Preclinical and Translational Imaging Center MRI Safety Training Manual

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Level 1 Training - Research Magnetic Resonance Imaging (MRI) Safety

MRI Safety

You might be asking: why do we have training for MRI safety?

In July of 2001, a horrible accident occurred in which a 6-year-old boy was killed in a tragic MRI accident in the state of New York. In the intervening years, the safety of MRI has continued to improve, providing vital diagnoses for growing numbers of people (and information for research projects). In that same time frame, however, the number of preventable accidents, which can injure patients (and investigators), has continued to rise. The same safety issues that need to be dealt with every day in the clinical setting are also important in the research environment.

Incident at PTIC: PTIC had a recent incident in which a researcher tried to put a metal broomstick down the bore of the magnet to dislodge part of a probe that was stuck within the bore. The broomstick flew out of his hand causing a laceration which required stitches. Service engineers had to de-energize the magnet in order to remove the broomstick costing thousands of dollars and disabling the magnet for weeks.

MRI Awareness



The MRI scanner uses a strong superconducting magnet, radio waves and a computer to create images. The strong magnetic field can pose hazards to the working environment since it can pull metal objects into the bore of the magnet with great force and speed. This can greatly harm a person if in the path of the metal object or harm an animal inside the bore. Also, the force of the metal object hitting the magnet would cause damage to the magnet itself making it inoperable. The MR scanner in PTIC is at a magnetic field strength of 9.4T, which is many times stronger than clinical MR scanners (i.e. 1.5T - 3T). Since the bore size is smaller on this animal scanner, the fringe magnetic fields do not extend out as far as clinical scanners, however, the magnetic pull once you get close is much stronger.

MRI Hazard Warning Signs

Warning signs at the entrance of the MRI show you that you are entering an area with special hazards. The special precautions are due to the strong magnetic field from the MRI. These special precautions may affect you personally if you have a pacemaker, aneurysm clip or other metal implanted device in your body.

Magnetic Pull

An important safety concern with MRI is the magnet's ability to attract metal objects. The PTIC's MRI is 100,000 times more powerful than the earth's gravitational field. Metal objects that get close to the magnet can be pulled into the bore with great force and speed.

One important misunderstanding is that a MRI unit is safe when not in use. However, the MRI magnetic field is **NEVER** turned off. The strong





magnetic field is always present even when nothing is in the scanner.

The 5 gauss line, which indicates a low level of magnetic field, is indicated with yellow and black checkered tape on the MR room floor. Non-MR safe objects should never be taken past the 5 gauss line.

Therefore, safety precautions to **remove all metal items** in your possession prior to getting near the MR scanner (passing the checkered tape on the floor) are essential. Metal items such as pens, scissors, stethoscopes, tools, etc. including stainless steel objects, must never get near the MR scanner because these items may be pulled into the scanner from your pocket or hand. Experts have reported that a metal wrench pulled from just two feet away from an MRI unit will hit the machine at a speed of about 30 to 40 miles per hour or greater near a clinical scanner.

Examples of Dangerous Metal Objects

Research related items:

- Oxygen tanks stainless steel
- Carts
- Animal cage lids
- Medical supplies: scissors, needles, clamps, pens, stethoscope, etc.
- Monitoring equipment (respiration etc.)
- Injection pumps, anesthesia vaporizers, heat pumps

Staff related items:

- Fire extinguishers
- Cleaning equipment: floor buffers, buckets, mops, vacuums, etc
- Hand tools: wrenches, screwdrivers, etc.
- Keys
- Coins
- Watches
- Pagers
- Cell phones
- Credit cards
- Id badges
- Jewelry

Working in an MRI Environment:

Missiles (flying metallic objects) are a major safety concern for MR imaging, however, other safety issues must be considered before working in the MR environment. Any metal object in or on the body can also be affected by the magnetic force from an MRI. Metallic objects in the body, like surgical wires, clips and pacemakers can be affected or damaged by the magnetic field. Serious injury or death can occur if someone enters the MRI room with such

devices. While metal objects on or in the body can create serious health hazards, the magnet alone does not affect normal tissue.

If you have any of the following, please inform PTIC personnel.









Absolute contraindications to working in an MRI Environment include:

- Pace maker
- Defibrillator
- Non-MR safety aneurysm clip
- Retained pacemaker leads
- Insulin pumps
- Other contraindications may exist, check <u>www.mrisafety.com</u> (see last page) for more details.

<u>Hazards from implanted devices</u>: – Many implanted objects such as surgical clips, electronic devices such as pacemakers, stimulators, etc are magnetic and may move and cause harm or death if exposed to a high magnetic field (i.e. non-MR safe aneurysm clip)

<u>Malfunctioning devices:</u> – Electronic devices such as pacemakers, or defibrillators can malfunction and cause harm or death if exposed to a high magnetic field

Other considerations must also be considered when working with the MR scanner. Metal objects on or in the animal that you are imaging may move or cause heating and burns due to the time-varying magnetic fields (gradients) pulsed during acquisition, as well as the exposure to radiofrequency pulses.

- a) Heating MR scanning can cause internal or external metal objects to heat up and cause burns (i.e. clips, wires, implants)
- b) Some objects or devices are safe to scan only under certain conditions as directed by PTIC staff.

What You Need to Do Before Getting Near the MRI

- Always remove watches, wallets, pagers, cell phones, ID badges, pens, clipboards, and all other metal items before crossing the checkered tape near the magnet. This also protects your possessions from having all magnetically stored information erased.
- Never rush to the magnet, even in an emergency

The Tripod of MRI Safety

MRI safety can be thought of as a tripod:

- Magnet safety (device safety, procedures, etc.)
- Operational safety (animal screening, staff training, etc.)
- Facility safety (access controls, screening support, etc.)

What is your role in MRI Safety?



As staff personnel, or a visitor, working in the MR environment stop and review the functions/processes:

• <u>Magnet Safety</u> by stopping before you enter the MR suite to look for non-MR compatible objects on your person or in your possession. For the research environment you need to also check all equipment used to transport/treat the research animal. Did you leave the portable oxygen tank outside the MR field? Did you stop and check your pockets for metal objects before you entered the MR field? Review and understand the "What to do in case of an emergency in the MR suite" procedure.



- <u>Operational Safety</u> by reviewing the protocol information to determine if the animal you are scanning has non-MR compatible devices implanted or is connected to non-MR safe devices.
- <u>Facility Safety</u> by not sharing badge/code entry with others who have not been trained.

What to do in case of an emergency in the MR

A "quench" is when the liquid helium gas that is used to cool the superconducting magnet rapidly escapes from the magnet vessel and the vapor rapidly disperses into the magnet room. This vapor will displace the air and is extremely cold. Do not breathe in this air.

If the magnet quenches (loses its cryogenic helium gas):

- Leave the room immediately, closing all doors behind you
- Make sure everyone leaves the area
- Call for help from the MR Director

If cooling cryogens (liquid helium or nitrogen) are spilled:

- Cryogens can cause severe damage to human tissue
- Cryogens can displace the oxygen in the room and therefore cause asphyxiation
- Therefore, turn off the source if it can be done safely
- Then leave the room, closing all doors behind you
- Do not reenter the room until the cryogens have had time to dissipate

If a metal object gets lodged in the scanner:

- Immediately attend to the animal and if possible remove the animal from the scanner
- Call for help from the MR Director or technician
- MR Director will determine how to proceed with removing the object
- Do NOT attempt to pull the object out of the scanner if it is large. This is for <u>your</u> safety as well as the safety of others

If a person is injured in the MR room:

- Check ABC and perform CPR if necessary
 - Airway make sure that nothing is obstructing the airway
 - \circ **B**reathing check to see that they are breathing and how: fast/slow, deep/shallow, quiet/noisy
 - **PTIC**culation if you can, check for a pulse. If there's any severe bleeding, cover and apply pressure, if possible. Do not tourniquet, nor tape-up any wounds
- Call for additional help as soon as possible
- If the person is near the magnet, move them away from the scanner before help arrives

LEVEL 1 MRI SAFETY POST-TEST FOR PTIC USERS/PERSONNEL

Name (PRINT)		_Date
ID number: Jo	b Title	
Performance Standard Post-Test		If false please state correct answer
1. There has never been a fatal MRI accident in the U.S.?	T or F	
2. For the 9.4T magnet in PTIC, the 5 gauss line is indicated by the yellow and black tape on the floor.	T or F	
3. If a large metal object gets lodged in/on the scanner, quickly try to pull it out/away.	T or F	
4. If the magnet quenches it is ok to stay in the room.	T or F	
5. I should ALWAYS check my pockets and remove all metal objects that may become a missile from my person BEFORE I get near the MR.	T or F	
6. The MRI magnet is always on, even if there is nothing in the scanner.	T or F	
7. Anyone with a pacemaker is NEVER allowed in the MR room for any reason.	T or F	
8. The MRI magnet is capable of pulling metal objects at high speeds into the scanner.	T or F	
9. In the case of an emergency it is ok to enter the MRI room as quickly as possible with medical/metal equipment.	T or F	
10. If you cross the 5 gauss line with your ID badge on or credit cards, the magnet will erase the information on the magnetic strip	T or F	
11. Magnetic fields can harm human tissue following prolonged exposure.	T or F	
12. Cryogens used to cool the magnet are not harmful to human tissues.	T or F	

Walk-thru check list and signatures on reverse side of this test.

Walk-thru Check List:

- □ Fire extinguisher location
- □ Eye wash
- □ First aid kit
- □ Cryogen storage
- □ Gas storage
- □ Tools
 - o Safe
 - o Unsafe
- □ 9.4T
 - Power supply
 - o 5 gauss line
 - Quench valve
 - o Chiller
- \Box Personal effects that need to stay outside the checkered line
 - o Wallets
 - o Keys
 - o Phones
 - o Pagers
 - o Laptops
 - o Backpacks
 - o Tools

Walk-thru conducted _____(date) by _____

Employee Signature_____

Manager/Supervisor Signature

Level 2 Training - Research Magnetic Resonance Imaging (MRI) Safety

A. Establish, Implement, and Maintain Current MR Safety Policies and Procedures

- 1. The Center for Imaging Research (PTIC) at UCI, irrespective of magnet format or field strength, will maintain current MR safety policies.
- 2. These policies and procedures will be reviewed concurrently with the introduction of any significant changes in safety parameters of the PTIC MR environment (e.g., adding faster or stronger gradient capabilities or higher RF duty cycle studies) and updated as needed. In this review process, national and international standards and recommendations will be taken into consideration prior to establishing PTIC guidelines, policies, and procedures.
- 3. PTIC will name a MR Supervisor whose responsibilities will include ensuring that MR safe practice guidelines are maintained as current and appropriate.
- 4. Procedures are (See Appendix 1) in place to ensure that any and all adverse events, MR safety incidents, or "near incidents" that occur in the PTIC facility are reported to the Director in a timely fashion (e.g., within 24 hours or 1 business day of their occurrence) and used in continuous quality improvement efforts.
- 5. There are three areas of concern when working in the MR environment which are covered in the next sections:
 - 1. static magnetic fields (missile effect)
 - 2. time-varying magnetic fields (induced currents)
 - 3. radiofrequency exposure (heating and burns)

B. Static Magnetic Field Issues: PTIC Access Restriction

1. Zoning

INSERT Floorplan

Fig. 1—Actual PTIC floor plan illustrates access restriction considerations as determined by the Office of Radiation Safety on 9/19/2000 and 1/4/2008. See Appendix 2 for personnel and zone definitions.

The PTIC MR site is conceptually divided into four Zones (see Figure 1 and Appendix 2):

- **Zone I**: This region includes all areas that are freely accessible to the general public. This area is outside the MR environment and is the area through which PTIC users access the MR environment.
- **Zone II**: This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Typically, individuals are not free to move throughout Zone II at will, but should be under the supervision of MR personnel. It is in Zone II that collaborations and research requirements are discussed.

- Zone III: All access to Zone III is to be strictly restricted, with access to all regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, PTIC personnel. Specifically, identified PTIC personnel are to be charged with ensuring that this MR safe practice guideline is strictly adhered to for the safety of non-MR personnel and the equipment itself. Zone III regions are physically restricted from general public access using key codes unique to each trained MR person. Only trained MR personnel (Level 1 and 2) will be provided free access to Zone III. There should be *no* exceptions to this guideline. Specifically, this includes Medical Center or University administration, physicians, security, and other non-MR personnel. Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become "MR personnel" themselves. Zone III, wherein the static magnetic field strength exceeds 5 gauss, is demarcated and clearly marked as being potentially hazardous.
- Zone IV: This area is synonymous with the MR scanner magnet room itself, that is, the • physical confines of the room or area within which the MR scanner is located. Zone IV, by definition, is always located within Zone III, as it is the MR magnet and its associated magnetic field that generates the existence of Zone III. Zone IV is demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields (>5 gauss). As part of the Zone IV restrictions, Level 2 personnel have direct visual observation to access pathways into Zone IV. Zone IV should be clearly marked with appropriate warning signs. In case of cardiac or respiratory arrest or other medical emergency within Zone IV for which emergency medical intervention or resuscitation is required, the person should be rapidly moved to the hallway, which is Zone II, where basic life support or CPR can be administered. All priorities should be focused on stabilizing and evacuating the person as rapidly and safely as possible from the magnetic environment that might restrict safe resuscitative efforts. Quenching the magnet (for superconducting systems only) is not routinely advised for cardiac or respiratory arrest or other medical emergencies, since quenching the magnet and having the magnetic field dissipate could easily take more than a minute. Also, quenching a magnet can theoretically be hazardous; so ideally one should evacuate the magnet room, when possible, for an intentional quench.

2. MR personnel designations

- a. There are two levels of MR personnel:
 - Level 1 MR personnel: Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III will be referred to henceforth as Level 1 MR personnel. They must be under Level 2 MR personnel supervision when working in Zone III or IV.
 - Level 2 MR personnel: Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to henceforth as Level 2 MR personnel. It is the responsibility of the MR Director not only to identify the necessary training (See Appendix 3), but also to identify those individuals who qualify as Level 2 MR personnel. It is understood that the Director will have the necessary education and experience in MR safety to qualify as Level 2 MR personnel. (See Appendix 2.)
- b. All individuals independently working within Zone III and IV of the MR environment will be documented as having successfully completed Level 2 safety training (See Appendix 3)

approved by the MR Director. Training will be repeated annually, and appropriate documentation will be maintained by the MR Director to confirm these ongoing educational efforts. These individuals shall be referred to henceforth as MR personnel.

- c. All those not having successfully complied with this MR safety instruction guideline shall be referred to henceforth as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not undergone the required training in MR safety issues as defined by the MR Director of the PTIC.
- d. *All* non-MR personnel wishing to enter or work in Zone III/IV must first pass a MR safety screening process. Only Level 2 MR personnel are authorized to perform a MR safety screen before permitting non-MR personnel into Zone III.
- e. Any individuals entering Zone III or Zone IV must remove all readily removable metallic personal belongings and devices on or in them (e.g., watches, jewelry, pagers, cell phones, body piercings [if removable].
- f. While the use of conventional metal detectors is not recommended, the use of ferromagnetic detection systems is recommended as an adjunct to the thorough and conscientious checking of persons and devices approaching Zones III and IV. It should be reiterated that their use is in no way meant to replace a thorough screening practice but is intended as a supplement to the screening process.
- g. Metal detectors should not be necessary for the detection of large metallic objects, such as oxygen tanks. These objects are fully expected to be detected—and physically excluded—during the routine screening process.
- h. Non-MR personnel will be accompanied by, or under the immediate supervision of and in visual or verbal contact with, a specifically identified Level 2 MR person for the entirety of their duration within Zone III or Zone IV restricted regions.
- i. Level 1 MR personnel are not permitted unaccompanied access to Zones III or Zone IV. Level 1 MR personnel are *not* permitted to directly admit, or be designated responsible for, non-MR personnel in Zones III or IV.
- j. In the event of a shift change, lunch break, etc., no Level 2 MR personnel shall relinquish their responsibility to supervise non-MR personnel still within Zone III or Zone IV until such supervision has been formally transferred to another of the PTIC's Level 2 MR personnel.

3. MR personnel screening

- a. All potential MR personnel are to undergo a screening process to determine if they have implanted cardiac pacemakers, auto defibrillators, diaphragmatic pacemakers, or other electromechanically activated devices upon which they are dependent as part of their screening process. <u>Any potential personnel that have such devices will not be able to work in the MR environment for their own safety and health.</u> For their own protection, all MR personnel must immediately report to the MR Director any trauma, procedure, or surgery they experience or undergo in which a ferromagnetic metallic object or device may have become introduced within or on them. This will permit appropriate screening to be performed on the employee to determine the safety of permitting that employee into Zone III.
- b. Any MR personnel and/or visitiors (e.g., volunteers, varied hospital and University employees, and professionals) with implanted cardiac pacemakers, auto defibrillators, diaphragmatic pacemakers, or other electromechanically activated devices will not be allowed to enter Zones III or IV.
- c. Firefighter, police, and security safety considerations: For the safety of firefighters and other emergency services responding to an emergency call from the PTIC MR facility, all fire

alarms, cardiac arrests, or other emergency service response calls originating from or located in the MR facility will be forwarded simultaneously to the MR Director. The Director should, if possible, be on site prior to the arrival of the firefighters or emergency responders to ensure that they do not have free access to Zone III or Zone IV.

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

As part of the Zone III and Zone IV restrictions, the PTIC has an accessible MRconditional fire extinguisher physically stored in Zone III. All conventional fire extinguishers and other firefighting equipment not tested and verified safe in the MR environment are restricted from Zone III and Zone IV.

For superconducting magnets, the helium and nitrogen is not flammable and does not pose a direct fire hazard. However, the liquid oxygen that can result from the super cooled air in the vicinity of the released gases might well increase any fire hazard. If there are appropriately trained and knowledgeable MR personnel available during an emergency to ensure that emergency response personnel are kept out of the MR scanner or magnet room and away from the 5-gauss 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 where Zone III or Zone IV needs to be entered for whatever reason by firefighting or emergency response personnel and their firefighting and emergency equipment, such as air tanks, 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 responding 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 at least sufficiently attenuated as to no longer present a potential hazard to one moving by it with, for example, large ferromagnetic objects such as air tanks or axes.

4. Screening of research animals for an MR examination

- a. Research subjects (i.e. animals, tissues and cells) must be verified to be free of ferromagnetic material before entering Zones III and IV. All experimental subjects must have ear tags and other metallic items removed from their bodies.
- b. Monitoring of research subjects/animals in the MR scanner is necessary as the potential for thermal injury from excessive RF power deposition exists. Sedated, anesthetized, or unconscious animals may not be able to express symptoms of such injury. Distortion of the electrocardiogram within the magnetic field makes interpretation of the ECG complex unreliable, even with filtering used by contemporary monitoring systems. However, routine monitoring of heart rate and rhythm may be accomplished using pulse oximetry, which also eliminates the risks of thermal injury from electrocardiography. Research subjects who require ECG monitoring and who are unconscious, sedated, or anesthetized should be examined after each imaging sequence, with potential repositioning of the ECG leads and any other electrically conductive material with which the research subject is in contact.

Alternatively, cold compresses or ice packs could be placed upon all necessary electrically conductive material that touches the research subject during scanning.

 c. Final determination of whether or not to scan any given research animal with any given implant, foreign body, etc., is to be made by the MR Director, or specifically designated Level 2 MR personnel.

For implants that are strongly ferromagnetic, an obvious concern is that of magnetic translational and rotational forces upon the implant which might move or dislodge the device from its implanted position. If an implant has demonstrated weak ferromagnetic forces on formal testing, it might be prudent to wait several weeks for fibrous scarring to set in, as this may help anchor the implant in position and help it resist such weakly attractive magnetic forces that might arise in MR environments.

For all implants that have been demonstrated to be nonferrous in nature, however, the risk of implant motion is essentially reduced to those resulting from Lenz's forces alone. These tend to be quite trivial for typical metallic implant sizes of a few centimeters or less. Thus, a waiting period for fibrous scarring to set in is far less important, and the advisability for such a waiting period may well be easily outweighed by the potential benefits of undergoing an MR examination at that time. As always, assessment of the risk–benefit ratio for the particular situation and research subject at hand are paramount for appropriate decision making in these scenarios.

d. It is possible that during the course of an MRI examination an unanticipated ferromagnetic implant or foreign body is discovered within a research subject undergoing the examination. This is typically suspected or detected by means of a sizable field distorting artifact seen on spin-echo imaging techniques that grows more obvious on longer TE studies and expands markedly on typical moderate or long TE gradient-echo imaging sequences. In such cases, it is imperative that the Director and/or principal investigator (PI) in charge be immediately notified of the suspected findings. They should then assess the situation; review the imaging information obtained, and decide what the best course of action might be.

It should be noted that there are numerous potentially acceptable courses that might be recommended which in turn depend upon many factors, including the status of the research animal, the location of the suspected ferromagnetic implant/foreign body relative to local anatomic structures, the mass of the implant, etc. Appropriate courses of action might include proceeding with the scan under way, immobilizing the research subject and the immediate removal of the research subject from the scanner. Regardless of the course of action selected, it is important to note that the forces on the implant will change, and may actually increase, during the attempt to remove the research subject from the scanner bore. Further, the greater the rate of motion of the research subject/device through the magnetic fields of the scanner bore, the greater the forces acting upon that device will likely be. Thus, it is prudent to ensure that, if at all possible, immobilization of the device during research subject from the bore, will likely result in weaker and potentially less harmful forces on the device as it traverses the various static magnetic field gradients associated with the MR imager.

5. Device and object screening

Ferrous objects, including those brought by investigators, visitors, contractors, etc., should be restricted from entering Zone III.

As part of the Zone III site restriction and equipment testing and clearing responsibilities, PTIC has a strong handheld magnet ($\geq \Box 1000$ gauss) which is stored in C-1029. This will enable

PTIC personnel to test external, and even some superficial internal, devices or implants for the presence of grossly detectable ferromagnetic attractive forces.

- a. All portable metallic or partially metallic devices that are on or external to the research subject are to be positively identified, and labeled, as ferromagnetic or, alternatively, non-ferromagnetic and safe or conditionally safe in the MR environment prior to permitting them into Zone III. Some examples of devices that need to be positively identified include fire extinguishers, oxygen tanks, aneurysm clips, computers, carts, monitoring equipment, infusion pumps, vaporizers, ladders, cage lids, etc.
- b. External devices or objects demonstrated to be ferromagnetic and MR unsafe or incompatible in the MR environment may still, under specific PTICcumstances, be brought into Zone III if, for example, they are deemed by MR personnel to be necessary and appropriate for research subject care. They should only be brought into Zone III if they are under the direct supervision of specifically designated Level 1 or Level 2 MR personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction to Zone III. The safe utilization of these devices while they are present in Zone III will be the responsibility of specifically named Level 1 or 2 MR personnel. These devices must be appropriately physically secured or restricted at all times during which they are in Zone III to ensure that they do not inadvertently come too close to the MR scanner and accidentally become exposed to static magnetic fields or gradients that might result in their becoming either hazardous projectiles or no longer accurately functional.
- c. Never assume MR compatibility or safety information about the device if it is not clearly documented in writing. All unknown external objects or devices being considered for introduction beyond Zone II should be tested with a strong handheld magnet (≥□1000 gauss) for ferromagnetic properties before permitting them entry to Zone III. All objects are to be appropriately labeled utilizing the current FDA labeling criteria developed by ASTM (American Society for Testing and Materials) International (http://www.astm.org) (see Fig. 2). Those items which are wholly nonmetallic should be identified with a square green "MR safe" label. Items which are clearly ferromagnetic should be identified as "not MR safe" and labeled appropriately with the corresponding round red label with a slash through it. Objects with an "MR conditional" rating should be affixed with a triangular yellow MR conditional label prior to being taken into the scan room/Zone IV. Green, yellow, or red tape can also be used to mark tested items. If a device has not been tested, or if its MR compatibility or safety status is unknown, it should *not* be permitted unrestricted access to Zone III.
- d. All portable metallic or partially metallic objects that are to be brought into Zone IV must be properly identified and appropriately labeled utilizing the current FDA labeling criteria developed by ASTM (American Society for Testing and Materials) International (http://www.astm.org) (see Fig. 2). Those items which are wholly nonmetallic should be identified with a square green "MR safe" label. Items which are clearly ferromagnetic should be identified as "not MR safe" and labeled appropriately with the corresponding round red label with a slash through it. Objects with an "MR conditional" rating should be affixed with a triangular yellow MR conditional label prior to being taken into the scan room/Zone IV. If MR safety data are not prospectively available for a given device, initial testing for the purpose of this labeling is to be accomplished by NIL's MR personnel by exposing the metallic object to a handheld magnet (≥□1000 gauss). If grossly detectable attractive forces are observed between the object being tested or any of its components and the handheld magnet, it is to be labeled with a PTICcular red "not MR safe" label. If no or negligible attractive forces are observed, a triangular yellow "MR conditional" label is to be attached to the object. It is only when the composition of an object and its components are known to be

nonmetallic that the green "MR safe" label is to be affixed to a device or object. Particularly with regard to non-clinical and incidental equipment, current products marketed with ill-defined terminology such as "non-magnetic," or outdated classifications such as "MR-compatible," should not be presumed to conform to a particular current ASTM classification. Similarly, any product marketed as "MR safe" but with metallic construction or components should be treated with suspicion. Objects intended for use in Zone IV, including non-clinical incidental products such as stepping stools or ladders, which are not provided with manufacturer or third-party MR safety test results under the new ASTM criteria, should be tested by PTIC personnel as described above.

e. It should be noted that alterations on MR safe, MR unsafe, and MR conditional equipment or devices may alter the MR safety or compatibility properties of the device. For example, tying a ferromagnetic metallic twisting binder onto a sign labeling the device as MR conditional or MR safe might result in artifact induction—or worse—if introduced into the MR scanner.



Fig. 2: U.S. Food and Drug Administration labels (developed by ASTM [American Society for Testing and Materials] International) for portable objects taken into Zone IV. The square green "MR safe" label is used for wholly nonmetallic objects, the triangular yellow label is used for objects with "MR conditional" rating, and the round red label is used for "not MR safe" objects.

C. Pregnancy-Related Issues

1. Staff pregnancies

Pregnant MR personnel are permitted to work in and around the MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning research subjects, scanning, archiving, injecting contrast material, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant MR personnel are requested not to remain within Zone IV during actual data acquisition or scanning.

D. Time-Varying Gradient Magnetic Field–Related Issues: Induced Currents

Animals with implanted or retained wires in anatomically or functionally sensitive areas (e.g., myocardium or epicardium, implanted electrodes in the brain) should be considered to be at higher risk, especially from faster MRI sequences, such as echo-planar imaging (which may be used in such sequences as diffusion weighted imaging, functional imaging, perfusion-weighted imaging, MR

angiographic imaging, etc.). The decision to limit the dB/dt (rate of magnetic field change) and maximum strength of the magnetic field of the gradient subsystems during imaging of such research subjects should be reviewed by the Level 2 MR personnel supervising the research subject.

- 1. All unnecessary or unused electrically conductive materials should be removed from the MR system before the onset of imaging. It is not sufficient to merely "unplug" or disconnect unused, unnecessary electrically conductive material and leave it within the MR scanner with the research subject during imaging. All electrical connections, such as on surface coil leads or monitoring devices, must be visually checked by the scanning MR personnel prior to each use to ensure the integrity of the thermal and electrical insulation.
- 2. Electrical voltages and currents can be induced in electrically conductive materials that are within the bore of the MR imager during the MR imaging process. This might result in the heating of this material by resistive losses. This heat might be of a caliber sufficient to cause injury to tissue. Among the variables that determine the amount of induced voltage or current is the consideration that the larger the diameter of the conductive loops, the greater the potential for induced voltages or currents, and thus the greater the potential for resultant thermal injury to adjacent or contiguous tissue.

Therefore, when electrically conductive material (wires, leads, implants, etc.) are required to remain within the bore of the MR scanner with the research subject during imaging, care should be taken to ensure that no large-caliber electrically conducting loops are formed within the MR scanner during imaging. Furthermore, it is possible, with the appropriate configuration, lead length, static magnetic field strength, and other settings, to introduce resonant PTICcuitry between the transmitted RF power and the lead. This could result in very rapid and significant lead heating, especially at the lead tips, in a matter of seconds to a magnitude sufficient to result in tissue thermal injury or burns. This can also theoretically occur with implanted leads or wires, even when they are not connected to any other device at either end.

Further, it is entirely possible for a lead or wire to demonstrate no significant heating while undergoing MR imaging examinations at low field strength but heat up significantly at higher field strengths. Thus, at no time should a label of "MR conditionally safe for thermal issues at [a given field strength]" be applied to any field strength, higher or lower, other than the specific one at which safety was demonstrated.

Thus, exposure of electrically conductive leads or wires to the RF transmitted power during MR scanning should only be performed with caution and with appropriate steps taken to ensure significant lead or tissue heating does not result.

- 3. When electrically conductive materials are required to be within the bore of the MR scanner with the research subject during imaging, care should be taken to place thermal insulation (including air, pads, etc.) between the research subject and the electrically conductive material, while simultaneously attempting (as much as feasible) to keep the electrical conductor from directly contacting the research subject during imaging. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of the MR scanner if the body coil is being used for RF transmission. When it is necessary that electrically conductive leads directly contact the research subject during imaging, consideration should be given to prophylactic application of cold compresses or ice packs to such areas.
- 4. It is important to ensure the research subject's tissues do not form large conductive loops. Therefore, care should be taken to ensure that the research subject's limbs are not positioned in such a way as to form a large-caliber loop within the bore of the MR imager during the imaging process. We are also aware of unpublished reports of thermal injuries that seem to have been associated with skin folds, such as in the region of the inner thighs. While the cause of this is not

yet fully understood, it might be prudent to consider ensuring that skin folds and other such examples of tissue-to-tissue contact are minimized or eliminated.

5. Skin staples and superficial metallic sutures: Animals for MR studies in whom there are skin staples or superficial metallic sutures (SMS) may be permitted to undergo the MR examination if the skin staples or SMS are not ferromagnetic and are not in the anatomic volume of RF power deposition for the study to be performed. If the non-ferromagnetic skin staples or SMS are within the volume to be RF-irradiated for the requested MR study, it is recommended that a cold compress or ice pack be placed along the skin staples or SMS if this can be safely accomplished during the MRI examination. This will help to serve as a heat sink for any focal power deposition that may occur, thus decreasing the likelihood of a significant thermal injury or burn to adjacent tissue

E. Radiofrequency Exposure–Related Issues: Thermal

- 1. It has been demonstrated that resonant PTICcuitry can be established during MRI between the RF energies being transmitted and specific lengths of long electrically conductive wires or leads, which can thus act as efficient antennae. This can result in heating of the tips of these wires or leads to temperatures in excess of 90°C in a few seconds. This is especially true for higher-field systems and for imaging protocols utilizing fast spin-echo or other high-RF duty cycle MRI sequences. Each research subject with electrically conductive leads should be reviewed and cleared by attending Level 2 personnel and a risk–benefit ratio assessment performed prior to permitting them access to the MR scanner.
- 2. The potential to establish substantial heating is itself dependent on multiple factors, including, among others, the static magnetic field strength of the MR scanner (as this determines the transmitted radiofrequencies [RF] at which the device operates) and the length, orientation, and inductance of the electrical conductor in the RF-irradiated volume being studied. *Virtually any lead lengths can produce substantial heating*. Innumerable factors can affect the potential for tissue heating for any given lead. It is therefore critical to recognize that of all electrically conductive implants, it is specifically wires, or leads, that pose the greatest potential hazard for establishing substantial power deposition/heating considerations.
- 3. For research animals with extensive tattoos in order to decrease the potential for RF heating of the tattooed tissue, it is recommended that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MRI process if these tattoos are in the volume in which the body coil is being used for RF transmission. This approach is especially appropriate if fast spin-echo (or other high RF duty cycle) MRI sequences are anticipated in the study. If another coil is being used for RF transmission, a decision must be made if high RF transmitted power is to be anticipated by the study protocol design. If so, then the above precautions should be followed.

F. Cryogen-Related Issues

For superconducting systems, in the event of a system quench, it is imperative that all personnel and research subjects be evacuated from C1028 as quickly as safely



feasible and that room access be immediately denied to all individuals until the arrival of MR equipment service personnel. This is especially so if cryogenic gases are observed to have vented partially or completely into C1028, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. Please see picture. It is especially important to ensure that all police and fire response personnel are restricted from entering C1028, 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, because there may still be a considerable static magnetic field present despite a quench or partial quench of the magnet.

G. PTIC Emergency Preparedness

There are many factors to consider in order to ensure that the PTIC MR imaging facility is adequately and appropriately prepared to handle any of several types of emergencies that might impact the MR scanners. Appendix 4 addresses these issues in some detail and provides specific guidelines to help anticipate and safeguard PTIC equipment and personnel from some of the more common emergencies and disasters.

Appendices 1-4 appear on the following pages.

APPENDIX 1: Adverse Event Reporting and Resolution

When an adverse event occurs the **PTIC** – **Problem Report and Solution Guide** will be completed. A copy will be kept with the equipment involved and a copy forwarded to the MR Director. The MR Director will forward a copy to the Office of Radiation Safety.

The electronic copy of the **PTIC – Problem Report and Solution Guide** can be found on the shared drive in the Center's directory.

PTIC – Problem Report and Solution Guide

Equipment Type:	\Box Hardware \Box Software	□ Both
□ 9.4T MRI	□ Other (specify):	

Report Date:	Solution Date:	
Found By:	Manufacturer Rep:	
Solution By:	Phone Number:	

Description of Problem:

Solution:

(please be very detailed, if a protocol is developed to prevent recurrence please attach)

Forwarded to MR Director by:	Date:
Forwarded to Rad Safety by:	Date:

APPENDIX 2: Personnel and Zone Definitions

PERSONNEL DEFINITIONS Non-MR Personnel

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 terminology 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 Director of the Center for Imaging Research (PTIC).

Level 1 MR Personnel

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work in Zone III will be referred to as Level 1 MR personnel. Level 1 MR personnel are permitted unaccompanied access throughout Zone III but must be accompanied by Level 2 MR personnel in Zone IV.

Level 2 MR Personnel

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including 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. Only Level 2 MR personnel will be allowed to escort non-MR personnel in Zones III and IV.

ZONE DEFINITIONS

Zone I

This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which research personnel and other employees of the PTIC MR facility access the MR environment.

Zone II (outside C-1026 & C-1028)

This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III (see below). Typically, research personnel are greeted in Zone II and are not free to move throughout Zone II at will, but rather are under the supervision of MR personnel.

Zone III (outside 5 gauss line but in C-1026 & C-1028)

This area is the region in which free access by unscreened non-MR personnel, ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the particular environment of the MR scanners. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of Level 2 MR personnel.

Zone IV (within 5 gauss line)

This area is synonymous with the MR scanner magnet room or demarcated area. 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. Non-MR personnel will be accompanied by, or under the immediate supervision of and visual contact with, a specifically identified Level 2 MR person for the entirety of their duration within Zone III or Zone IV restricted regions.

APPENDIX 3: MR Personnel Screening and Training

Hiring – As part of the interview process, all potential MR personnel will be questioned to determine if they have implanted cardiac pacemakers, auto defibrillators, diaphragmatic pacemakers, or other electromechanically activated devices upon which they are dependent. For their own safety and health any potential employees that have such devices will not be able to work in the MR environment.

Level 1 training – will consist of reading the MR Safety training module and completing the MRI Level 1 Safety Post-Test

Level 2 training – will consist of Level 1 training plus reading this document and completing the MRI Level 2 Post-Test.

Documentation of training will be kept in the PTIC facility.

APPENDIX 4: Generalized MR Facility Emergency Preparedness Guidelines

1. Water Damage

Whether from roof failure, burst pipes, or a storm surge, every facility has the potential for water damage to equipment and facilities. Damage can range from inconveniences cured by a couple of hours with a wet–dry vacuum to flooding of equipment electronics. It takes only a small quantity of water in contact with an MRI scanner to incapacitate or destroy the equipment.

To keep leaking roofs, burst pipes, or other overhead damage from dousing MRI equipment, it is recommended equipment be covered with sturdy plastic, taped in place, when water damage is an anticipated possibility. To keep processors and gradient cabinets from becoming swamped in a flood situation, electronics that can be lifted off the ground should be moved as far off the floor as possible. RF shields, particularly the floor assembly, may be significantly damaged and need to be replaced in a flood situation if they are not designed for protection against water damage.

2. Structural Damage

MRI presents a particular challenge with structural failure. Although unlikely with current magnet systems, vibrations from seismic events do have the potential to initiate a quench of the magnet system. Structural damage or motion may also damage the RF shield enclosure, potentially degrading image quality until the shield is repaired.

3. Power Outage

If there is any power outage all available Level 2 personnel should make sure all computers and MR electronics are turned off and left off until power is properly restored.

Without electrical power to the vacuum pump/cold head to keep the cryogen within a superconducting MRI magnet liquefied, the cryogen will begin to boil off at an accelerated rate. Depending upon cryogen vent design and boil-off rate, the additional cryogenic gas discharge may freeze any accumulated water in the cryogen vent, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench.

At some point, if power to the vacuum pump is not restored, likely a couple days to perhaps a week after power is lost, the magnet will spontaneously quench, discharging most or all of its remaining cryogenic gasses. This poses a safety risk to anyone near the discharge and runs a small but finite risk of potentially permanently damaging the magnet coils.

However, if power to the vacuum pump/cold head and cryogen levels is restored prior to a quench, there should be no long-term consequences to the magnet's operation from a power interruption.

4. Quench

A quench is a sudden explosive release of all cryogenic gases from the magnet housing. With loss of cooling, the magnet coils will lose superconductivity and they will no longer produce a magnetic field. A quench pipe may be attached to the top of the magnet and is designed to vent the escaping gases to the outside, however, a gaseous helium vapor can escape and displace air within the magnet room. The vapor is extremely cold and should not be breathed in. Under the best PTICcumstances, a quench subjects a magnet to a change of 500°F (260°C) thermal shock within a few dozen seconds, which can cause major physical damage.

Because of the risks to personnel, equipment, and physical facilities, manual magnet quenches are to be initiated only after careful consideration and preparation. In addition to following those specific recommendations provided by the MRI manufacturer, a facility should initiate a preemptive quench in non-emergency situations only after verifying the function of emergency exhaust systems, verifying or providing means of pressure relief, and performing a preliminary visual inspection of the cryogen vent pipe as it leaves the MR unit to check for signs of water or ice inside the pipe (including water leaking from fittings or condensation forming on vent pipe sections).

5. Fire and Police

Though very infrequent, MR suites have been the scene of emergencies requiring fire and/or police response. While it is quite likely this will be the first time many of the responders have been to an MR suite, this should not be the first time that responding organizations have been introduced to the safety issues for MR.

6. Prevention

While it is the nature of emergencies to be surprises, we can anticipate the types of incidents that have higher likelihoods given our facilities, practices, and locations. Every facility can anticipate the potential for flooding, fire, and code situations. In addition to these California can expect earthquakes.

State and federal offices of emergency preparedness are dedicated to anticipating and preparing for the specific threats to your region. These offices can serve as an excellent resource regarding risks and strategies for preparation.

Once a disaster has struck, it is important to assess the immediate needs of the community and to restore those critical services first.

UCI have emergency preparedness plans. In addition the PTIC has defined:

- Only the MR Director has the authority to authorize non-emergency quenches
- Information needed to restore MR function are:
 - MR vendor: Bruker
 - 9.4T BH # **BH092001**

Electronic System Information:

Scott Shaw- MRI Manager 978-667-9580 ext 5370 978-239-0857 Cell Scott.Shaw@bruker-biospin.com John Montalbano- Senior Service Engineer 978-667-9580 ext 5120 978-204-8609 Cell John.Montalbano@bruker-biopsin.com Paulo Casella- Service Engineer 978-667-9580 ext 5428 978-761-4452 Cell Paulo.Casella@bruker-biospin.com

Magnet/Refrigeration System Information Scott Shaw- MRI Manager 978-667-9580 ext 5370 978-239-0857 Cell Scott.Shaw@bruker-biopsin.com Peter Storm- Senior Magnet Service Engineer 978-761-5258 Cell storm@attglobal.net John Laumann- Magnet Service Engineer 978-667-9580 ext 5492 508-572-1270 Cell John.Laumann@bruker-biospin.com Paul Tanner-Magnet Service Engineer 978-667-9580 ext 5272 978-821-0673 Cell Paul.Tanner@bruker-biospin.com

- Cryogen contractor
 - Nitrogen Praxair thru a PTIC contract
 - Helium Praxair thru a PTIC contract
- 9.4T magnet vents to the exterior of Bldg 833

• Level 2 - MRI Safety Post-Test for PTIC Personnel

Employee Name (PRINT)		Date
Employee ID number:		Job Title
Performance Standard Post-Test		If false please state correct answer
1. Non-MR personnel and Level 1 MR-personnel must have verbal and visual contact with Level 2 trained MR-personnel at all times when they are in Zones III & IV.	T or F	
2. After a quench there is no longer a magnetic field present.	T or F	
3. Non-MR safe objects should never be taken in to Zone IV.	T or F	
4. Conventional metal detectors are adequate for MR screening procedures.	T or F	
5. Insulation should be placed between the subject and any wires that need to be left in the magnet during imaging to prevent thermal burns.	T or F	
6. Traditional ECG monitoring while the subject is in the magnet is not reliable and the leads can cause thermal burns.	T or F	
7. All persons accessing Zone III should undergo MR screening.	T or F	
8. Cardiac arrests and other medical emergencies must be moved to the hallway or outside Zone IV before treatment starts.	T or F	
9. Implanted metal objects in a subject can cause induced currents and burns.	T or F	
10. Firefighters and emergency personnel, along with their equipment, are allowed full access to Zones III & IV.	T or F	
11. When the magnet is quenched, for any reason, everyone must quickly leave the room and shut all doors to the MR rooms.	T or F	
12. Briefly explain the 3 levels of MR safety markings. What colors and shapes are used and what do they indicate?	·	

Employee Signature_____

Manager/Supervisor Signature

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