SAFETY MANUAL

Dynamic Imaging Science Center
0.55 Tesla MRI

UNIVERSITY OF SOUTHERN CALIFORNIA

USC Viterbi
Dynamic Imaging Science Center

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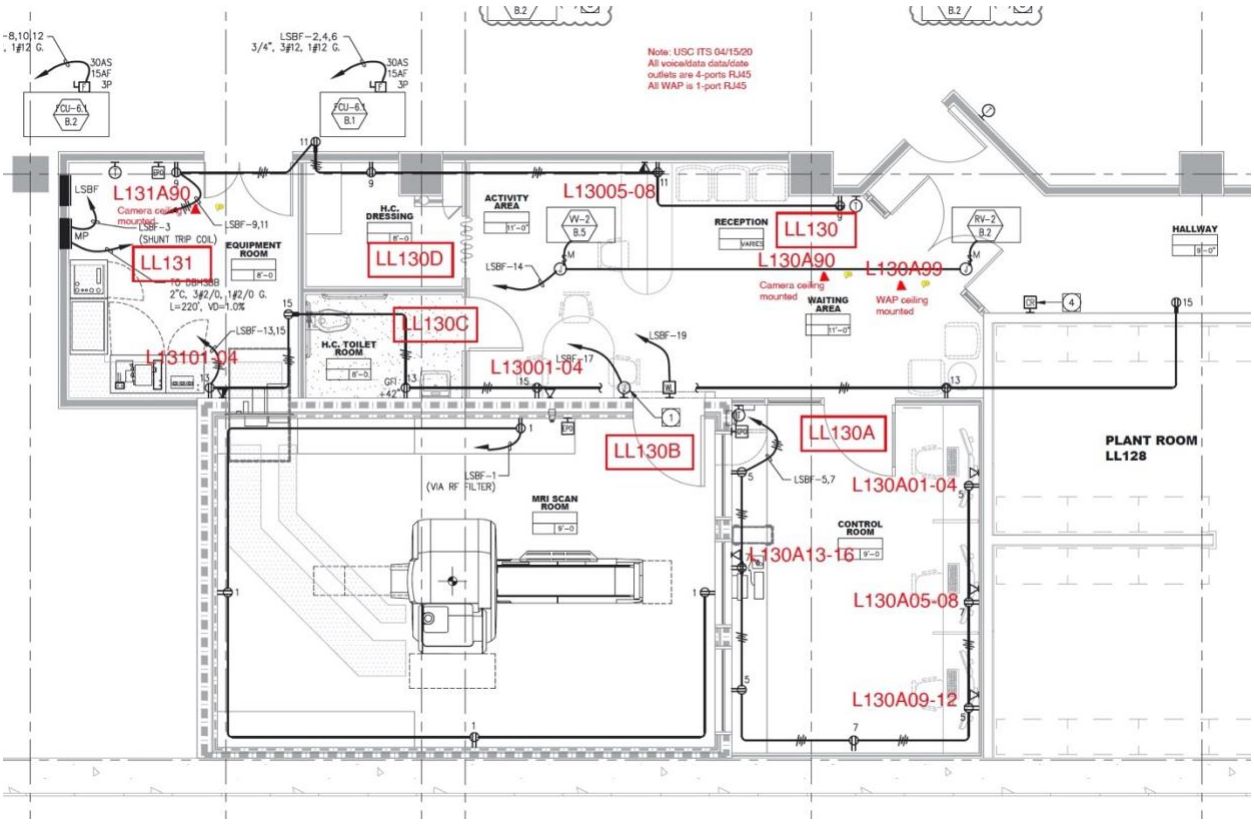
II. DIAGRAM OF THE MRI FACILITY



III. SAFETY ORGANIZATION WITHIN THE MRI UNIT

The Dynamic Imaging Science Center (DISC) facility is a research-only unit. No clinical studies are undertaken at the Center. With respect to safety, the Center's activity falls under the general guidelines of germane institutional policies at the University of Southern California, and other relevant policy-making bodies of the state and federal governments.

The final responsibility for safety within the MRI facility rests with the Management Committee, which is comprised of individuals knowledgeable about experimental procedures in MRI, medicine, neuroscience, physiology, physics, and electronics. If an unsafe condition arises, or if a safety policy has been violated, the Management Committee has the authority and responsibility to revoke approval of the protocol involved until the condition is corrected. The Committee and the MRI Staff Physicist have this authority *pro tempore*.

The MRI Staff Physicist is experienced and knowledgeable about the operation of the MRI scanner, safety hazards, and safety policies of MRI facility. The Staff Physicist has the authority to suspend any activity in the MRI facility that in his judgment violates the safety policies of the Management Committee (or University), or that otherwise constitutes an unsafe condition. He may transfer this authority to an approved operator of the facility. The Staff Physicist will perform the following safety-related tasks:

1. Ensure that the safety policies of the Management Committee are followed during the execution of approved MRI research protocols.
2. Coordinate training classes concerning safe conduct of research in the MRI facility.
3. Maintain a permanent file of incident reports and any corrective actions taken.
4. Ensure adequate distribution of the manual governing safety within the MRI facility.
5. Remain updated on all new governmental and non-governmental policies and recommendations regarding MRI safety.
6. Report employee accidents to the university safety department and to the Management Committee.

A qualified MRI operator will be responsible for performing all MRI procedures. He/she must have the following qualifications:

1. Have completed successfully a formal training on safety conducted by the Staff Physicist.
2. Have completed hands-on training on the MRI scanner of the Center under the supervision of an experienced MRI technologist.
3. Have been approved or certified by the Management Committee.

IV. SUMMARY OF EMERGENCY PROCEDURES FOR THE MRI UNIT COVERED BY THE SAFETY TRAINING

A. MEDICAL EMERGENCIES

1. In case of emergency, dial x04321 from campus phone or 213-740-4321 from mobile phones to report the nature of the emergency along with the location of the emergency to the response team.
2. Emergency procedures shall NOT be administered in the magnet room, and NO medical equipment shall be allowed in the magnet room. Instead, the MRI operator or emergency team shall remove the subject immediately from the magnet room and transport her/him to an area within the center where the emergency will be handled by the medical response team.
3. The magnet room door shall be closed upon removal of the subject to avoid entry of any metallic objects.
4. If not already onsite, the principal investigator shall be contacted and informed of the nature of the emergency.
5. All adverse events shall be documented on an incident report. The IRB and the Staff Physicist will be notified immediately via a telephone and within 48 hours in writing.

B. FIRE EMERGENCIES

1. The MRI operator shall immediately remove the subject from the magnet room and building.
2. All doors shall be closed to contain the fire.
3. x04321 shall be dialed identifying the type and location of fire.
4. If the fire occurs in the magnet room, the fire shall be extinguished using a non-ferrous fire extinguisher (magnet is always on unless it is quenched). The white fire extinguishers inside the control room and the one outside by the control-room door are non-ferrous and suitable for use in case of an electrical fire.

C. QUENCH

What is a quench?

The MRI scanner uses a super-conducting magnet. Its magnetic field does not diminish even if electrical power is cut to the scanner. A “quench” will be required to shut down the magnetic field quickly in an emergency. **Quench can be initiated by pressing the “Magnet Stop” button, which is located in the control room and in the magnet room.**

During a quench, the magnet loses its super-conductivity. The magnetic field ramps down in a matter of seconds - typically at a rate of approximately 20 seconds. The magnet begins to warm up. Depending on the current fill level, liquid helium boils off at 500 to 1500 liters within a few minutes and expands quickly. The exact amount depends on the fill level as well as the field strength of the magnet. One liter of liquid helium translates into approximately 700 liters of gaseous helium. During maximum conditions this means approximately 1000 m^3 gas. The purpose of the quench line is to securely exhaust gaseous helium to the outside. In view of these precautions, how does one explain a quench? A quench may be released by pressing the magnet's "emergency shut-down" switch (the one with a red "do not touch" label). Another source for quenching is a helium fill level that decreases to a point where the magnet begins to warm up. In rare instances, a spontaneous quench may be observed that cannot be explained by the presence of obvious external sources.

A quench is accompanied by hissing or whistling noises caused by the quickly escaping stream of cold helium gas. Plumes of white fog sink to the floor mainly from the upper part of the magnet and the vicinity of the quench line due to condensation of both water vapor and air. The stream of gas diminishes in a matter of minutes. Air near the non-insulated components of the magnet and the quench line condenses into liquid air and drips to the floor.

Risks associated with a failing quench line

The possibility of a quench was taken into careful consideration during the design of both the magnet and the helium quench line. As a result, a quench is expected to be safe to personnel and equipment. Risk exists and is often associated with a failed quench line needed for venting the excess helium.

Helium is lighter than air, non-poisonous and non-flammable. However, since it displaces oxygen, the risk of suffocation exists. Cryogenic helium escaping into the ambient air leads to white clouds caused by condensation. These clouds adversely affect visibility.

Persons may be rendered unconscious by the amount of helium entering their respiratory system. Depending on the helium concentration present, a few breaths suffice to result in unconsciousness.

In addition, escaping helium is extremely cold, causing hypothermia and frostbite. The latter results in injuries resembling burns (cryogenic burns) after the skin is exposed to normal temperature levels. Skin contact with cold parts or liquid air may also lead to frostbite.

In case the quench line fails, the following may occur:

1. **Small leaks**: Smaller amounts of helium gas are exhausted to the outside via the heating and air conditioning system and replaced by fresh air. This is not a critical situation as long as the heating and air conditioning system function as required.

Leakages are the result of construction errors and need to be corrected.

2. **The quench line fails in part only:** only part of the helium gas is exhausted to the outside via the integrated venting system. Larger amounts of helium are present in the examination room. The heating and air conditioning no longer ensure a quick air exchange. Large clouds form, impairing visibility. Additionally, the pressure in the room increases. Depending on the size of the leakage, **hazardous conditions may be present for the personnel involved.**

3. **Total failure:** the venting line fails completely, e.g., through blockage or breaks in the line. The entire amount of gas is blown into the examination room. **Loss of life** is imminent in the case of a complete failure. Up to 1000 m^3 gas are blown into the room, which frequently has a volume of less than 100 m^3.

Steps taken by the operator to minimize risks:

The planning and installation of room venting, and quench lines must adhere to the planning requirements and will be checked by trained personnel.

Checking the exhaust system and room venting.

The helium boil-off system as well as the venting system must be visually inspected at regular intervals to determine changes.

In particular:

1. Constructional changes inside and outside the shielded RF-room
2. Inappropriate changes by unauthorized personnel
3. Damage to the thermal insulation of the exhaust line
4. Damage to the exhaust line
5. Obstructed exit, e.g., presence of bird nests (is the protective grid still intact)?
6. Damage to protective rain covers (these are regularly required for vertically exiting quench lines. Depending on the design, they are also frequently in place for horizontal exits).
7. Was the exhaust to the outside changed after the system was handed over to the customer, endangering third parties through the gas exhausted? This may involve, for example, windows installed at a later date, exits and entrances put in place for heating and air conditioning systems, new buildings or temporarily installed containers.
8. Was the heating and air conditioning system or venting of the room changed, e.g., by adding additional venting inlets or outlets in adjacent rooms?
9. Were additional MR systems installed?
10. Is the same quench line used for additional MR systems?

Since each system is subject to either changes or remodeling of the building during its operating life, the operator needs to be thoroughly familiar with the importance of the quench line and the venting system. For this reason, we recommend visual inspections on a daily basis (e.g. with respect to construction changes in the vicinity of the quench line, severe weather-related changes such as ice or snow). In case of questionable system functionality, contact the customer service center.

What to do in the case of a quench? - Establishing an emergency plan

The following recommendations are designed to help the operator in establishing an emergency plan that should include the following:

1. MR-suite related conditions: windows, escape routes
2. Emergency personnel available (e.g., ambulance personnel, on-site firefighters)
3. Instructions and information provided to firefighters (must be provided before an actual emergency as described in the operating manual).
4. The plan should include rescue exercises performed with the respective personnel.

While a quench may cause a certain level of anxiety in patients and operators that have not been instructed sufficiently, it is usually quite harmless.

The following applies in the case of a quench: for safety reasons, personnel should leave the system and its vicinity if evacuations are necessary.

The operating personnel should be trained in overseeing the evacuation of the MR suite and adjacent rooms.

Personnel should only return to the MR suite after the situation is back to normal, that is, noises have stopped and visibility is no longer obstructed. For safety reasons, all rooms should be thoroughly aired; windows and doors to the outside should be open. Usually the air conditioning system will provide for effective air exchange.

If personnel are present in the magnet room, consider the following:

1. **Standard scenario:** the quench line works as planned. The patient can be easily removed. Contact with **cryogenic** parts is prohibited.

2. **Small leaks:** these would lead to small clouds of fog that clearly remain above head level and are frequently visibly sucked off by the heating and air conditioning system. White fog-like plumes sink to the floor. They consist of cold air and do not lead to suffocation. In this case, overpressure is not present. There is no risk of suffocation for either patient or personnel. The patient can be removed, either immediately or after a few minutes depending on the patient's reaction to the situation. Contact with cryogenic parts is

prohibited.

3. **Partial or complete failure of the quench line:** large fog-like clouds leading to impaired visibility are present. These clouds spread at the level of a person's head. In this case, the pressure in the RF-room will increase as well. **Open all doors (the control room door first, and then the RF-room) and evacuate immediately. Depending on the extent of the leak, persons and rescue personnel may be endangered. As a rule, rescue personnel should not work alone, but in groups of two or more people.**

Usually, the strongest gas flow occurs only after several minutes and will subsequently subside. However, the course of gas flow is not fully predictable, since at the time of occurrence the type of error in the quench line is not fully known.

Prior to opening the door to the RF-room, all available doors and windows of the control room should be opened to ensure sufficient ventilation. All personnel in the vicinity of the system who are not needed for rescue activities should leave prior to the rescue of the patient from the examination room. When opening the door, overpressure in the room should be factored in as follows:

1. If the door opens in the direction of the control room, the door may fly open due to overpressure. The operator should be aware of this possibility so that he can avoid injuries caused by the unexpected opening of the door.

2. If the door opens in the direction of the RF-room, it may be impossible to open it due to the overpressure in the room. In this case, existing openings (windows or emergency flaps) must be opened. The over- pressure may lead to windows or flaps swinging unexpectedly. If there are no emergency openings, the observation window may be smashed in (hazardous situation caused by splinters).

After opening the door to the examination room, the helium gas may escape to adjacent rooms, endangering the safety of the rescue personnel. It is possible to check the air with an oxygen monitor. A gas mask does not protect against oxygen displacement by the helium gas. An oxygen tank must remain in the facility for emergencies due to escaping helium. In addition to the risk of suffocation there is also the additional risk of hypothermia.

Since the helium gas warms up quickly and spreads downward from the ceiling, a rescue worker standing upright is exposed to greater danger than a patient lying in the magnet.

After the patient has been removed from the examination room, no personnel should remain in the vicinity of the system until the quench has been stopped and ventilation has been ensured.

During a total failure of the quench line in the magnet room, the room will be quickly filled with cryogenic helium gas. After a quench, the usual service procedure goes into effect (please refer

to the Siemens System Manual located in the cabinet in the control room). Customer service has to be notified as quickly as possible to put the system back into operation.

D. EMERGENCY MAGNET STOP

The device for initiating a quench, the **Emergency Magnet Stop** or Emergency Field Shut-down Unit (ERDU) button, pictured below, allows for the rapid reduction of the magnetic field in about 20 s from activation of the ERDU button to the moment when the magnetic field intensity in the magnet isocenter has dropped to 20 mT. There are two Magnet Stop switch available at the MR system:

1. an individual switch installed inside the examination room
2. an integrated switch built into the alarm box installed at the operator console.

Only the MRI Staff Physicist or directors of the MRI center are authorized to trigger the rundown UNLESS A HUMAN LIFE IS AT RISK (i.e., do not quench the magnet if a piece of furniture or equipment got into the bore. Such objects can be safely removed by calling Siemens' service engineer to slowly power down the magnet). The Magnet Stop button should be triggered to free someone pinned to the magnet or to remove a large ferromagnetic object captured in the magnetic field when injury to the subject is imminent. After triggering a quench, the MRI Staff Physicist must:

1. Use the intercom to *alert the patient to stay calm and remain on the table* until the operator gains access to the room to help.
2. *Prop open the magnet room door* to promote air circulation.
3. *Transport the patient out of the room*.
4. *Evacuate all personnel from the area.*

5. *Inform the director and call Siemens Uptime.*

E. EMERGENCY OFF

The **Emergency Off** button pictured below is located on the wall in the MRI magnet room and on the operator's console. It removes ALL electrical power from the MRI console and the patient table, including any power sources from the Uninterrupted Power Supply (UPS) devices. The effect of pushing the Emergency Off button is to turn off the entire MR system, EXCEPT for the static magnetic field and the magnet quenching unit (described above), hence this **DOES NOT PRODUCE A QUENCH**. The button should only be used DURING A SERIOUS EQUIPMENT FAULT OR HAZARD, such as fire or water in the vicinity of the MR equipment.

F. PROCEDURE FOR POWER FAILURE OR OUTAGE

In the event of a power failure or outage while an MRI study is in progress, the patient will first be removed from the bore manually. Simply release the brake on the patient table and pull the patient table out of the bore. Once patient safety is secured, the MRI operator will return to the MRI suite and properly shutdown all computers (which should be receiving power from UPSes), thus preventing corruption of the software on the MRI scanner. The MRI center and ancillary systems will remain off until the Engineering Department notifies the MRI Staff Physicist of adequate power return.

V. GENERAL SAFETY CONSIDERATIONS FOR MRI SCANNING AT 0.55 TESLA

The low field MRI system at the facility is a 1.5T Siemens MAGNETOM Aera MRI system modified to operate at 0.55T. The modifications include ramping down the field, retuning the body coil, receive coils and cable traps, and providing new RF hardware. The SAR monitor and gradient safety watchdog will be fully operational in this modified investigational system. All components, including ones modified, are developed, and tested according to Siemens' standards for investigational devices for human use (investigator/site sponsored study). Safety tests were performed in factory and following installation on site.

The system will be used solely for research purposes that involve animal and human subjects, as well as MRI phantoms (containers filled with gelatinous materials or chemicals).

A. GENERAL SAFETY PROCEDURES IN THE MRI CENTER

1. All research subjects must be evaluated by the principal investigator, or designee, as to their physical and mental status before entering the MRI suite.
2. All individuals must undergo screening for metallic objects, using an established questionnaire (appended to this document), before entering the magnet room, and those with critically implanted magnetic objects (i.e., aneurysm clips, pacemakers etc.) will not be allowed in the room.
3. All research subjects must be always attended to while present in the MRI suite.
4. No human research will be performed within the MRI center without prior approval of the university's IRB.
5. All human subjects (or legally authorized representative) must sign an IRB-approved informed consent form before entering the magnet room.
6. When the MRI scan is in progress, subjects will be given a signaling device to hold so that he or she can alert the MRI operator in case of an emergency or discomfort.
7. All subjects will remain in view of the technical personnel, either via direct eye contact or via a camera system while the MRI scan is in progress.
8. When scanning a human subject, another person must be in the control room in addition to the operator.
9. No animals will be scanned at the Center.

B. MRI-SPECIFIC RISKS

The risks of MRI scanning can be classified into one of four categories, those associated with 1) Acoustic Noise Levels, 2) Gradient or Time-Varying Magnetic Fields, 3) Radiofrequency (RF) Magnetic Fields, and 4) Static Magnetic Fields.

1) Acoustic Noise

The acoustic noise associated with MRI imaging is related to the mechanical movement of the gradient coils during the scanning process.

FDA Guidelines: "The acoustic noise levels associated with the device must be shown to be below the level of concern established by pertinent Federal Regulatory or other recognized standards setting organizations. If the acoustic noise is not below the level of concern, the sponsor must recommend steps to reduce or alleviate the noise perceived by the patient." Current FDA guidelines follow the regulations of the International Electrotechnical Commission (IEC) Standard 601-2-33, which stipulate that for MR equipment used in medicine, hearing protection is required when the system can produce acoustic sound levels above 99 dBA and that the protection should be able to reduce noise levels to below 99 dBA.

Acoustic noise is caused by operating the gradient system in conjunction with the static magnetic field and scales linearly with field strength. The FDA has approved systems for which noise levels have been quantified, ranging up to 105 dB RMS for scanners operating at field strengths of 1.5 Tesla. The 0.55T MRI has the same gradient system as the FDA approved 1.5 T MAGNETOM Aera scanner while operating at lower field strength of 0.55 T. Therefore, acoustic noise produced by the 0.55T scanner will be roughly 3 times lower than acoustic noise produced by an equivalent 1.5 T scanner and will be much lower than that recommended by the FDA.

Summary of Risks: The acoustic noise levels perceived by human subjects when undergoing MRI examination in the 0.55 Tesla magnet constitutes a non-significant risk; specifically, this system will not be operated in a way that will present more noise to human subjects than is recommended by the FDA.

Ensuring Safety from Acoustic Noise: As suggested by the FDA, steps will be taken to reduce or alleviate the noise levels experienced by subjects in this protocol. This will be accomplished by one of two methods:

1. Use of disposable earplugs
2. Use of acoustically shielded headsets

2) Peripheral Nerve Stimulation

The time-varying magnetic fields used in MRI can, in some instances, induce stimulation of peripheral nerves, thereby producing sensations such as 'twitching' or 'tingling'. In very rare instances, this nerve stimulation can be painful. Nerve stimulation is particularly likely when subjects are physically positioned in a way that increases the likelihood of inducing stimulation, such as with hands clasped or arms folded. The ability to produce time-varying magnetic field is determined by the gradient system of the scanner. The 0.55T MRI has the same gradient system as the FDA approved 1.5T MAGENETOM Aera and therefore do not produce greater Peripheral Nerve Stimulation.

FDA Guidelines: The FDA Guidance of 1995 was developed specifically to consider the fact that many clinical systems were capable of exceeding levels of dB/dt that could produce nerve stimulation. It was originally considered that a warning level should be implemented to guard against peripheral nerve stimulation, but the FDA finally concluded that: *'... this warning level is not considered critical since there are no harmful effects associated with mild peripheral nerve stimulation'.* The current guidelines therefore include monitoring procedures to help avoid painful peripheral nerve stimulation, and without specific dB/dt limitations.

Summary of Risks: The gradients used in the 0.55 Tesla MRI system will typically be operated at levels below those considered to be negligible according to FDA guidelines. This system, like most commercially available, FDA-approved systems, have the capacity to exceed this level, but it will include the same safeguards that are included in FDA-approved clinical systems. Furthermore, policies and procedures will be implemented according to FDA guidelines to avoid the possibility of painful peripheral nerve stimulation. Therefore, in all circumstances the system will be operated in a way that poses non-significant risk to the participant.

Ensuring Safety from Peripheral Nerve Stimulation:

1. All consent forms for studies that might induce peripheral nerve stimulation will provide this information.
2. If the built-in stimulation monitor is bypassed by a user sequence, record of dB/dt value will also be included with the imaging data to help in an analysis of levels of peripheral nerve stimulation perceived by subjects.
3. If the built-in stimulation monitor is bypassed by a user sequence, detailed calculations of the changes in magnetic field over time of which the gradient system is capable will be calculated, and conservative values will be selected as limits that will be used to determine when special additional monitoring is indicated. In these cases, monitoring procedures recommended by the FDA will be used.
4. The gradient switching times and strengths will be monitored together with the routine assessment of all electrical components of the system.
5. All MR operators will receive special training to prevent peripheral nerve stimulation.
6. Before any scanning procedure that might stimulate peripheral nerves, an operator will:
    - Inform the subject that peripheral nerve stimulation may occur
    - Describe the nature of the sensation to the subject
    - Instruct subjects not to clasp their hands, since this may create a conductive loop which will increase the possibility of stimulation
    - Maintain constant verbal contact with the subject
    - Instruct subjects to inform the MR operator if they experience discomfort or pain
    - Terminate the scan if the subject complains of discomfort or pain
    - Complete a report of any incidents involving severe discomfort or pain, including a description of the associated circumstances (imaging parameters, dB/dt value, level of pain, etc.), and submit this report immediately to both the IRB and to the MRI Safety Committee

3) Tissue Heating

MRI scanning induces some heating of body tissues. This specific absorption rate (SAR) that determines heating is the amount of radiofrequency (RF) energy deposited (typically by a coil or "helmet"-like apparatus placed over the subject's head) per unit volume of tissue per unit time. RF energy in MRI examinations is not a function of the strength of the static magnetic field. Rather, the Specific Absorption Rate (SAR) for RF radiation is related to the amplitude of RF power, the duration of the RF pulse, the type of RF coil used, the frequency of RF radiation, the resistivity of the tissue, the configuration of the anatomical region being examined, and several other parameters.

FDA Guidelines: "The following are levels of concern at which the reviewer shall exercise appropriate actions to ensure that the safety of the device is substantially equivalent to a predicate device: A) If SAR < 0.4 watts per kilogram (W/kg) whole body; and if SAR < 8.0 W/kg spatial peak in any 1 gram of tissue; and if SAR < 3.2 W/kg averaged over the head: **below level of concern**. Or B) If exposure to radiofrequency magnetic fields is insufficient to produce a core temperature increase more than 1°C and localized heating to greater than 38°C in the head, 39°C in the trunk and 40°C in the extremities: **below level of concern**. The parameter SAR cited above must be shown to fall below either of the two levels of concern by presentation of valid scientific measurement or calculation evidence sufficient to demonstrate that SAR is of no concern."

It should be noted that this guideline is based on the calculation of a system that has no thermoregulatory response, and thus it is a very conservative estimate compared with the temperature change that would be experienced in any living subject. Normal diurnal temperature variations in humans, for example, are about +/-1°C from the normal set point 37°C, and healthy people with normal thermoregulatory responses can easily dissipate any excess (or, in this instance, deposited) heat by increasing their peripheral blood flow or sweat rate. Thus, the heating effect of MRI with the SARs used in accordance with these guidelines is extraordinarily unlikely to cause any acute effects in healthy human subjects.

Summary of Risks: Because all experiments performed on the 0.55 Tesla system will comply with FDA guidelines regarding SAR, and because appropriate RF power safety checks are in place, the criterion for classification of NSR is satisfied.

Ensuring Safety from Tissue Heating Risks: The magnitude of temperature increase during MRI scanning is minimal. Increases are always within FDA guidelines, which include core temperature increases less than 1°C, as well as localized heating to less than 38°C in the head, 39°C in the trunk, and 40 °C in the extremities. The 0.55 Tesla system has in place a means to monitor RF power levels and ensure that energy deposition is sufficiently low to stay well within these guidelines for temperature increases. First, a "system security" unit is employed to integrate the output of the RF amplifiers. This integration takes into account the amplitudes and duty cycle of the transmitter. If system security detects an output that might exceed the guidelines noted above, it automatically shuts down the entire RF power system. Secondly, all

pulse sequences are evaluated, based on calculations and sound scientific measurements, to ensure that SAR remains within FDA-approved guidelines, prior to their use in humans. Any experiment performed on the 0.55 Tesla system will comply with all FDA guidelines regarding RF power deposition. Proper and routine monitoring of all RF electronics (e.g., coils, transmitters, system security, etc.) will be performed on a regular basis. All pulse sequences will be evaluated (by calculation and by valid scientific measurement) prior to use in humans.

4) Static Magnetic Fields

The possible risks of static magnetic fields have received much attention in the lay press, but scientific consensus on these risks has yet to be fully reached. The FDA has deemed those systems operating at 8.0 Tesla or less do not pose a significant risk. Moreover, experience with thousands of clinical studies over the past decade, and with multiple human investigations carried out at higher field strengths over this period, have not revealed risks of exposure to higher static magnetic fields. The most significant risk associated with static magnetic fields is that ferromagnetic objects, such as aneurysm clips or heart valves, can interact with the magnetic field of an MRI scanner, causing the device to malfunction or to move, and injuring the subject. For some patients, rapid head movement while in the magnetic field may cause dizziness, vertigo, or a metallic taste in their mouth.

FDA Guidelines: “Studies conducted at 8T or less are not considered significant risk" (FDA Center for Devices and Radiological Health, memorandum 7-14-03).

Summary of Risks: This category of risk applies to work conducted around superconducting magnets of any kind (including standard clinical diagnostic MRI units). It is not unique to this 0.55 Tesla facility. The MRI facility will maintain a safety policy to safeguard subjects and staff members from these incidental risks. Systems with static magnetic field less than 8.0 Tesla have been considered to represent a nonsignificant risk (NSR) by the FDA. The static magnetic field of this system (0.55 Tesla) is therefore to be classified as posing NSR to human subjects.

Ensuring Safety from Static Magnetic Field Risks: The minimization of risks associated with the static magnetic field of 0.55 Tesla is related to incidental risks (see below). These risks are the same as in commercially available clinical systems, and like clinical MRI centers, this facility will incorporate a complete range of procedures, including:

1. Assure the security of the restricted access area. Entrance doors to the MRI department will be kept always closed. Access to the MRI suite will be tightly controlled, allowing access for only personnel and research subjects who have legitimate reason to be there. Doors to the MRI suite will be securely locked.
2. Entryways to the MRI suite will be labeled with clear visible signs warning of the presence of the magnetic field and the exclusion from entry by individuals with implanted metal objects such as prostheses, pins, clips, IUD’s, pacemakers, etc.
3. The MRI operator will conduct careful screening of potential subjects before they enter the magnet room (appended at the end of this document).
4. To minimize the potential for dizziness or a metallic taste, it is recommended that the

patient remain still while in the region of high static magnetic field.

5. Incidental Risks

The physical confinement and isolation produced by the scanner could cause mild to moderate emotional distress, although extensive past experience has shown that subjects tolerate the procedures remarkably well.

All subjects will be able to communicate directly with the operators and study staff to inform them of any emotional or physical distress during the scanning procedure. If they wish, the scan will be terminated immediately, and the subject will be removed from the scanner

Ensuring Data Safety:

All MRI data will be stored behind firewalls at the MRI facility.

VI. SPECIFIC HAZARDS WITHIN THE MRI CENTER

A. ELECTRICAL HAZARDS

1. The MRI scanner will be evaluated regularly for electrical hazards by the Siemens Field Engineer, as detailed in the service agreements with the MR system manufacturer.
2. All modifications to the equipment will be performed only by the Siemens Field Engineer and will be rigorously evaluated in terms of electrical safety.
3. Safety tests will be carried out on a regular basis by the Siemens Field Engineer regarding radiofrequency and magnetic field levels, as detailed in the service agreements with the MR system manufacturers. After safety tests are completed, the service engineer will leave a comprehensive service report relating all results and action taken to restore any faults in MRI system.

B. CRYOGEN HAZARDS

A superconductive magnet in the MRI scanner uses cryogens to supercool the electrical conductor that creates the magnetic field. Temperatures as low as -269°C (-452°F) are achieved to create the proper superconducting environment within the magnet. A quench, which is a sudden boil-off of the entire volume of cryogenic liquid, causes a rapid loss of the static magnetic field.

Cryogens come in large vacuum containers called “dewars”. Liquid helium is generally used for cooling purposes, although some service procedures also require liquid nitrogen. Nitrogen dewars weigh from 400 to 500 pounds when full. Helium dewars weigh from 700 to 800 pounds. In addition to large dewars, there may be smaller helium gas cylinders present. This helium gas is used to fill the magnet to the correct cryogen levels. The cryogens boil off as they cool the magnet wires and must be replenished periodically by qualified personnel. Contact with the cryogenic liquids or gas could result in severe frostbite, and care is needed when in proximity to these substances. Furthermore, leaking helium or nitrogen gas will displace oxygen from the room. An ambient air oxygen concentration of less than 17% to 18% is not sufficient for human respiration, and therefore a large cryogen leak or quench of the magnet is dangerous to humans and animals in the room.

Safety Procedures:

1. All dewars and gas cylinders must be non-magnetic.
2. Dewars should be stored in a well-ventilated area.
3. Gas cylinders should be stored upright and secured to the wall with a chain with a metal protective cap in place (if the cylinder falls over or the valve is knocked off, the container may act like a rocket, as a full cylinder has enough power to penetrate walls).

4. The valves of dewars and cylinders should not be tampered.
5. Because cylinder caps may be metal, they should be removed before bringing the cylinder into the magnet room.
6. If possible, all personnel should stay out of the magnet room when a qualified service engineer is filling cryogens in the magnet. If personnel from the MRI suite must be present, they must wear proper gloves, a face shield, and ear protection.
7. Flammable material must not be brought near the cryogen containers.
8. The wearing of protective clothing is essential during all work performed with liquified cryogens. Such clothing consists of:
    - Safety gloves
    - Work gloves
    - Face shield
    - Laboratory coat or overalls (cotton or linen)
    - Non-magnetic safety shoes

C. FIRE HAZARDS

General Safety Procedures:

1. Necessary equipment (fire extinguishers, etc.) will be stored within the MRI suite to manage all classes of fire. All equipment will be non-magnetic.
2. To protect against the possibility of fire, no flammable liquids more than five gallons will be brought into the MRI suite.

Fire with Operators On-Site:

1. The Operator will know all fire emergency related procedures, including a patient evacuation plan, and its proper execution. The front entrance, located on the first level, has been assigned as the point of exit for evacuation during a fire.
2. The MRI Staff Physicist or the Research Director of the center will evaluate the need for an emergency quench of the magnet.
3. In the event of a fire requiring outside response, the MRI Staff Physicist, MRI research committee or the Director will quench the magnet if ferromagnetic equipment must enter the MRI magnet room. They will direct entry and exit to the magnet room until the magnetic field reaches zero.

Fire During Off Hours or No Operators On-Site:

1. Contact the Director of the center, the MRI Staff Physicist, or the Chair of the Technical Committee immediately. These phone and pager numbers are at the front of this manual.
2. Once contacted, the co-Director of the center, the MRI Staff Physicist, or the Chair of the Technical Committee will instruct firefighting personnel and Security staff as to the means of entry to the MRI suite and to the proper means of quenching the magnet, if necessary.
3. If, for any reason, these individuals cannot be contacted, the emergency responders

should contact the Director of the Center for the decision to quench the magnet.
4. For purposes of access in an emergency, the Public Security Department will have access to the MRI suite.

D. INFECTION CONTROL PROCEDURES FOR HUMAN STUDIES

1. Hands must be washed between subjects.
2. The MRI table and headrest must be covered using exam paper sheets. Sheets must be discarded after each subject.
3. All contaminated products must be discarded in the gray trash bin.
4. The sharps container must be removed if 3/ 4 full.
5. The magnet room table and headrest must be wiped with a Sani-wipe at the end of the day.

E. SAFETY PROCEDURES FOR MRI EXPERIMENTS INVOLVING CONTRAST AGENTS

1. Specific IRB approval for using contrast agents in MRI scan must be obtained prior to the studies.
2. The IRB proposal, consent form, and a scan record must include indications for use, recommended dose levels, warnings, and contraindications which are identified on the product inserts.
3. Contrast agents can *only* be administered by a nurse under the direction of a physician, or by the physician himself.

F. SAFETY PROCEDURES FOR MRI EXPERIMENTS INVOLVING CHILDREN SUBJECTS

1. Consent forms, consent procedures, and research procedures must be age-appropriate and follow IRB guidelines. Consent procedures are typically adjusted according to the following age ranges:
    - Age0 -7: Parent consents
    - Age 7-13: Parent consents, child assents on a “short-term” consent written for a 7-year old.
    - Age 13-17: Parent consents, child assents on the standard consent form
2. The child subject must be accompanied by a parent or an adult representative.
3. The child subject will be instructed to remain motionless for approximately 30-60 minutes.
4. If the child subject cannot lie still for the duration of the scan and/or experiences anxiety, no scan will be performed. No sedation is used for any volunteer. The use of sedation is not currently under consideration.

G. SAFETY OF SECURITY PERSONNEL

1. Security staff will have access to the magnet room within the Center only under the supervision of the MRI Staff Physicist, or a certified MRI operator.
2. In the event of an emergency, the Security Officer will have a telephone number for the Center's Co-director and MRI Staff Physicist on file. Once contacted, the Staff Physicist or the Co-director will advise the Security Officer in safe methods to access the facility and the safety procedures to follow once the restricted area is entered.

H. INCIDENT REPORTS

It is the duty of the MRI Staff Physicist to report all violations of safety procedure and accidents to the Management Committee. The MRI operator will document any the following incidents in writing and immediately submit this report to the Staff Physicist.

1. Incidents in which any person was injured.
2. Incidents requiring the emergency quench of the magnet.
3. Incidents involving damage or potential damage to MRI and ancillary equipment.
4. Conditions that constitute a safety hazard.
5. Incidents in which an approved protocol was not followed, causing an unsafe condition.

Nothing in the foregoing is to be interpreted as preempting the legal and institutional responsibilities of the college's Institutional Review Board or regulations of the University of Southern California.

VII. GLOSSARY

Cryogen: A superconductive magnet in the MRI scanner uses cryogens to super-cool the electrical conductor that creates the magnetic field.

Exclusion Zone: The magnet room and the MRI suite are considered the exclusion zones. All ferrous equipment must remain outside the exclusion zone.

Ferromagnetic vs Ferrous: Ferromagnetic, a substance that is ferromagnetic and has a large positive magnetic susceptibility (e.g., iron). Ferrous items can possess intrinsic magnetic fields and react strongly in an applied magnetic field. (Iron, Nickel, Cobalt).

Peripheral Nerve Stimulation: Sensations such as 'twitching' or 'tingling', usually in an arm or leg. In exceedingly rare instances, this nerve stimulation can be painful.

Quench: Quench is the term used to describe a rapid loss of field strength in a superconducting magnet. During a quench, the magnetic current dissipates as heat and causes the liquid Helium to boil off in gaseous form. MRI installations are designed with ventilation systems to handle the rapid boil off of liquid helium.

Restricted Access Area: All of MRI Unit except patient waiting area.

Security Zone: The Security Zone warning sign will be posted on the entrance to the magnet room to alert personnel to the high magnetic field and warn not to bring ferromagnetic objects into the magnetic room.

Static Magnetic Field: Static magnetic fields are measured in Gauss (G) or Tesla (T), with 10,000 G being equal to 1 T. For comparison's sake, the earth's magnetic field varies from approximately 0.3 to 0.7 G between the equator and the poles, respectively, while a small refrigerator door magnet may be used as strong as 150 G to 250 G. The strengths of the static magnetic fields used in clinical and research MR systems for imaging and/or spectroscopy range 0.012 T to over 10 T (100,000 G). According to the most recent recommendations and guidelines provided by the United States Food and Drug Administration (FDA), clinical MR systems are permitted to function on a routine clinical basis at static magnetic field strengths of up to 4.0 T.

Tissue Heating: MRI scanning induces some heating of body tissues.

Unrestricted Area: The unrestricted area in the MRI suite is the patient waiting room.