

***DRAFT*: MRI Safety Program for the UC Davis Research Imaging Center**

1. Assurances

The active "Affirmation of Safety Program" was signed by Contracts and Grants Analyst at The Regents of the University of California, on May 13, 1997.

2. Safety Information

2.a: Research Operations

Description of safety procedures

The UC Davis Research Imaging Center (RIC) at the UC Davis Medical Center has standard operating procedures for safe clinical and research operations on its MRI systems. These procedures are derived from recommendations in the Signa Horizon LX Scan Assistant Manual (2148091-100 Revision 2) (1/98), Chapter 2 entitled "Safety". Detailed training for persons employed within the MRI suite is provided by the RIC Technical Director, MRI Specialists and MRI Physicists. General training of all other persons involved with the MRI suite is given by the MRI Specialist. Hazards associated with working at the MRI suite are discussed with all UC employees involved with the MRI suite based on the established "Worker Right to Know" that is covered under the Hospital's Hazard Communication Plan. This Plan is found in the IIPP (Injury, Illness Prevention Plan), and enforced by EH&S. Training includes discussions on 1. Indications for use of the MRI system, 2. Restrictions on use of the MRI system, 3. Contraindications for use of the MRI system, 4. Use of visual hazard warning signs, 5. Patient implant and prostheses hazards, 6. Burn hazards (including precautions on patient positioning, precautions for larger patients, effective use of patient comfort monitor, precautions on using surface coils, warnings associated with using EKG pads and electrodes, and warnings associated with using peripheral pulse hemodynamic gating), 7. Radiofrequency (RF) heating, 8. Warnings associated with body temperature increases during scanning, 9. RF power deposition considerations, including face and eye hazards associated with cosmetics and exposure to metal slivers, 10. Magnetic fringe field warnings and hazards, 11. Acoustical noise hazards during scanning, 12. Psychological hazards associated with MR scanning (e.g. claustrophobia), 13. Precautions associated with scanning pregnant or infant patients, 14. Biomagnetic hazards such as subtle genetic or molecular changes, 15. Precautions associated with scanning high risk patients (such as those likely to develop seizure or claustrophobic reactions, patients greater than normal risk of cardiac arrest, unconscious, heavily sedated, or confused patients with whom no reliable communication can be maintained), 16. Problems associated with the Technologist's limited view of the patient while the patient is in the MRI system.

Additional training is provided in MRI emergency treatment and prevention, such as how to inform the patient about the risks of the procedure, how to explain to the patient the use of the alert system within the MRI system, reviewing the procedures to follow in the event that the patient requires medical emergency attention during the scanning session, reviewing the

Written by: Michael H. Buonocore

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procedures in the event that the magnet quenches or that the cryogen venting system fails. The patient alert system, and the magnet bore temperature monitor within the system, are provided to aid the technologist in the assessment of acute patient distress. Finally, a review is done of situations requiring radical action on the part of the technologist, e.g. an MRI system failure that risks patient well-being, an acute medical condition of the patient such as a heart attack, or a life-threatening situation such as the patient becoming pinned against the magnet by a ferromagnetic object, requiring an emergency “controlled rundown” of the main magnetic field.

As part of the safety training, all persons that will be involved in the MRI suite (e.g. technologists, fire, housekeeping services) are required to watch a video (MR Magnet Safety: Warning Invisible Force. GE Medical Systems, 3/90, 11 minutes) demonstrating the hazards of the MRI associated with the main magnetic field that is always “on”. Visual signs are posted throughout the MRI suite indicating the hazard of metal objects, and the 5 gauss line delimiting the FDA-established hazard line for persons with pacemakers and other implanted electronic devices.

Description of safety procedures for performing MRI protocols

In general, the scanning protocols that are implemented on the MRI systems at the RIC have no special procedures or features that result in more risk to the patient than is present in routine clinical imaging. Therefore, the RIC uses standard operating procedures similar to those used in the clinical Radiology Department, for operating the MRI systems and for determining if the patient is at undue risk with exposure to the magnetic field and scanning. The determination of undue risk includes a detailed questionnaire regarding personal risk factors (e.g., electronic prostheses, or metallic particles in their body, previous surgeries, claustrophobia) and a personal interview by the principal investigator or designate, to obtain these answers and additional information when needed.

Description of any special skills, training, standard operating procedures to assure safe operations (include emergency procedures).

Training programs and literature given by GE Medical Systems provides information on the unique hazards and associated safety procedures for safe clinical and research operation of the MRI system. The unique safety precautions of the MRI environment are those designed to keep metal objects outside of the magnet room (approximately 20 gauss line), to keep persons with pacemakers and other implanted devices outside the 5 gauss line. Unique emergency procedures are those associated with 1. sudden loss of the magnetic field (field quench), 2. patient entrapment and injury by a large metal object (e.g. anesthesia cart) pinned to the system housing by the magnetic force, 3. patient with aneurysm clip or other contraindicated metal object inappropriately allowed to be scanned, and 4. various MR equipment failures increasing the patient’s risk while in the MRI system.

Description of medical surveillance and support

Monitoring of heart rate, breathing, respiration, O₂ and CO₂ saturation is available using MRI compatible monitors at the MRI suite. Such physiological monitoring will usually not be necessary, because most patients scanned at the RIC will be medically stable.

Description of security controls necessary to assure accountability

During scanning sessions, traffic into the MRI suite is prevented by double doors which remain closed. The double door separates the hallway of the RIC from the general waiting area of the MRI suite. This waiting area is contiguous with the “on-deck” area where patients are loaded on and off the detachable MRI table that docks with the MRI system. The “on-deck” area is adjacent to the main magnet room where the magnet is located. The door into the main magnet room is not locked, but hazard signs are posted prominently on this door, and entry requires manually rotating a large handle that is not easy to rotate. Generally, patients and patients’ friends (if they wish to be with the patient during scanning) are escorted from the general waiting area to the “on-deck” area. Questionnaires are filled-out and information regarding the hazards of MRI are given to the patient and friends during discussions in the waiting area or on-deck area. Thus, all persons moving into the MRI magnet room are educated about MRI hazards.

2.b: Equipment and Description

Description of MRI suite

The UC Davis Research Imaging Center is a one story, 13,000 sq. ft building located on the UC Davis Medical Center Campus, 4701 X Street, Sacramento, CA 95817. The MRI suite of the RIC occupies the north-west corner, and consists of the magnet room, technologist’s control room, small waiting area, and computer room. The “on-deck” area is part of the technologist control room. The MRI system is a GE Signa 1.5T CV/i MR system, running version 8.2.5 of the LX operating system. Down the hall from the MRI suite are visitor reception and general waiting areas, bathrooms and patient dressing rooms. Patient preparation may done in the general waiting and dressing areas adjacent to the MRI suite, or in the small waiting area and on-deck areas of the MRI suite.

Description of safety equipment, including biosafety cabinets, personal protective equipment, etc.

Equipment associated with having safe operations includes non-metallic carts, non-metallic IV poles, and non-metallic wheelchairs and stools. Keyed lockers are provided and visual reminders are posted in the waiting and on-deck area for patients and staff to remove magnetic and potentially hazardous objects (e.g. pens, pen-lights, paper clips) and magnetic cards (e.g. credit cards) from their persons prior to entering the main magnet room. MRI scanning does not involve the use of the biohazardous materials.

Description of methods, analyses, and tests used to identify hazards

Environmental Health and Safety has surveyed the magnetic field strengths in the MRI suite using a standard gauss meter to insure compliance with manufacturer safety guidelines. In particular, EH & S used this gauss meter to assess forces on ferrous structural objects (e.g. building support beams) and the associated distortions of the main magnetic field to insure that image quality would not be compromised. RF power and gradient power sources are maintained through a service contract with GE Medical Systems. The MRI system, using both hardware and software constraints, automatically limits the power and rates of change of magnetic fields according to FDA regulations.

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2.c: Hazard Information

Description of each hazard identified

The hazards of the MRI system have been described in a FDA draft document entitled “A primer on medical device interactions with magnetic resonance imaging systems”, released for comment on Feb. 7, 1997 (at <http://www.fda.gov/cdrh/ode/primerf6.html>, 08/29/01). This document was prepared by the CDRH Magnetic Resonance Working Group. The following hazards are identified: 1. static main magnetic field (always on), causing rotational force (torque) on metal objects to align with the main field, with consequent tissue damage during rotation of object, 2. Static magnetic field spatial gradient (always on), causing translational force on magnetic objects and movement of object into the bore of the magnet (missile effect), with consequent tissue penetration and damage, 3. Gradient magnetic field (pulsed on and off during imaging), causing induced currents from temporal changes in magnetic flux, with consequent malfunction or failure of electromechanical devices, or peripheral nerve stimulation, 4. Radio frequency field (pulsed on and off during imaging), causing RF induced currents resulting in heating, with consequent thermal and electrical burns of tissue, or causing electromagnetic interference, with consequent malfunction of active implanted devices, or increased noise in the case of monitoring devices.

Hazard analysis based on credible event

The most likely accident to occur within the MRI suite would be a result of having a ferromagnetic object (e.g. IV pole, anesthesia cart) pulled into the magnet. Ferromagnetic IV poles and carts from other departments are sometimes (fortunately, rarely) brought into the MRI suite by untrained and unattentive personnel. At the MRI unit of the UC Davis Health System Main Hospital, there has been single incidences of an IV pole, anesthesia cart, and video projector being attracted into the magnet. No incident has been associated with bodily or psychological injury. There have been no incidences at the MRI suite of the UC Davis Research Imaging Center.

Recommendation to minimize or eliminate hazard:

The standard operating procedures developed by the RIC for patient evaluation, use of equipment, and training of staff and all other persons involved with the MRI system, minimizes the risk.

2.d: Health Hazards

Analysis of potential health hazards such as infection, toxic substances, and ionizing and non-ionizing radiation. Sufficient detail shall be provided to clearly define the specific problem, issues involved and analysis.

MRI scans have minimal risk with respect to infection, toxic substances, and radiation. The radiation used in MRI is non ionizing (highest frequency of electromagnetic waves is in the Radiofrequency (10-200 MHz) range. Risks of this non-ionizing radiation are described in detail in sections above. When an intravenous (IV) MRI contrast agent is used, there is small risk of infection using the IV injection (using a wide gauge butterfly needle) of the agent. Contrast agents will be injected by a licensed nurse or certified MRI Technologist, using standard hospital

procedures and infection precautions. Typically, contrast agents used in MRI scans will be Gd-based chelates, such as Gd-DTPA, which is classified by the FDA as non-toxic. The health hazard of other contrast agents used in MRI scans will be detailed in Human Subject Protocols written specifically for those scans.

The pre-MRI screening questionnaire that each subject fills out and discusses personally with the principal investigator or designate insures that the subject is not put at undo risk. Patients with cardiac pacemakers, or implanted neural stimulators, with metal clips in the brain, with history of metal sliver exposure (e.g. work in workshop), with large tattoos, or with possible pregnancy, are specifically excluded from having MRI scans. All persons wishing entry into the magnetic field environment are also similarly screened by the receptionist or technologist on duty. Employees of the RIC are given detailed training (as described above) prior to starting their employment, and so are aware of the contraindications to being in the magnetic field environment.

The chelated Gadolinium (Gd) contrast agents to be routinely used at the RIC are very safe. The adverse reaction rate for any of these agents is around 2.4%. The more commonly experienced adverse reactions are nausea, emesis, hives, headache, and local injection site reactions. Allergic and true anaphylactoid reactions have been reported, but are rare. At worst, the rate of true anaphylactoid reaction from any of these agents is in the 1:100,000 range, and may be as high as 1:450,000 at standard doses. None of these agents appears to be nephrotoxic. There are no known contraindications to any of these agents, although caution should be exercised in patients with either known hypersensitivity to the agent or a history of asthma or other allergic respiratory disorders where there is a higher incidence of adverse reactions. Reference for this material is "Safety reference manual on magnetic resonance imaging contrast agents", Kanal E, Shellock FG. 1996. Lippincott-Raven Healthcare, 2 Ridgedale Avenue, Cedar Knolls, New Jersey, 07927.

2.e: Pollution prevention and Toxic Substances

Identification of hazardous and environmentally unacceptable materials used in MRI scans:

MRI scans at the RIC will not require hazardous or environmentally unacceptable materials. Indication of possible alternative materials, specification of action to eliminate or reduce the use of these materials, and discussion of exposure concerns to personnel or the public during these scans, is not applicable.

2.f: Radioactive materials

MRI scans at the RIC will not use radioactive materials.

2.g: Recombinant DNA

MRI scans at the RIC will not use recombinant DNA.

2.h: Other Safety Documentation:

The UC Davis Imaging Research Center has on file at the MRI Suite, the following documents regarding safety. (1) Signa Horizon LX Scan Assistant Manual, Chapter 2 (2148091-100 Revision

2) (1/98) (2). Instructional Video entitled "MR Magnet Safety: Warning Invisible Force", GE Medical Systems, 3/90. (3). Injury/Illness prevention program distributed by the Environmental Health and Safety Department of UC Davis. (4). Publication on MRI Safety, by Kanal, Shellock, Talagala Radiology 1990; 176: 593-606. (5) "Magnetic Resonance: Bioeffects, Safety, and Patient Management", by Shellock FG, Kanal E; Lippincott-Raven Publishers, 1996. (6) "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems", Draft document, CDRH Magnetic Resonance Working Group, US Dept. of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. 2/7/97.