FAU
FLORIDA ATLANTIC UNIVERSITY

Division of Administrative Affairs

Environmental Health and Safety
Policy #MAN15
FAU MRI Safety Manual

Version #1.0

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1. PURPOSE:

Cover page for FAU MRI Safety Manual

2. CONTENTS:

FAU MRI Safety Manual 23 pages.

Approved and issued by order of:

Stacy Volnick, PhD
Vice President, Administrative Affairs
Interim President, Florida Atlantic University

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POLICY MAINTENANCE SECTION

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FLORIDA ATLANTIC UNIVERSITY

ENVIRONMENTAL HEALTH AND SAFETY

MRI Safety Manual

Florida Atlantic University

Office of Environmental Health and Safety

January 2024

1. Table of Contents

1. INTRODUCTION

Magnetic Resonance (MR) Imaging is an ever changing, evolving technology. There are potential risks in the MR environment, not only for the research participants but also for the facility support staff, researchers, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security, housekeeping personnel, firefighters, police, etc. This manual has been developed to help guide the MR staff regarding these issues.

It is the intent of the MRI Safety Manual to:

- Protect and educate all subjects/patients, direct and ancillary personal about the possible risks, associated with the MR Facility including but not limited to static, time-varying magnetic fields and radio frequency (RF) pulses.

- To be in compliance with the most up to date MR safety information provided by the Joint Commission and the American College of Radiology (ACR).

- Prove helpful as the field of MRI and research using MRI continues to evolve and mature.

The MRI Safety Program is administered by the MRMD, the MRI Safety Committee, and the Office of Environmental Health and Safety. This manual has been developed as part of the overall FAU MRI Safety Program. The policies written in this manual are required as a standard of care at FAU. It is at the discretion of the MRMD to divert from any policy in an emergency. Please refer to the section on "Exemptions" for further detail.

All MRI equipment housed in facilities owned/leased by FAU must comply with the safety practices and procedures outlined in this manual.

The policies and procedures identified herein form the basis for several policies and procedures that must be developed and maintained by each MRI Facility. Reference Section 5 for more information.

2. KEY PERSONNEL

Role	MRI Facility	Company/Title/Person	Location	Email and Cell Phone
MRI Medical Director	Building 71 - CRU	FAU MRI Medical Director Dr. Andrew Newburg	Boca Raton	anewberg@health.fau.edu; 610-308-7319
MRI Physicist	Building 71 - CRU	FAU MRI Physicist TBD	Boca Raton	TBD
MRI Technologist	Building 71 - CRU	FAU MRI Technologist Tal Fuchs	Boca Raton	tfuchs@health.fau.edu 561-906-7227

Role	MRI Facility	Company/Title/Person	Location	Email and Cell Phone
Service Contractor	Building 71 - CRU	GE Account Imaging Manager	Remote	Beau Konz 561-214-5020
EH&S Contact	Building 71 - CRU	FAU Assistant Director EH&S Bill Ware	Boca Raton	Warew@fau.edu (561) 213-3056
Building Manager	Building 71 - CRU	FAU Director, Building Operations Debra Bradley	Boca Raton	dbradley@health.fau.edu 561-926-1889

3. ADMINISTRATION AND RESPONSIBILITIES

MRI safety is a cooperative effort between Florida Atlantic University, its employees, students, volunteers, research participants, and affiliate organizations. The MRI Medical Director, MRI Technologists, MRI physicist, EH&S, the MRI Safety Committee, faculty, staff and students all must work in concert to minimize the risk of exposure, injury or illness associated with activities involving the use of MRI at FAU.

For the purposes of this plan, the specific job roles and responsibilities are described below. Qualified persons can hold more than one role.

3.1. MRI Medical Director

This role serves as the Medical Director (Magnetic Resonance Medical Director or MRMD) for the MRI Facility(s). This responsibility will be assumed by a physician/radiologist, licensed in the State of Florida, with appropriate training in MR safety. This role assumes overall and ultimate responsibility for MR facility operational safety. The Medical Director shall ensure, at all times, either in person or via delegation to another qualified individual, the satisfactory performance of the following responsibilities:

1. Must obtain ACR MRMD certification
2. Ensures safe execution of all MR operations
3. Appoints an MRSO and MRSE
4. Develops, implements, and maintains required policies and procedures pertaining to the safe operation of MRI
5. Approves training programs for Level I and Level II personnel.
6. Implements and maintains appropriate MR safety and quality assurance programs
7. Develops and maintains an appropriate system for record keeping and analysis of adverse events (with the MRSO and MRSE as needed)
8. Develops an appropriate ongoing assessment of risk for the facility
9. Develops an appropriate investigation and recording of all reported MR safety adverse events.
10. Serves as chair of the MRI Safety Committee

11. Assures compliance with the recommendations of the MRSE

3.2. MRI Technologist

This role serves as the MRSO (Magnetic Resonance Safety Officer) and oversees safety practices within MRI Facility at all times. The MRSO responsibilities include

1. Must obtain ACR MRSO certification
2. Ensuring accessibility at all times to the operators of active MR facilities
3. Ensuring that proper policies and procedures of the MRMD are implemented and enforced on an ongoing basis
4. Development, documentation, and execution, in conjunction with and under the authority of the MRMD, of safe working procedures for the MR environment
5. Ensuring that adequate written safety procedures, emergency procedures, and operating instructions are issued, in consultation with the MRMD and MRSE as needed
6. Ensuring the implementation and monitoring of appropriate measures for minimizing risks to staff and subjects/patients, in cooperation with the MRMD
7. Managing hazards posed by the MR equipment and monitoring the measures taken to protect against such hazards
8. Ensuring, in cooperation with the MRMD, that medical, technical, nursing, emergency, and all other relevant staff groups (including ancillary workers) who may be exposed to the MR environment are educated appropriately and updated as necessary as to MR safety requirements
9. Providing and/or ensuring the provision of MR safety education and training in cooperation with and as per the policies of the MRMD and maintaining records of personnel education
10. Consulting the MRMD and/or MRSE when further advice is required regarding MR safety
11. Reporting back to the MRMD in a timely fashion all MR safety-related issues
12. Ensuring that there is a clear policy for purchasing, testing, and clearly marking of all equipment that will be taken into Zones III and IV
13. Providing safety advice on the modification of MR protocols (in cooperation with the MRMD and/or MRSE) if/as needed
14. Maintaining regular contact with other relevant groups or committees responsible for the safety and welfare of personnel on site
15. Providing expertise in root cause analyses, solutions meetings, etc, related to MRI adverse events
16. Participates on the MRI Safety Committee

3.3. MRI Physicist

This role is held by a qualified Magnetic Resonance Safety Expert or MRSE. This individual is expected to serve as a resource for the MRI Medical Director and MRI Technologist for nonmedically related MR safety issues (ie, issues other than contrast agents, anxiolytics, and other pharmaceuticals). The MRSE responsibilities include

1. Must obtain ACR MRSE certification.
2. Providing advice on the engineering, scientific, and administrative aspects of the safe use of MR equipment, which includes quantification assistance for energy, force, and risk exposures;

3. Providing advice on the development and continuing evaluation of a safety framework for the MR environment;
4. Providing advice for the development of local rules and procedures to ensure the safe use of MR equipment;
5. Providing safety advice regarding nonroutine MR procedures, which includes advice regarding safety related to implanted devices and other similar issues;
6. Providing advice on the choice of MR Safety programs and MR Quality Assurance programs, evaluations, and audits;
7. Providing safety advice regarding equipment acceptance testing;
8. Establishing and maintaining links with appropriate regional and professional bodies and reporting back to the MRMD and MRSO on safety-related issues; and
9. Providing expertise in root cause analyses, solutions meetings, etc, related to MRI adverse events.

3.4. Environmental Health and Safety (EH&S)

EH&S provides services, advice, and compliance assistance to ensure employees, students and visitors follow safe work practices. The MRI Safety Program within EH&S monitors compliance with University safety policies and procedures regarding the use of MRI at FAU. The Director of EH&S has overall responsibility for environmental, health and safety programs at FAU, including enforcement of the MRI Health and Safety Program requirements.

3.5. MRI Safety Committee

The MRI Safety Committee (MRISC) is administered by the Office of Environmental Health and Safety. The committee is charged by the Vice President for Administrative Affairs to oversee compliance with policy and procedures related to the use of MRI at FAU, including approval of research protocols utilizing the FAU MRI Facility.

3.6. Principle Investigators/Employees/Students

Individuals granted access to the MRI Facility are responsible for compliance with all safety practices and procedures required for work inside the Facility.

4. GENERAL MRI SAFETY PROGRAM REQUIREMENTS

4.1. Personnel Designations and Required Training

Personnel are placed in one of four categories to clarify who will have access to the MRI Facility and who has decision making responsibility in ambiguous cases.

Every person entering Zones III and IV must be screened to determine personal risk for entering the MR environment. The method of screening will vary as described below.

MRI safety training will vary with each individual's level of security clearance. All training will be through online learning modules with online examinations and must be renewed at appropriate intervals such that it does not expire. The following are the personnel categories and screening/training requirements:

4.1.1. Non-MR personnel

Includes:

- Research participants
- General FAU staff, faculty, and students
- Housekeeping and maintenance staff
- Visitors
- Family/escorts of research participants
- Vendor representatives
- Inspectors

Screening:

- Must be supervised/escorted for access into Zone III or IV
- MUST be screened (medical questionnaire and metal screening) each time they enter Zone III.
- MUST be screened by at least one Level II MR personnel face-to-face with written documentation of screening

Training:

None required

4.1.2. Level I MR personnel:

All staff working in the MR environment with access to controlled areas.

Includes:

- All MRI support staff
- Police Department
- EH&S
- Researchers with MRI protocols
- MRI Service Vendors
- Comparative Medicine Staff

Screening:

- Clinical screening refers to the evaluation of medical, neurological, and psychological aspects of a subject/patient's health and must be done prior to each entry into Zone III
- Metal Screening refers to the evaluation of any metal that might be in or on a subject/patient's body that would prevent them from safely entering the MRI environment and must be done prior to each entry into Zone III

Training:

Completion of the current online Basic MRI Level I Safety training module annually.

4.1.3. Level II MR personnel:

Includes:

- MRI Technologist
- MRI Medical Director
- MRI Physicist
- Members of the MRI Emergency Response Team
- Anyone required to work in Zone IV

Screening:

Same as Level I

Training:

Completion of the current online MRI Level II Safety training module annually.

4.1.4. Level III MR personnel:

- These individuals have decision-making power in ambiguous cases.

Includes:

- MRI Medical Director
- MRI Physicist

Screening:

- As for Level I

Training:

MRI Medical Director and the MRI Physicist with extensive knowledge of and experience with MRI and those who have completed further training for MRI credentials of MRMD and MRSE respectively.

4.2. Safety/Security Zones

The MRI Facility is divided into four safety zones as indicated on the floorplan of the facility. These zones are labelled I-IV, and each zone is progressively more restrictive.

Zone I: Outside the MRI Facility. Unrestricted access.

Zone II: The minimally secured, interface area between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Subjects/patients are greeted, registered, and screened in Zone II.

Zone III: Control Room. Secure areas immediately adjacent to Zone IV. “If you can walk over and touch the door to Zone IV, you are within Zone III” Only Level I or higher MRI personnel may enter unaccompanied. Secured by card access system. Only Level I or

higher personnel may hold cards coded to open these doors. Doors to have automatic closing and locking devices.

Zone IV: The MR scanner magnet room. Secured by card access system or controlled key lock. Only Level II or higher MRI personnel may enter unaccompanied. Doors to have automatic closing and locking devices. Only MR personnel are provided free access, via methods such as the access card or keys or, to Zone III.

Zone	**Activity**	**Personnel Designation**
I	Non-MRI Specific activities	Non-MR Personnel
II	Limited access control Participant Interviews Clinical Screening Metal Screening Participant Gowning Animal Transfer Area Ferrous Quarantine Storage Medical staging (emergency response)	Those officially supporting or participating in operation of the MR Facility.
III	Strict Access Control Screened prior to entry Situational Awareness MR Conditional/Safe devices only 5-gauss line	Level II or higher unescorted Only MR personnel can provide escort to others in Zones III and IV.
IV	Strict Access Control Screened prior to entry Harmful aspects of magnetic field Cryogen hazards MR Conditional/Safe devices only Infection Control Practices	Level II or higher unescorted.

4.2.1. Site Access and Restrictions

4.2.1.1. General

Access control is required <u>at all times</u> for Zones II-IV. The purpose of controlling access to the magnetic environment is to prevent injury, which could be fatal, to individuals entering the area. Access control also prevents damage to equipment due to the ever present and uncontrollable attraction of objects within the magnetic field of the scanner.

4.2.1.2. Access Points

- The door to Zone IV must be closed and locked when no one is within the immediate control room.
- The doors leading to Zones II and III must be closed and locked when not withing the immediate line of sight of MR personnel
- Failed access control points or other security breaches in Zones II through IV must be reported to EH&S immediately.

4.2.1.3. Personnel

- MRI Safety Training must be completed before an individual is granted badge access to the MRI area or hallway.
- MRI Safety Training must be completed before an individual is allowed unescorted into Zone IV.
- Training is verified and approved by the MRMD and MRI Safety Committee prior to granting access.
- Individuals who have not completed MRI Safety Training must be escorted and supervised at all times while in the MRI area.

4.2.1.4. Research Subjects

- Individuals who are participating in research studies must undergo MRI Safety screening BEFORE entering Zone III. Animals must also be screened to exclude any metal that might injure the animal or damage the MRI scanner/facility.

4.2.1.5. Equipment

- Equipment must be approved by the MRI Medical Director prior to use for a research study, or entry into the magnetic environment.
- The MRI scanner will be maintained to ensure its optimal imaging performance and safety by the Medical Director.
- ONLY MR safe equipment or MR Conditional equipment (provided that all conditions are met), may be brought into Zone IV. If a ferromagnetic device must be used within Zone IV, it must be installed or secured in place by qualified personnel as designated by the Medical Director for MRI Services. The installation of such a device must be completed before any research subject is allowed to enter the room. No such unsecured device may be introduced into Zone IV while a research subject is within Zone IV
- Medical device (e.g., ventilator, implant) safety must be based on manufacturer's FDA approved usage, not on local testing of devices. Only in exceptional circumstances would a medical device be tested on site as approved by the MRMD and/or MRISC.

- Testing:
    - Implants: NO on-site testing for MR compatibility is permitted. Only the manufacturer's statement of safety will be relied upon.
    - Equipment: A strong hand magnet (>0.1 Tesla) can be used to test new equipment. Testing of equipment with a hand magnet must ONLY be performed by personnel appropriately trained and credentialed to know how to perform testing and how to interpret the results of testing. These personnel include Level III MR personnel. The hand magnet itself is a significant safety hazard, which could lead to equipment damage, serious injury or death if it were inadvertently brought near the magnetic field. Therefore, the magnet is kept secured and is not available in the MRI Facility (Zones III and IV).
    - If a device/equipment leaves MRI Facility for repair/service, it must be tested/verified again for MR safety and labeled appropriately before it is introduced in the MR Facility.
    - If the MR safety of an object is unclear or in dispute, Level III MR personnel must make the determination as to safety. If there is any doubt as to safety, err on the side of caution.
- Within Zones III and IV, ALL equipment, regardless of size, must be labeled "MR Safe", "MR Unsafe" or "MR Conditional" using ASTM approved symbols. Equipment that is permanently fixed in place is exempt from this requirement.
- Use of equipment in Zone III and Zone IV.
    - MR safe equipment – MRI safe models of basic medical equipment can be used and kept in MRI controlled Zones (III and IV) (for example, stethoscope, sphygmomanometer, scissors, ambu bag and mask, physiologic monitoring equipment).
    - Only MR Conditional fire extinguishers may be brought into and kept within Zones III and IV.
    - MR Conditional equipment – All MRI conditional equipment located in Zone III and Zone IV that is not permanently fixed in place must be listed in a log, which specifies the device and the associated conditions for safe use. This log will be available within the MRI Facility.
- Ventilators, anesthesia machines, physiological monitors, power injectors and infusion pumps:
    - Only devices manufacturer-certified and FDA-approved for the MRI environment may be used and only within the conditions specified by the manufacturer. Certain devices may be certified with specific field strength ("gauss line") restrictions. Such devices may only be used after (1) the safe use zone has been measured by the MRI physicist,

(2) the floor path of acceptable field strength is permanently marked on the floor and (3) the Medical Director has approved the safe use plan. Such field-strength limited devices must always be tethered to a permanently installed wall anchor at a location outside of the marked path when in Zone IV. The purpose of this tether is to maintain the device in a safe position, not to restrain the device if drawn by the magnetic field. The location and device must be marked using standard signage.

- Transport equipment:
    - Only MR safe stretchers, wheelchairs, cribs, etc. are to be used within Zones III and IV. Subjects/patients are to be transferred to an MR safe transport device OUTSIDE of the secure entrance to Zone III. Transport personnel are to remove the non-MR safe transport equipment.
- Oxygen/Gas cylinders are prohibited within Zones III and IV. Subjects/patients requiring oxygen therapy must be connected to wall oxygen and all cylinders must be left OUTSIDE Zone III. The only exception allowed is for emergency backup tanks for anesthesia machines. These tanks must be tested as a part of monthly inspections and labeled MRI Safe.

4.2.1.6. Researchers in the magnetic environment

- Individuals must undergo MRI Safety screening BEFORE entering Zone III.
- Researchers must be listed on an approved protocol (IACUC, IBC, IRB) and meet requirements for Level II before access is granted to the Zone IV.

4.2.1.7. Children

Children may only enter the scan rooms as participants in an IRB approved research study of children. Children not involved in the research study may not enter the scan room. Equipment room doors must be kept closed whenever children are present. All other policies on children in the workplace apply to the MRI Facility.

4.2.1.8. Visitors

Visitors are not permitted in Zone IV without approval from the MRI Medical Director.

4.2.2. Signage

- Signage must be installed at the entrances to Zones II-IV (whether interior or exterior) clearly indicating the zone and relevant access control and “authorized personnel only.”
- The entrance to Zone IV should be clearly marked with a prominently displayed red illuminated sign stating, “The Magnet is Always On.” Signage must inform the magnetic field exists even during an intentional or inadvertent power loss. This light and sign must be always illuminated and must be provided with a battery backup energy source to continue to remain illuminated in the event of a loss of power to the facility.
- Perimeter doors must have signage for emergency personnel.
- The location of Fire Department emergency shut off and emergency venting for cryogenic gases are considered Zone III and must be marked accordingly.

4.3. Screening

All Non-MR Personnel needing to enter Zone III must first pass an MR safety screening process. Before Non-MR Personnel enter Zone III, final authorization must originate from Level 2 MR Personnel.

Subjects should be MR safety screened at least twice prior to being granted access to the MR environment, both metal detection and the completion of the screening form.

The screening process and forms for non-MR personnel and MR Personnel should be essentially identical. A special form will be used for screening animal subjects with the Principal Investigator. Specifically, one should assume that screened Non-MR Personnel or MR Personnel might enter the bore of the MR system and be exposed to the static and/or time-varying magnetic fields at any time.

Careful screening for ferromagnetic materials by direct inspection and use of a ferromagnetic detector is required prior to entering Zone IV. MR Conditional devices may be ferrous, which can lead to activation of ferromagnetic detectors prior to entry into Zone IV. The manufacturers of ferromagnetic detectors today do not claim utility or sensitivity for screening of implants or foreign bodies within subjects/patients, although if sufficiently large and/or superficial, implant detection may be possible.

4.3.1. Clinical Screening

4.3.1.1. Clinical screening is required for all research subjects and patients who are planning to enter the MRI facility and must be performed prior to entering Zone III

4.3.1.2. Annual clinical screening is required for personnel who must perform work in Zone III

4.3.2. Metal Screening (Personnel and Research Subjects)

Anyone preparing to enter Zone IV must complete a metal screening form, and this form must be reviewed before access to Zone IV is granted. Separate forms should be available for research subjects and for all other individuals. MR Personnel (Level II and III) must maintain an annual form on file.

If there are any doubts regarding the metal screening responses, **do not allow the individual to enter Zone IV**. The fact that the individual has been scanned in an MR scanner previously (even at FAU) is **never** a sufficient basis upon which to conclude that the subject can enter Zone IV safely, since risks vary according to magnetic field strength. Dental fillings and orthodontic braces do not constitute significant risks (though the latter may produce unacceptable artifacts) and do not preclude scanning. Subjects with tattoos or permanent eyeliner should be advised of the small risk of local redness or irritation, as well as the potential for local burns (these body areas should be protected by sufficient padding between the skin and MRI surface), and asked to report any discomfort immediately. Scanning should be stopped immediately if such discomfort develops. These small risks may be further reduced by applying a damp cloth to the area during scanning.

Before entering Zone IV, research subjects and staff must remove all objects from their person that might constitute a risk in the MR environment. It is the MR Technologist's responsibility to assure that this has been done. Subjects should be asked to turn pockets inside out to demonstrate that no potentially hazardous objects have been overlooked. Alternatively, subjects may be asked to change into hospital gowns that are available in the MRI Facility. Silver, gold and platinum jewelry is not ferromagnetic. Nonetheless, subjects should remove jewelry before going in the scanner since these metals can still conduct electricity and therefore pose a risk for burns in the presence of time-varying magnetic fields. Jewelry that forms large loops is particularly hazardous.

Ferromagnetic screening wands, specifically designed for screening subjects prior to MR examinations, are available in Zone III as an additional screen for metal hazards. These should only be used **after** all of the conventional screening methods described above, not as a substitute for them. They should never be used to screen a subject who has not already been deemed safe for MR scanning since they do contain weak magnets that could potentially disrupt pacemakers or cause injurious movement of small metallic fragments in the eye. The wands need to be held one inch or less from the body to be fully effective and should not be rubbed directly over the eyes. For sensitive areas, subjects can place their own hands over the area and be screened through their hands. The ferromagnetic screening wands are **NOT** MR safe/conditional and should never be taken into Zone IV.

4.3.3. Screening for Work with Animal Subjects

Similar to screening personnel, a thorough metal screening will be conducted with the principal investigator and the research animal present, utilizing a modified form.

4.4. MRI Facility Maintenance

4.4.1. Personnel

Maintenance activities within the MR Facility will be conducted by qualified personnel only and in accordance with all FAU policy.

4.4.2. Equipment, Supplies, and Tools

Only MR-conditional and MR-safe equipment, supplies, and tools may be used for building maintenance activities within Zones III and IV.

4.4.3. Maintenance Procedures

The MR Facility policy and procedures must clearly describe the procedure for all maintenance activities.

5. MRI SAFETY POLICIES

The MR Medical Director will develop a set of Standard Operating Procedures (SOPs) for maintaining and operating the magnet, and all procedures must be approved by the MRI Safety Committee. The SOPs will include but not be limited to the following:

- MRI Facility Access Control
- Equipment and Materials
- MRI Facility Safety Breach Reporting
- Implants and Devices
- Infection and Allergy Control
- MRI Safety Training
- Pregnancy and MRI Safety
- Adverse Event Reporting Requirements
- Safe MRI Scanning
- General Scanner Usage
- Study Personnel Responsibilities
- Safe Scanning of Animal Subjects
- Emergency Response Plan
- MRI Facility Housekeeping and Maintenance Plan
- Magnet Maintenance Plan

6. MRI EMERGENCIES

The FAU MRI Facility will have specific emergency procedures to address potential emergencies including:

- Water damage

- Structural damage
- Power outage
- Quench
- Medical emergencies
- Metal objects pinned in the magnet
- Fire
- Preventive measures
- Hurricane preparedness
- Post-event inspections

The FAU MRI Facility should arrange to prospectively educate their local fire marshals, police and security personnel about the potential hazards of responding to emergencies in the MR Facility.

It should be stressed that even in the presence of a fire or other emergency the magnetic field may be present and fully operational. Free access to Zone IV by firefighters and other non-MRI personnel with air tanks, axes, crowbars, guns, etc. can prove to be catastrophic or even lethal. Helium is not flammable and does not pose a fire hazard directly; however, the liquid oxygen that can result from the super cooled air might well increase the fire hazard in this area. If there are appropriately trained MRI personnel available during the emergency who are able to keep the emergency responders from Zone IV and the five-gauss line, then quenching the magnet should not be a requirement. As part of the Zone III and IV restrictions, the MRI Facility must have clearly marked, readily accessible MR Conditional or MR Safe fire extinguishing equipment physically stored within Zone III or IV.

If the fire or emergency is in Zone IV, and the emergency response personnel and their equipment must enter the room, a decision to quench the magnet should be made to protect the health and lives of the emergency responders. Should a quench be performed, appropriately designated MRI personnel still need to ensure that all non-MRI personnel continue to be restricted from Zone IV until the designated MRI personnel have verified that the static field is either no longer detectable or at least sufficiently attenuated to no longer present a potential hazard.

6.1. Medical Emergencies

The following procedures are designed on the assumption that a physician or nurse is not immediately available in the MR laboratory at the time of the emergency. If a physician or nurse is present, the medical recommendations may be adjusted as deemed medically appropriate for the subject's condition. However, all non-medical aspects of these guidelines, **particularly those related to removing the person from the magnet or Zone IV, must be followed** to avoid unnecessary injury to the subject or personnel.

6.1.1. Person Pinned in Magnet by Metal Object

1. If (**and only if**) the medical emergency involves the subject being pinned to the magnet by a metal object held in place by the magnetic field, quench the magnet following the procedure described elsewhere in this manual.
2. Contact 911 immediately after quench.
3. Remove the person from Zone IV to the designated location in Zone II.
4. Render medical assistance in accordance with training until EMS arrives.

6.1.2. Other Medical Emergency in the Magnet or elsewhere in Zones III or IV

1. Contact 911 immediately upon determining medical emergency.
2. Remove the person from Zone IV to the designated location in Zone II.

3. Render medical assistance in accordance with training until EMS arrives.

Under no circumstances should emergency medical or law enforcement personnel be permitted/required to enter Zones III or IV to render assistance. Always remove the subject from the instrument and from Zones III and IV first.

6.2. Fire Emergencies

1. Call 911 immediately
2. If smoke or fire is coming from the scanner, equipment room or console, perform an emergency electrical shutdown as described elsewhere in this manual.
3. If you are scanning and smoke or fire is NOT coming from the scanner, equipment room or console, stop the scan and release the bed. If time permits, initiate a routine electrical shutdown.
4. If you determine that it is necessary or appropriate to attempt to extinguish a fire in Zone IV yourself (e.g., if your subject is on fire), use an MR safe/compatible fire extinguishers in the MR Facility. **NEVER BRING A STANDARD RED FIRE EXTINGUISHER FROM ELSEWHERE IN THE BUILDING INTO ZONE IV.**
5. Remove the subject from the scanner and escort the subject out of the building.
6. Do not return to the building until advised by fire personnel that it is safe to do so.
7. Execute the emergency contact process in the MRI Facility SOP.

6.3. Non-Fire Facility Emergencies

The following non-fire, non-medical emergencies, may warrant a shutdown of the equipment:

- Unscheduled Power Shutdowns
- Magnet Quench (catastrophic boil-off of helium)
- Water Leaks
- Foreign Metal Objects in the Magnet

1. Perform a routine electrical shutdown, or if circumstances such as a rapid flooding threaten to reach the equipment before a routine shutdown could be completed, perform an emergency electrical shutdown. Both shutdown procedures are described elsewhere in this manual.
2. Remove the subject from the scanner
3. If appropriate, evacuate the building and do not return until advised that it is safe to do so.

6.4. Fire Alarms

When an unscheduled fire alarm sounds:

1. Remove the subject from the scanner and escort the subject out of the building.
2. Do not return to the building until advised by fire personnel that it is safe to do so.
3. Execute the emergency contact process in the MRI Facility SOP.

6.5. Unplanned Magnet Quench (not deliberately initiated by MR personnel)

In the event of a magnet quench it is imperative that all personnel/subjects/patients be evacuated from the Zone IV as quickly and as safely feasible.

1. Stop all scanning and open the scan room door immediately. If the door to the scan room is closed the pressure may build up making it impossible to open the door. In this event, it may become necessary to break the glass window to allow the gasses to escape and the pressure to lessen so that the scan room door may be opened.
2. The access to the scan room should be immediately restricted to all individuals until the arrival of the MR equipment service personnel.
3. Do not rely upon the oxygen sensors in the room to warn of low oxygen levels in the room. This technology is now considered by industry experts not to be sufficiently reliable to allow for continued operations during situations of power outage, etc.
4. It is especially important to ensure that all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air tanks, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, as there may still be considerable static magnetic field present despite a quench or partial quench of the magnet.
5. Execute the emergency contact process in the MRI Facility SOP.

6.6. Emergency Magnet Quench

Users of the MRI facility should only quench the magnet in the event that the magnetic field itself poses an **immediate risk to life or major property**. Two such circumstances are:

1) A metal object is lodged in the scanner in a way that poses an immediate serious threat to a person (e.g., the person is pinned to the magnet by a metal object that is causing internal injuries).

2) Fire personnel determine that there is ***no other alternative*** to entering the room with axes or other heavy gear when fighting a fire.

If the absence of a major emergency, facility users should **never quench the magnet by themselves**, even if they are convinced that a magnet quench will ultimately be necessary (e.g., if a large object has been drawn into the magnet but poses no immediate risk to a person).

Quench Procedure

1. Follow the steps in the MRI Facility specific SOP.
2. When the magnet is quenched, the helium in the scanner boils off. Although the helium should vent out of the room to outside vent, **make sure the door to Zone IV is wide open before quenching the magnet**. If possible, exit all persons from Zone IV before quenching the magnet to minimize the chance of asphyxiation in the event that the helium is improperly vented.
3. If emergency medical assistance is needed, dial 911 and request medical assistance as detailed elsewhere in this manual.
4. The helium vent ducts become dangerously cold during a quench. Do not touch them.
5. Execute the emergency contact process in the MRI Facility SOP.
6. The quench procedure will interrupt continued research in the MRI Facility for an indeterminant amount of time.

6.7. Emergency Electrical Shutdown

The following events should prompt an emergency electrical shutdown:

- You see smoke or fire coming from the scanner, equipment room or console.
- Flooding has carried or is threatening to carry water into electrical equipment

Electrical shutdowns do not turn off the magnetic field—the magnet is <u>ALWAYS ON unless the magnet has been quenched.</u>

1. Locate and press one of the large red electrical shutdown buttons in Zone IV or Zone III. **Make sure that it is the electrical shutdown button, not the quench button.** The electrical shutdown buttons are all uncovered, and there is no writing on the button itself.

2. Electrical shutdown immediately stops all power to the scanner, the scanner equipment and the console computers. It does not turn off the lights. Also, power to the simulation equipment will not be interrupted, so be aware that electrical or fire hazards may still be present.

3. In the case of fire or medical emergency, call 911.

4. Remove subject from Zone IV.

5. Execute the emergency contact process in the MRI Facility SOP.

6. Circumstances that justify an emergency electrical shutdown do not typically justify quenching the magnet. Do not quench the magnet unless there is a specific reason to do so (possible reasons for quenching the magnet are discussed elsewhere in this manual).

7. It will take an indeterminant amount of time to restore the scanner to operational status.

6.8. Routine Electrical Shutdown

A routine electrical shutdown may be necessary if a situation is developing that might predispose the equipment to electrical damage or that might soon warrant an emergency electrical shutdown. **Electrical shutdowns do not turn off the magnetic field—the magnet is always on unless the magnet is quenched.** A routine electrical shutdown requires 3-5 minutes to complete. **If an emergency electrical shutdown becomes warranted at any time, follow the emergency electrical shutdown procedure described elsewhere in this manual**, even if a routine electrical shutdown has already been initiated. Situations that would warrant a routine electrical shutdown include:

- Receiving notice that an electrical outage in the building is likely

- Development of a minor water leak that is not expected to flood electrical equipment before a routine shutdown can be completed

- Alarms sounding indicating that the magnet has quenched or that helium is unacceptably low (a routine warning message on the console that the helium needs to be refilled and instructing you to call service is not an alarm and does not warrant an electrical shutdown).

- Error messages from the scanner console indicating that correction of a problem requires rebooting the equipment.

- Failure of the scanner bed to respond to its controls

Per the manufacturer's updated recommendations, a routine electrical shutdown should NOT be routinely performed at the end of the day. The scanner should be left in operational status.

1. Follow the MRI Facility SOP for procedures on performing a routine electrical shutdown.
2. Reenergize the equipment in accordance with the SOP when appropriate.

7. POLICY EXEMPTIONS

MRI safety policies are based on FDA standards, manufacturer's recommendations, current research and experience, they exist to create a safe standard of care required by the FAU MRI Safety Committee. Exceptions to these policies may be made at the discretion of the MRI Medical Director, such as in the rare instance of an acute, life-threatening condition.

Any exemptions should be taken seriously and the rationale for the exception must be documented by the MRI Medical Director.

"Standing" deviations from MRI Policies and Procedures are not permitted. In these cases, the appropriate MRI Policy and Procedure must be revised and presented to the MRI Safety Committee for approval.

Necessary changes to this policy must be provided to EH&S for revision.

8. REPORTING

8.1. Adverse Event Reporting

All potential safety and security breaches must be reported immediately based on the facility procedure for reporting security breaches. All breaches must be investigated and reported with corrective actions to EH&S within 24 hours. Adverse events include but are not limited to:

- MRI-related accidents and injuries
- Security breaches
- Safety breaches

All medical adverse events must be reported to the MRMD immediately and the MRI Safety Committee according to standard AE reporting. Adverse events include but are not limited to:

- MRI-related accidents and injuries

- Study related AEs
- Contrast reactions
- Anticipated adverse events such as physical discomfort in the scanner or claustrophobic reactions should be noted in case report forms and reported based on standard regulatory guidelines.

9. ENFORCEMENT

Failure to comply with the safety and security requirements of the MRI Facility as required by the university may result in revocation of or prohibition of access to the FAU MRI Facility for any reason.

The MRI Medical Director and the Director of Environmental Health and Safety have the authority to immediately cease MRI operations or deny access to the controlled areas of the MRI Facility for the protection of people or the University prior to bringing the matter before the MRISC for further investigation.

The MRISC shall have the full authority and obligation to enforce compliance with all relevant MRI policies and ensure reasonable standards of safety and health. The MRISC shall delegate the routine operational authority for this program to the MRI Medical Director and advise on the performance of such duties.

For situations of non-compliance that are brought to the attention of the MRISC, the MRISC (or designee) will provide a prompt report of the circumstances to the VPAA, and EH&S with a copy to the person in non-compliance, respective college dean and department chair (as appropriate.) Within 3-5 business days (or as soon as feasibly possible) following the halting of the activity or project, the MRISC will convene to assess the situation. The MRI Medical Director will be charged to present the circumstances surrounding the incident with a written report provided to the MRISC, which will include a written report from the person in non-compliance. The MRISC will consider all available facts and evidence, decide regarding the incident and follow up with a final, written report to all parties concerned including the VPAA, College and Provost's offices (as appropriate). If the MRISC determines that the event or activity constitutes non-compliance, the person in non-compliance will be required to present a corrective action plan to address the non-compliance with a plan that such an event or activity will not occur again in the future.

The MRI Medical Director will work with the person in non-compliance, department chair and college dean (or other as appropriate) on this corrective action plan and the final plan will be submitted to the MRISC for review and final approval. Only once the corrective action plan has been reviewed and approved by the MRISC can the project or activity be resumed. All communications associated with the non-compliance must be appropriately documented. Once the corrective action plan has been approved by the MRISC the person in non-compliance will be given a timeline to implement the plan and follow up with the MRISC. If the person in non-compliance does not follow the corrective action plan within the required timeline, the MRISC will notify the person in non-compliance that they have thirty (30) days from the date of the follow up notice to satisfactorily implement the corrective action plan. Should this deadline not be met, the MRISC will notify the FAU Vice President of Administrative Affairs, the Provost's office, the College Dean and Department Chair (as appropriate) for further action.

Should any faculty or staff believe that they have been or will be adversely affected by action or inaction of the MRISC, or have concerns related to and the MRI safety program at FAU, those persons will be encouraged to openly discuss such instances with and resolve any differences directly with the

MRISC. If a faculty or staff member objects to a MRISC recommendation concerning a violation of a MRI policy or procedure, a written complaint must be filed with EH&S within 30 days of the recommendation. The complaint shall state the nature of the objection(s) including any adverse effects, specify the actions or inactions that are at issue, and specify the remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome shall be noted in this document. Within thirty (30) days after receipt of the complaint, the respondent (i.e., MRISC) shall provide a response, in writing, to the appellant. If the appellant and the respondent are unable to resolve the written complaint informally, EH&S shall schedule a meeting between the respondent, the appellant, the MRISC Chair, the MRI Medical Director (if not chair), the Director of EH&S, to discuss and resolve the issue. Ultimate decision-making is with the VPAA.

Violations of this policy may result in disciplinary action up to and including termination or expulsion in accordance with applicable university and Florida Board of Governors regulations and/or collective bargaining agreements. Such disciplinary actions may also include reprimand, suspension, or other sanctions. Violations of this policy by visitors, contractors, guests and other third parties may be grounds for terminating or suspending their access to and/or use of university property.

10. DEFINITIONS

MR Safe: A designation indicating that the object or device is safe in all MR environments, without conditions. It is reserved for nonmetallic, nonconducting, and nonmagnetic objects that pose no known hazards in any MR environment.

MR Conditional: A designation indicating that the object or device may be safely used in the MR environment, provided the conditions for safe use are met. Decisions based on published MR Conditional or safety claims should recognize that all such claims apply to specifically tested static field and spatial gradient field strengths and only apply to the precise model, make, and identification of the tested object. For example, “MR Conditional having been tested to be safe at 3 T at spatial gradient strengths of 1130 G/cm or less and normal operating mode.”

MR Unsafe: A designation indicating that the object or device is known to present safety risks in the MR environment. These are primarily ferromagnetic objects.

Level I MRI Personnel - Level I MR Personnel are individuals who have had MRI safety training as approved by the MRISC.

Level II MRI Personnel - Level II MR Personnel have completed all requisite MRI safety and user training established by the MRISC. Level II users may operate the scanner without supervision, supervise Level I personnel, escort non-MRI personnel within Zones III and IV, and administer the MRI safety screening to study participants.

Level III MR Personnel – Level III MR Personnel are Level II personnel with authority to make interpretive decisions in ambiguous situations.

Level I MRI Safety Training – Essential MRI Safety training for Level I individuals is designed for those who frequent the MR area on practices and procedures to keep themselves and others safe.

Level II MRI Safety Training - Comprehensive MRI Safety for Level II MR Personnel is a focused, detailed course designed for physicians, including radiologists and anesthesiologists, CRNAs, MRI

technologists, nurses, and other healthcare providers who conduct medical/metal screening, operate the MRI, and/or supervise individuals in Zones III and IV of the MRI environment.

Zone I - General facility area freely accessible to the public. This area is typically outside the MR environment.

Zone II - Limited Access: This is the Zone located between the public uncontrolled Zone I and the strictly controlled Zone III. This area has limited access available to research subjects and MRI staff personnel who have been safety trained or safety screened by Level 2 MR personnel. It is in Zone II that the answers to MRI screening questions, medical histories, medical insurance questions, etc. are typically obtained.

Zone III - The MR scanner (Zone IV) itself is located adjacent to this space. Zone III can be defined as regions from which potentially hazardous energies (related to the MR imaging process) may be accessed. Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III. Individuals that have undergone safety screening will be allowed access to this area only when accompanied by appropriate MR personnel.

Zone IV - Is the room housing the MR scanner itself. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field which generates the existence of Zone III. Only research subjects, researchers, and FAU personnel accompanied by Level II MR personnel who have undergone safety screening or safety training will be admitted to this Zone.