaining access to MR safety zones unless accompanied by MR personnel.

All individuals working within at least Zone III of the MR environment must be documented as having successfully completed at least one of the MR safety lectures or pre-recorded presentations approved by the MR Medical Director or MR Safety Officer. Attendance should be repeated at least every three years, and appropriate documentation should be provided to confirm these ongoing educational efforts. These individuals are referred to as MR personnel.

Levels of MR personnel

There are two levels of MR personnel:

- a. Level 1 MR personnel: Individuals who have passed minimal safety educational programs to ensure their own safety as they work within Zone III are referred to as Level 1 MR personnel.

- b. Level 2 MR personnel: Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues (e.g., issues related to the potential for thermal loading or burns, and direct neuromuscular excitation from rapidly changing gradients) are referred to as Level 2 MR personnel. It is the responsibility of the MR Medical Director or

MR Safety Officer not only to identify the necessary training, but also to identify those individuals who qualify as Level 2 MR personnel. It is understood that the MR Medical Director and MR Safety Officer will have the necessary education and experience in MR safety to qualify as Level 2 MR personnel themselves.

MR technologist:

- i) MR technologists must be CMRTO registered technologists in MR. Furthermore, all MR technologists must be trained as Level 2 MR personnel during their orientation, prior to being permitted free access to Zone III or IV.
- ii) All MR technologists must maintain current certification in basic life support at the health care provider level.

Anyone other than Level 2 MR personnel who enters the MR scanner room (e.g., housekeeping or nursing staff) *must* be under the direct supervision of Level 2 MR personnel.

All individuals not having successfully completed MR safety training as outlined above are referred to as non-MR personnel. Specifically, the term “non-MR personnel” refers to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues as defined by the MR Medical Director of an MRI facility.

SCREENING

Patient and Non-MR Personnel Screening:

14. Each MRI facility shall develop and implement a screening process and screening form for patients and other non-MR personnel. Policies and procedures must exist and be followed for: emergency response personnel such as police and firefighters; objects carried on or in the bodies of non-MR personnel; and the monitoring of patients' vital signs while they are in the MR scanner. A sample screening form from the ACR appears in Appendix B.
- a. All non-MR personnel wishing to enter Zone III or IV must first pass an MR safety screening process. Only Level 2 MR personnel are authorized to perform an MR safety screen prior to permitting non-MR personnel into Zone III or IV.
 - b. The screening process and screening forms for patients, non-MR personnel, and MR personnel should be essentially identical. It should not be assumed that non-MR personnel, health care practitioners, or MR personnel would not enter the bore of the MR imager during the MRI process. Only MR technologists and MRI-trained physicians can perform the final safety screen of patients and of those entering the magnet room.
 - c. Non-MR personnel must be accompanied by, or be under the immediate supervision of and in visual and verbal contact with, one specifically identified Level 1 or Level 2 MR personnel for the duration of their time within Zone III or IV.

Level 1 MR personnel are permitted unaccompanied access throughout Zones III and IV. Level 1 MR personnel are also permitted to be responsible for accompanying non-MR personnel into and throughout Zone III, but *not* Zone IV. Level 1 MR personnel are *not* permitted to directly admit — or be designated responsible for — non-MR personnel in Zone IV.

In such events as a shift change or a lunch break, Level 2 MR personnel shall not relinquish their responsibility to supervise non-MR personnel still within Zone IV until such supervision has been formally transferred to another Level 2 MR personnel.

- d. Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices on or in their persons. Such items include watches, jewellery, pagers, cell phones, body piercings (if removable), contraceptive diaphragms, metallic drug delivery patches, cosmetics containing metallic particles (such as eye makeup), and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads. The Committee therefore advises MRI facilities to provide patients and research subjects with gowns or pants that have no metal fasteners for wear during the MRI procedure.
- e. The monitoring of the vital signs of patients in the MR scanner is sometimes necessary. The potential for thermal injury from excessive radiofrequency (RF) power deposition exists, especially in higher-field whole-body scanners (i.e., 1 T and above). Sedated, anesthetized, or unconscious patients may not be able to express symptoms of such injury. Accordingly,

each MRI facility must develop and use a vital signs monitoring policy based on best practice, or use the policies of an expert source such as the ACR White Papers on MR Safety.

- f. Entry into an MRI facility on an emergency basis by non-MR personnel, such as firefighters or police officers, requires special consideration. All MRI facilities must develop written policies detailing the procedures to be followed in such situations. Ontario MRI facilities may use the ACR White Papers guidelines (below) or a modification thereof. An example of such a protocol developed by an Ontario MRI facility can be found in Appendix C.

From the ACR White Papers:

For the safety of firefighters and other emergent services responding to an emergent call at the MR site, it is recommended that all fire alarms, cardiac arrests, or other emergent service response calls originating from or located in the MR site be forwarded simultaneously to a specifically designated individual from among the site's MR personnel. This individual should, if possible, be on-site prior to the arrival of the firefighters or emergent responders to ensure they do not have free access to Zone III or IV. The site might consider assigning appropriately trained security personnel, who have been trained and designated as MR personnel, to respond to such calls.

All MR sites should arrange to prospectively educate their local fire marshals, firefighter associations, and police or security personnel about the potential hazards of responding to emergencies in the MR scanner room. It should also be considered that yearly reminders or

education be provided to emergency personnel regarding location and layout of MR scanner rooms.

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

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

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

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

Device and Object Screening:

15. Each MRI facility shall develop and implement a screening process for all devices and objects that may be introduced into MR safety zones. The MR safety or MR compatibility of any device or object must never be assumed. All unknown, external objects and devices must be tested and labelled before being brought into an MR safety zone.
 - a. As part of the Zone III and IV site restrictions, which comprise equipment testing and clearing responsibilities, all MRI facilities should have an easily accessible, strong, handheld magnet (≥ 1000 G). This will enable MR personnel to test external — and even

some superficial internal — devices or implants for the presence of grossly detectable ferromagnetic attractive forces.

- b. The safety information or MR compatibility of any device must never be assumed. All unknown, external objects or devices being considered for introduction into Zone III or IV must be tested with a strong handheld magnet (≥ 1000 G) for ferromagnetic properties prior to permitting them entry into Zone III or IV. The results of such testing, as well as the date, time, name of the tester, and the methodology used for testing that particular device should be documented in writing. If a device has not been tested, or if its MR compatibility or safety status is unknown, it should *not* be allowed into Zone III or IV.
- c. All portable metallic or partially metallic devices that are on, or external to, a person wishing to enter Zone III or IV (e.g., oxygen cylinders) are to be positively identified *in writing* as non-ferromagnetic and either MR Safe or MR Compatible prior to permitting them into Zone III or IV. Examples of devices that need to be positively identified include fire extinguishers, oxygen tanks, and aneurysm clips.
- d. External devices or objects demonstrated to be ferromagnetic and MR Unsafe or MR Incompatible may still, under specific circumstances, be brought into Zone III or IV, *if* they are deemed by MR personnel to be necessary and appropriate for the care of the patient. Such devices should be brought into Zone III or IV only if they are under the direct supervision of designated Level 1 or 2 MR personnel who are thoroughly familiar with the devices, their functions, and the reasons supporting their introduction into Zone III or IV.

The safe use of these devices while they are present in Zone III or IV will be the responsibility of a specifically named Level 1 or 2 MR personnel member. The devices must be appropriately physically secured or restricted at all times during which they are in Zone III or IV to ensure that they do not inadvertently come too close to the MR scanner and accidentally become exposed to static magnetic fields or gradients, which might result in their becoming either hazardous projectiles or no longer accurately functional.

- e. All portable metallic or partially metallic objects that are to be brought into Zone IV must be appropriately labelled. The Committee recommends that medical and research institutions use the same MR safety labels across their various locations within Ontario, if applicable. For the purpose of labelling, testing metallic objects with a handheld magnet (≥ 1000 G) is to be performed by the site's MR personnel. If grossly detectable attractive forces are observed between a metallic object or any of its components and the handheld magnet, it is to be affixed with a red label. If no such forces are observed, the object is to be affixed with a green label prior to its introduction into Zone IV. For further details, the current standard for labelling can be found in Appendix C.

- f. Decisions based on published MR compatibility or safety claims should recognize that all such claims apply to specifically tested static field and static gradient field strengths. For example, "MR Compatible up to 3.0 T at gradient strengths of 400 G/cm" or "MR Safe tested up to 1.5 T up to maximum static gradient fields experienced in an unshielded 1.5 T [manufacturer name] whole-body MR scanner tested 1.5 feet within the bore."

- g. It should be noted that any alterations made to MR Safe or MR Compatible equipment or devices may alter the MR safety or compatibility properties of the device or equipment. For example, tying a ferromagnetic, metallic, twisting binder onto a sign labelling a device as MR Compatible might result in artifact induction — or worse — if the device is introduced into the MR scanner.

OTHER SAFETY ISSUES

16. Each MRI facility shall develop and implement policies concerning the following: pregnancy-related issues; time-varying gradient magnetic field-related issues; and cryogen-related issues.

Pregnancy-Related Issues:

MRI facilities should develop and implement a written policy concerning:

- pregnant health care practitioners working in the MR environment;
- the imaging of pregnant patients; and
- the admissibility of pregnant accompanying persons into the MR scanner room.

This policy should include a statement on whether informed consent is to be obtained from such persons. The content of the policy should be based on a trusted, expert source of MR safety information, such as the ACR White Papers on MR Safety.

Time-Varying Gradient Magnetic Field-Related Issues – Auditory Considerations:

All patients, accompanying persons, and research subjects should use hearing protection while undergoing imaging in the MR scanner or while in the MR scanner room as image acquisition is underway.

Cryogen-Related Issues:

For superconducting systems, in the event of a system quench, it is imperative that all personnel and patients be evacuated from the MR scanner room as quickly and as safely as possible, and that access to the site be immediately forbidden to all individuals until the arrival of MR equipment service personnel. This is especially important if cryogenic gases are observed to have vented partially or completely into the MR scanner room, as evidenced in part by the sudden appearance of white “clouds” or “fog” around or above the MR scanner. Furthermore, all police and fire response personnel must be restricted from entering the MR scanner room with their equipment (e.g., axes, air canisters, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, because despite a quench or partial quench of the magnet, there may still be considerable static magnetic field present.

Most, if not all, MR scanner rooms in Ontario have multiple safety mechanisms, including emergency pressure vents, in place to provide for the emergency venting of cryogenic gases. In addition, the regular room ventilation system is capable of dissipating the gases, albeit not as quickly as the emergency vent. Similarly, most facilities have wave-guides that provide an

additional venting conduit. An outwardly opening scanner room door is a further safety valve, but given the presence of other venting conduits, an out-swing door is not essential in and of itself for gas-venting safety purposes. Lastly, an in-room oxygen detector may be considered as an additional safety measure. If this option is chosen, such a monitor must be regularly maintained once it is installed.

EDUCATION MATERIALS FOR HEALTH CARE WORKERS, PATIENTS, AND THE GENERAL PUBLIC

17. The Committee recommends that the province produce public education materials that explain the basic function and design of MR scanners and the risks posed to those who are in or near such scanners, whether as patients, accompanying persons, or personnel.

Patients and General Public:

A critical component of safety and of effective health care is the active engagement of patients and their families in their own care. However, in general, patients, their families, and the general public are relatively unaware of the safety issues related to the use of MRI. The Committee believes it would be valuable for the province to produce some concise, clear, and simple public education materials that explain the basic function and design of MR scanners and the risks associated with being in or near such scanners. These materials could include tips and advice for MRI patients and their accompanying persons. For example, a question such as the

following may be included: “Do you know if you have a metal implant in your body? — Find out if it is MR Safe. If it is not, consider carrying a note in your wallet to indicate the presence of implants in your body.”

Health Care and Other Workers:

Most safety issues related to MRI will have an impact on anyone in the direct MR environment, including health care and other workers. While most MRI facilities have a screening process in place, there is no way to ensure full disclosure on the part of all health care workers regarding implants or other devices they may have in their bodies. The Committee believes it would be valuable for the province to develop educational materials for workers in MR environments, explaining the risks associated with MRI and why disclosure of certain information would help ensure their safety.

All educational materials should be developed through a collaborative effort by appropriate organizations, MR experts, health care professionals, and consumers.

STANDING COMMITTEE

18. The Committee recommends that the province establish a standing committee comprising of MR experts such as doctors and technologists, as well as other stakeholders such as patients and

policy makers, to examine periodically the evolution of MR technology and application, in order to advise and modify as necessary the recommendations in this report.

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APPENDIX A: DEFINITIONS

PERSONNEL DEFINITIONS

Non-MR Personnel

Patients, visitors, or facility staff who do not meet the criteria of Level 1 or Level 2 MR personnel will be referred to as non-MR personnel. Specifically, non-MR personnel will be the term used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR Medical Director or MR Safety Officer of a particular MRI facility.

Level 1 MR Personnel

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

Level 2 MR Personnel

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

MRI FACILITY DEFINITION

For the purposes of this report, an MRI facility is defined as one that operates an MR scanner of field strength $\leq 4T$ for the purpose of imaging human beings or other large animals. Normally, the MR scanner would be approved by Health Canada.

ZONE DEFINITIONS

Zone IV

This is the MR scanner magnet room itself. Zone IV, by definition, is always located within Zone III; it comprises the MR magnet and its associated magnetic field, which generates the existence of Zone III.

Zone III

This is the area outside the actual MR scanner room in which free access by unscreened non-MR personnel or by ferromagnetic objects or equipment can result in serious injury or death, caused by interactions between the individuals or equipment and the MR scanner's particular environment. These interactions include, but are not limited to, those involving the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV) controlled by, and entirely under the supervision of, MR personnel. For all intents and purposes, Zone III equates to the area within the 5 Gauss perimeter line.

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

Level 1 and 2 MR personnel may move freely about both Zones III and IV.

APPENDIX B: LABELING

MR Safe

The term MR Safe, as defined in the American Society for Testing and Materials (ASTM) standard, can be applied to “an item that poses no known hazards in all MR environments.” The ASTM definition notes “MR Safe items include non-conducting, non-magnetic items such as a plastic Petri dish.” The definition further states that “an item may be determined to be MR Safe by providing a scientifically based rationale rather than test data” (ASTM F2503-05).

Unlike the previous “MR safe” term, which could be applied even if a device was found to be safe only under specific conditions, the new MR Safe term means safe — without exception — regardless of magnet strength or any other field conditions.

The icon for MR Safe consists of the letters “MR” inside a green square. Two possible versions are shown in the figure. Items marked with an MR Safe icon can be taken into any MR environment — and placed or used anywhere within that environment — without risk.

MR Conditional

The ASTM standard specifies that the term MR Conditional be used for the following: “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 (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required” (ASTM F2503-05). (Note: SAR values would not be needed for devices that don’t go inside the bore of the scanner.)

The MR Conditional label is used to alert the user that there are limitations to the testing that has been performed on the item or that there are limits to the safe use of the device in a particular MR environment. For example, the device may have been tested at 1.5 T, but not at 3 T. Users must compare all the conditions under which the item was tested to the characteristics of their own MR system to determine if the item can be safely used in their MR environment. Items with the MR Conditional label will often have gauss-line restrictions or RF pulse-sequence limitations.

The icon for MR Conditional consists of the letters “MR” inside a yellow equilateral triangle, as shown in the figure.

MR Unsafe

ASTM specifies that the term MR Unsafe be used for the following: “An item that is known to pose hazards in all MR environments.” The standard notes “MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors” (ASTM F2503-05).

The icon for MR Unsafe consists of the letters “MR” inside a red circle with a red diagonal line over top of the letters, as shown in the figure. Unless there is an overriding need to do so, an item with this label should not be allowed in any MR environment.

One might question the usefulness of this term and icon. After all, it is unlikely that a manufacturer of ferromagnetic scissors, for example, would place this label on its product. However, a facility may find it helpful to apply this label itself to devices that it has determined to be unsafe for use in its MR environment. For example, an MR Unsafe label could be applied to devices that the facility has tested with a handheld magnet and found to be ferromagnetic.

APPENDIX C: EXAMPLE OF EMERGENCY PROTOCOL

DEPARTMENT OF DIAGNOSTIC IMAGING SAFETY PROCEDURE

EMERGENCY PROCEDURE FOR OPERATIONAL HOURS

EMERGENCY SHUTDOWN PROCEDURE

1. Only activate the Emergency Shutdown button if patient, personnel or equipment are in danger:
 - In case of fire (refer to Fire Safety Policy)
 - In case of electrical power accidents
 - In case of flood affecting the control, magnet and/or computer room
2. Location of the Emergency Shutdown button:
 - In the MRI scanner room next to the door below the Magnet Stop button
 - In the cabinet/computer room to the left of the electrical panel
3. If an emergency situation develops, bring the patient to a secure area and then activate the Emergency Shutdown button. **Be aware that the magnet is still on – the shutdown does not affect the magnet.** Therefore, metal objects (e.g., crash cart) cannot be taken into the MRI scanner room and anyone entering the scanner room will have to be screened with the MRI safety questionnaire.

EVACUATE THE MRI UNIT

FIRE EMERGENCY PROCEDURE FOR AFTER HOURS

DUE TO THE EXISTENCE OF VERY STRONG MAGNETIC FIELDS INSIDE THE SCANNER ROOM, THERE IS SIGNIFICANT RISK OF INJURY TO ANYONE NOT FOLLOWING PROPER PROCEDURE WHEN ENTERING THE SCANNER ROOM.

THE MAGNETIC FIELD IS ALWAYS ON! The MRI magnetic field will not be switched off by turning off the power. In case of emergency, it is possible to turn off the magnetic field by quenching the magnet (see below).

Note: Quenching the magnet should only be done in an emergency since the magnetic field is not easily turned back on.

THE MAGNET IS VERY POWERFUL. No one should enter the scanner room wearing or carrying anything metal unless the magnet has been quenched.

NO ONE IS TO ENTER THE MRI SCANNER ROOM UNTIL THEY HAVE BEEN PRE-SCREENED BY MRI PERSONNEL.

The magnet is strong enough that it may be unsafe for certain individuals to enter the magnetic field. Screening of anyone entering the scanner room is mandatory to ensure their safety.

It is recommended that all Ottawa fire fighters who work close to The Ottawa Hospital be pre-screened by an MRI technologist annually to ensure their safety.

PROCEDURE TO BE FOLLOWED IN CASE OF FIRE AFTER HOURS:

If there is a need to enter the MRI scanner room, call the MRI technologist on-call through locating XXX-XXXX

If there is a fire in the MRI scanner room and it is imperative to enter the room as soon as possible, follow these instructions carefully:

The Safety Officer or a member of the fire department is to quench the magnet using the MAGNET STOP (QUENCH) button located in the alarm box next to the doorway in the control room. (Diagram will be attached.)

The quench will reduce the magnetic field to less than 0.5 mT in ___seconds.

IT IS ONLY AFTER THIS TIME THAT ANYONE CAN ENTER THE MRI SCANNER ROOM WITHOUT BEING SCREENED BY MRI PERSONNEL.

In the control room next to the doorway there is a RED BOX. In it there are two keys. One is for the MRI scanner room and the other is for the high voltage cabinets located in the back room adjacent to the waiting room. Use this key to enter the scanner room if the door is locked.

Activate the Emergency Shutdown button. This button is located in the MRI scanner room next to the door below the Magnet Stop button.

Contact the DI personnel fan-out list. This can be done through telecommunications.

Fan-out list:

PRECAUTIONS:

A magnet quench will cause hundreds of litres of liquid helium to boil off in a few seconds. The helium gas should go directly into the quench exhaust line during the quench but if the exhaust system malfunctions helium gas could enter the scanner room. This could reduce the amount of oxygen in the room to dangerously low levels. The oxygen monitor will sound an alarm if the oxygen level in the scanner room drops below 140 ppm. The helium gas is also extremely cold and the danger of frostbite exists if enough helium gas has accumulated in the scanner room.

In the cupboard in the back of the MRI scanner room there are phantoms containing nickel sulphate (consult WHMIS sheet).

FIRE EMERGENCY PROCEDURE FOR OPERATIONAL HOURS

PROCEDURE TO BE FOLLOWED IN CASE OF FIRE DURING OPERATING HOURS:

1. Activate the fire alarm.
2. Evacuate the MRI unit.
3. If, in the opinion of the MRI staff, the fire can be extinguished, use the white and blue *MRI Compatible* fire extinguisher located beside the magnet room door. If the fire is inside the scanner room this is the only fire extinguisher that can be safely used (unless the magnet has been quenched).

Under no circumstances are MRI staff to place themselves in unnecessary danger.

4. If the fire was unsuccessfully extinguished or no attempt could be made to put the fire out or the fire is outside the scanner room, close the magnet room door.
5. If the fire is inside the scanner room, quench the magnet by activating the MAGNET STOP (QUENCH) button (consult the Magnet Stop procedure). The quench will reduce the magnetic field to less than 0.5 mT in ____ seconds.

Note: Quenching the magnet should only be done in an emergency since the magnetic field is not easily turned back on. If the fire can be extinguished **SAFELY** without quenching the magnet, this should be attempted first. If there is any doubt about safety then the magnet should be quenched.

DURING OPERATIONAL HOURS

MAGNET STOP (QUENCH) PROCEDURE

1. Only activate the MAGNET STOP button:

In order to save someone from an emergency situation in the magnetic field
In case of a fire (refer to Fire Emergency Procedure)

Note: Quenching the magnet should only be done in an emergency since the magnetic field is not easily turned back on.

2. Location of the MAGNET STOP button:

In the control room in the alarm box next to the doorway
In the MRI scanner room next to the door

3. The magnetic field at the centre of the magnet will be reduced to 20 mT in approximately 20 seconds. At this point the magnetic field strength outside the yellow and black tape on the floor is low enough that it will not pose a safety risk to anyone. However, the field inside this region could still be hazardous to certain individuals. Therefore, anyone entering the MRI scanner room must still be screened with the MRI safety questionnaire.

4. To reduce the magnetic field to less than 0.5 mT it will take ___ seconds. Only after this time can anyone enter the MRI scanner room without being screened.

5. Activate the Emergency Shutdown button. This button is located in the MRI scanner room next to the door below the Magnet Stop button.

PRECAUTIONS:

During a quench the helium gas should boil off into the exhaust line but if this system malfunctions some of the helium gas could get into the scanner room. This could reduce the amount of oxygen in the room to dangerously low levels. The oxygen monitor will sound an alarm if the oxygen level in the scanner room is below 140 ppm. The helium gas is also extremely cold and the danger of frostbite exists if enough of the helium gas has accumulated in the magnet room.

In the cupboard in the back of the MRI scanner room there are phantoms containing nickel sulphate (consult WHMIS sheet).