MAGNETIC RESONANCE IMAGING SAFETY

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides procedures for the safe conduct of Magnetic Resonance Imaging (MRI). *Authority: Title 38 United States Code 7301(b) and Title 38 Code of Federal Regulations 17.38.*

2. SUMMARY OF MAJOR CHANGES. This is a Handbook that:

- a. Defines staff responsibilities;
- b. Details patient preparation; and
- c. Describes safety training.

3. RELATED ISSUES. VHA Directive 1105 (to be published).

4. RESPONSIBLE OFFICE. The Radiology Program Office, (10P4D) Office of Patient Care Services (10P4) is responsible for the contents of this VHA Handbook. Questions may be referred to (202) 461-1778.

5. **RESCISSIONS.** None.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of July 2017.

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MAGNETIC RESONANCE IMAGING SAFETY

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides guidance for preventing injuries in Magnetic Resonance Imaging (MRI) suites. *Authority: Title 38 United States Code* 7301(b) and Title 38 Code of Federal Regulations 17.38.

2. RISK OF INJURY

a. Elements of a comprehensive MRI Safety Program and the prevention of injury. MRI may present a significant risk of injury to patients and employees. Risks include:

(1) **Static Magnetic Field Risk.** The magnetic field of a MRI machine is exceptionally strong. The field attracts certain metals and draws them to the magnet with uncontrollable force. This may damage the magnet or strike and injure a patient or employee near the magnet. Ferromagnetic metals (most commonly iron and some forms of steel) are most strongly attracted to magnets. Some other metals, such as cobalt, nickel, titanium, chromium, platinum and certain alloys, may be attracted to a much lesser degree. Examples of objects that may become lodged in the magnet include gurneys and beds (especially those with motors), Intravenous Therapy (IV) poles, oxygen tanks, and floor buffers. Implanted spring steel, such as early generation intracranial aneurysm clips, may become dislodged or twist in the magnetic field causing an intracranial hemorrhage. Steel fragments near the orbit may injure the optic nerve. Pacemakers and other medical devices may be damaged, reprogrammed, or turned off.

(2) **Radio-frequency (RF) Electromagnetic Field Risk.** Prolonged imaging may cause the patient's core body temperature to rise by deposition of energy from RF fields. The RF field may induce currents in electrically-conductive materials, such as wires that are lying on the patient, causing skin burns. It may also induce currents in intracardiac leads, resulting in inadvertent cardiac pacing.

(3) **Gradient Magnetic Field Risk.** While changes in magnetic fields do not cause harm under normal imaging conditions, extreme gradients may cause biological effects, such as contraction of peripheral muscles or perceived flashes of light from the retina. Potentially, extreme gradients could induce seizures or arrhythmias.

(4) **Cryogen Risk.** During an unplanned loss of magnetic field, helium in the magnet may evaporate suddenly. This gas is normally directed to the exterior of the building by large pipes. In the event that helium leaks into the magnet room, it may displace oxygen in the room which could result in suffocation.

(5) **Gadolinium Risk.** Gadolinium contrast agents are sometimes given intravenously to improve the visibility of structures during MRI studies. Administration of gadolinium contrast agents to patients may cause nausea and headache. Less common effects are severe allergic reactions. If gadolinium remains in the body for a prolonged time, as in a patient with chronic kidney disease, it may dissociate from the chelate. Free gadolinium may induce Nephrogenic

Systemic Fibrosis (NSF), an often fatal disease in which skin and internal organs become fibrotic.

b. Injuries to patients and staff, and damage of equipment may be avoided by safety training and strict adherence to safety procedures. Comprehensive safety procedures have been developed by the American College of Radiology (ACR) (see subpar. 16a and 16b).

3. DEFINITIONS

a. <u>**Cryogen.**</u> Cryogen is a gas, usually helium or nitrogen, cooled until it becomes a liquid. MRI magnet windings are cooled by cryogens which causes the wires to have a very low resistance to electricity, a phenomenon known as superconductivity.

b. <u>Estimated Glomerular Filtration Rate (eGFR)</u>. eGFR is a measure of kidney excretion that is based on the amount of creatinine in the blood. The formula used to make this calculation was devised by the Modification of Diet in Renal Disease (MDRD) Study Group. *NOTE: It is later referred to as MDRD-eGFR in this Handbook.*

c. **Ferromagnetic.** Ferromagnetic are metals, such as iron, steel, cobalt and nickel, that are strongly attracted to a magnet or become magnetized by the magnetic field.

d. <u>Gauss.</u> Gauss is a measure of the strength of a magnetic field. Ten thousand gauss is equal to one <u>tesla</u>.

e. <u>Magnetic Resonance Imaging (MRI)</u>. An MRI is a technique used to visualize internal organs that employs a powerful magnetic field, as well as, radiofrequency electromagnetic fields.

f. <u>Level-1 Personnel.</u> These are individuals who have completed a basic course in MRI safety (i.e., Level-1 training). Level-1 Personnel can enter the magnet scan room of a MRI suite, but only with approval of Level-2 Personnel. *NOTE:* VHA policy differs from the ACR which recommends that Level-1 personnel have free access to the magnet room while VHA requires entry to be approved by a Level-2 trained person.

g. <u>Level-2 Personnel.</u> Level-2 personnel are individuals who have completed an advanced course in MRI safety (i.e., Level-2 training) and have been designated by the Radiology Service Chief. Level-2 personnel can enter the magnet room freely without the need for prior approval, and can admit others into the magnet room by following established screening and monitoring procedures.

h. <u>Quench.</u> Quench is an abnormal loss of the superconducting magnetic field. A quench can result from a low-level of cryogens, or can be induced by increasing the resistivity of the magnet wires. A quench results in the heating and rapid boiling off of cryogens.

i. <u>Specific Absorption Rate (SAR)</u>. SAR is a measure of how quickly the body heats up when exposed to radiofrequency electromagnetic fields. The Food and Drug Administration (FDA) sets limits on SAR when humans are being imaged by MRI.

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j. <u>Untrained Personnel.</u> Untrained personnel are individuals who have not received training in MRI safety. They must be escorted into the magnet room by a Level-2 trained person following safety screening, and must be under the supervision of a Level-2 trained person while in the magnet room.

4. SCOPE

This Handbook applies to safety in all MRI suites and to MRI procedures performed on patients and human research subjects at any VHA facility. Among the elements of a comprehensive MRI safety program are:

a. Floor plans that control access to the magnet room;

b. Continuous observation of the imaging suite while the entry door is unlocked;

c. Safety training of all individuals who may enter the suite;

d. Safety screening of all individuals and objects that enter the magnet room;

e. Avoidance of intravenous contrast agents in patients with renal failure; and

f. Establishment of a MRI Safety Committee to perform safety audits and resolve safety problems.

5. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The Facility Director is responsible for:

a. Ensuring that imaging suites of MRI machines are constructed so that the MRI operator can observe a patient in the magnet, while having an unobstructed view of persons approaching the magnet room door and can therefore, readily intercept any unauthorized person or unsafe object from entering the magnet room;

b. Ensuring risk assessments and minutes of the MRI Safety Committee are approved by facility leadership;

c. Ensuring MRI safety training programs are in place;

d. Ensuring Radiology Service has policies for the safety screening of patients and staff requiring access to the magnet room, for the monitoring of patients in the magnet, and for gadolinium contrast administration to MRI patients;

e. Ensuring Radiology Service has policies for the sedation of MRI patients, if sedation is available or needed;

f. Ensuring that the MRI service is staffed such that a patient or other untrained person is never left unattended in the magnet room;

g. Ensuring Radiology Service has written policies and procedures for emergencies in the magnet area; and

h. Ensuring Radiology Service conducts drills for emergencies in the magnet area, including a patient cardiac arrest, a contrast reaction, a patient pinned in the magnet by a metal object, a fire, or a quench.

6. RESPONSIBILITIES OF THE RADIOLOGY SERVICE CHIEF

The Radiology Service Chief is responsible for:

a. Designating an MRI Section Chief who oversees safe operation of the MRI facility;

b. Appointing an MRI Safety Committee and Committee Chair, who may be the MRI Section Chief;

c. Concurring on MRI Safety Committee minutes, incident reviews and risk assessments;

d. Concurring on MRI policies and procedures;

e. Defining which individuals may be Level-2 trained personnel with unsupervised access to the magnet room;

f. Performing the following functions or delegating them to the MRI Section Chief:

- (1) Composing policies and procedures;
- (2) Supervising the composition of imaging and contrast protocols;
- (3) Supervising Level-2 training;
- (4) Ensuring drills are conducted; and

(5) Ensuring accidents are reported to the Patient Safety Manager.

7. RESPONSIBILITIES OF THE MRI SAFETY COMMITTEE

The MRI Safety Committee is responsible for:

a. Meeting periodically and whenever a serious adverse event or close call has occurred. Minutes of meetings must be prepared for approval by facility leadership.

b. Conducting a risk assessment of the MRI facility, ensuring that the recommendations of the ACR Guidance Document for Safe MRI Practices (see par. 16) are met. If recommendations are not met, a remediation plan or alternative measure that meets the intent of the recommendation must be devised.

c. Ensuring security of the facility, including use of physical barriers and signs.

d. Ensuring MRI-safe monitoring and transport devices have been provided.

e. Conducting emergency drills to simulate emergencies, including a patient who has suffered an allergic contrast reaction while in the magnet, a cardiac arrest in the magnet, a patient who is trapped in the magnet by a ferromagnetic object, and a fire in the magnet room. *NOTE: It is not necessary or desirable to actually perform an emergency quench when undertaking these drills.*

f. Ensuring that panic buttons, call systems and intercoms between patients and technologists are tested regularly.

g. Assisting the Radiology Service Chief and MRI Section Chief in the development of MRI safety policy and screening protocols, as well as procedures to be followed in the event of an arrest of a patient within the magnet room.

h. Discussing adverse events and close calls with the Patient Safety Manager, and with the Patient Safety Manager coordinator devising means to eliminate or mitigate risk.

i. Developing and testing lasting remedies, which may include erection of barriers or architectural changes to imaging area.

8. PHYSICAL SECURITY AND ACCESS

a. The ACR Guidance Document for Safe MR Practices describes a 4-zone floor plan that controls access to the magnet room. The essential elements of this plan shows that patients and visitors must first enter a reception and waiting room where they are interviewed and screened for dangerous objects or contraindications, and are changed into a gown or scrubs in an area with appropriate privacy. From there they are escorted to the magnet room through interior controlled space. Anyone approaching the magnet room door must be clearly seen by the MRI technologist. The entrance is near the operator's console so the technologist may readily intercept entry of any unauthorized person or unsafe object.

b. A design to be avoided is to have the magnet room door open directly into an uncontrolled corridor. This design provides little or no time for the MRI technologist to react if someone brings a dangerous object into the room, such as an oxygen tank.

c. The 5 gauss magnetic field line must not enter into adjacent space that is not supervised by the MRI operator.

d. The door to the control room or the magnet room, or both, must be locked whenever the technologist is not present. When technologists leave the control room to enter the magnet room, they no longer have control of the magnet room door. Therefore, it is recommended that the control room door or magnet room door be closed while the technologist attends to the patient in the magnet room. Placing a ferromagnetic detector with an audible alarm at the magnet room door, or an infrared beam door entry chime, provides an additional level of safety when the

technologist is not facing an open magnet room door. *NOTE:* A ferromagnetic detector supplements patient screening, but does not replace it.

e. Establishing physical security for a mobile MRI van presents special challenges because the door to the magnet room enters directly from an uncontrolled space at the side of the van and is not guarded by the technologist. For mobile units that are used for a prolonged period, it is recommended that ramps or decks built at the side of the van include a lockable gate that controls access to the magnet door, while allowing personnel access to the control room door.

f. Prominent magnetic field hazard signs with hazard icons must be posted at all approaches to the magnet room and mobile MRI vans. Signs near the magnet room door must say "the magnet is always on," and "you must ask the technologist for permission to enter" or equivalent language.

g. Ideally a sink needs to be present near the control room so the technologist doesn't have to leave the patient alone in the magnet or leave the access door uncontrolled to wash before handling the patient.

h. If MRI-safe tanks are used they must be clearly labeled along with the tank regulator and stand in which they rest. *NOTE:* It is recommended that wall oxygen be installed in the magnet room and the gurney transfer area so that oxygen tanks do not enter the magnet room. While MRI-safe oxygen tanks are available, these tanks can be confused with regular steel tanks by non-MRI personnel.

i. Fire extinguishers must be MRI safe or MRI conditional (see App. A) and readily identified by labeling.

9. SAFETY TRAINING

a. Two levels of safety training courses must be made available, they are:

(1) Persons who work in the MRI suite and enter the magnet room frequently must take an advanced Level-2 MRI safety course. These personnel include: MRI technologists, nurses assigned to radiology, radiologists who supervise MRI technologists, biomedical engineers, and manufacturers' representatives who service the magnet. The Radiology Service Chief must designate those individuals who qualify for Level-2 training and unsupervised access.

(2) Persons who need to enter the control room or magnet room of an MRI suite must be authorized to enter by Level-2 MRI staff and must take a basic Level-1 MRI safety training course. These employees include, for example: Ward or unit nurses and physicians who are monitoring patients, any personnel who assist in the lifting or moving of patients, housekeeping staff, police, and safety officers.

b. Training must be renewed annually. A Level-1 course is available on the Talent Management System (TMS) Web site at: <u>www.tms.va.gov</u>.

10. SAFETY SCREENING

a. All persons who enter the magnet room must be screened using a Patient Safety form approved by the service chief. Forms must be signed by the person who is performing the screening and by the individual requesting entry. Safety Forms of patients must be retained in their electronic health record. Forms of non-patient personnel must be kept in a secure location until no longer needed for safety or quality assurance purposes, or at least 2 years. An example screening form may be found in the ACR Guidance Document for Safe Magnetic Resonance (MR) Practices. *NOTE: A discussion of safe and unsafe devices is found in Appendix A*.

(1) Persons who enter the magnet room frequently, including Level-2 trained personnel, need not be screened on each entry. These persons can be screened once and the screening safety form retained in the MRI department. An important difference between Level-1 and Level-2 trained personnel is that Level-1 trained personnel must be safety screened before entering the magnet room and authorized to enter by a Level-2 trained individual. Level-2 trained personnel may enter the magnet room without permission or screening. Untrained personnel may enter the room only under escort of a Level-2 trained individual and must be continuously observed while in the room.

(2) Persons who enter the magnet room infrequently, but are not placed in the bore of the magnet, must be screened once per imaging session.

(3) Persons who are placed in the bore of the magnet (i.e., patients and research subjects) must be screened twice. This must be done for every imaging session. Examples of individuals who can perform the first screening include the ordering physician or clinic staff, the radiology scheduling clerk, and the radiology receptionist. The second screening must be performed by MRI personnel shortly before the patient enters the magnet room. The second screening may be more complete than the first screening. It is best to perform the first screening before the appointment is made in order to avoid unnecessary patient travel and unfilled appointment slots, and to arrange for alternative imaging as soon as possible. A screening Patient and Safety sheet like this can be prepared with local policies and contact numbers. Screening questions can also be incorporated in the computerized order entry dialogue of CPRS. *NOTE: Example questions that may be used for first screening are found in Appendix B*.

(4) If patients cannot give a history, and if the patient has not recently undergone an MRI without complication, the radiologist or referring physician must be consulted. If no history is available, the procedure needs to be cancelled, or else the physician must certify in an electronic medical record note that the study is urgently needed and that the potential benefits outweigh the risks.

b. If a potential contraindication is found on screening, and a decision is made to proceed with the MRI exam, resolution of this finding must be documented on the Patient Safety form or in a note and retained in the health record. If the safety of a device is unknown, the manufacturer must be contacted to provide a letter or written safety statement. If a medical device is investigated and it is determined the patient must not be imaged while the device is in place, the contraindication must be documented in the medical record. Likewise, complications resulting from MRI of a device must also be documented. *NOTE: It is recommended that the facility*

create a standard note title such as "MRI SAFETY NOTE" so this information can be found quickly. **NOTE:** A list of safe and unsafe devices may be found at www.mrisafety.com.

c. The technologist must keep a file of all manufacturer safety documents, web pages, and correspondence that are used to determine the safety of a device.

11. PATIENT PREPARATION

a. Patients must be changed into a hospital provided gown or scrubs and examined for hazardous objects and devices. A sheet or blanket must be offered for patient comfort. External devices must be removed or replaced with MRI safe devices, and patients transported into the magnet room using a MRI safe wheelchair or gurney. *NOTE:* A discussion of safe and unsafe devices is found in Appendix A. *NOTE:* A list of safe and unsafe devices may be found at www.mrisafety.com.

b. Objects that need to be removed before the patient enters the magnet include, but are not limited to:

- (1) Wallets;
- (2) Money clips;
- (3) Credit cards and other cards with magnetic strips;
- (4) Electronic devices such as, beepers or cell phones;
- (5) Hearing aids;
- (6) Metal jewelry or watches;
- (7) Pens;
- (8) Paper clips or safety pins;
- (9) Keys;
- (10) Coins;
- (11) Hair barrettes and hairpins;
- (12) Shoes;
- (13) Belt buckles; and

(14) Any article of clothing that has a metal zipper, buttons, snaps, hooks, underwires, or metal threads. *NOTE: Metallic items may be damaged by the magnetic field. The speaker magnets of pagers and cell phones may be pulled from their mount. Analog watches may*

become magnetized which prevents the hands from moving. Credit cards with magnetic strips may be erased by magnetic field exposure.

c. A metal detector may be used to augment the examination, but is not an adequate exam in itself.

d. Infusion pumps that are not MRI safe must be converted to gravity drip or heparin lock or MRI-safe infusion pump by a nurse or physician.

e. Monitoring equipment and cardiac leads must be replaced with MRI safe monitoring equipment and high impedance MRI safe leads.

f. Sandbags must be replaced with MRI safe bolsters. *NOTE:* So called sandbags often contain steel shot which is strongly attracted by the magnet. Even if they are filled with sand, the sand contains enough iron to cause imaging artifacts.

g. The technologist needs to exchange oxygen cylinders with MRI safe oxygen cylinders or wall oxygen regulators, taking care that the flow rate is unchanged.

h. Metallic drug delivery patches must be removed with physician approval.

i. External pumps, such as insulin pumps, must be removed with physician approval.

j. A set of ear plugs or MRI safe headset needs to be made available to the patient to attenuate noise from the magnet gradients.

k. The patient needs to be positioned so as to not form a loop by touching limbs distally. An example would be the knees held apart but the feet touching each-other. Sponges can be used to hold limbs apart and away from the cowling.

l. Patients who are claustrophobic or have survived traumatic events may require extra time and encouragement before being placed in the magnet. It is recommended that these individuals be allowed to inspect the magnet, be told how far in they will be placed in the bore, and be reassured that they will be removed immediately upon pressing the panic button. It is helpful to speak to them between each series. When possible the MRI procedure needs to be discussed with patients when appointments are scheduled. Those patients with concerns need to contact their referring provider for possible options to have open MRI testing.

m. Patients must be offered a panic button that allows them to signal the technologist that they require immediate attention or wish to be removed from the magnet. A panic button is not possible for patients who are paralyzed, sedated, or obtunded. Those patients must be checked between each imaging series.

12. PATIENT MONITORING

a. Patients in the magnet room must be under the direct observation of the technologist at all times, and must never be left unattended. *NOTE:* It is strongly recommended that two people, a

technologist and a second technologist or assistant, be assigned to the MRI room so that the second person can interview and prepare the next patient for imaging, obtain supplies, etc.

b. The magnet room door must never be locked while a patient in is the magnet.

c. There must be two-way communication available while a patient is inside the magnet.

d. If physiologic monitoring equipment is present, it must be removed and replaced by MRIsafe monitoring equipment. MRI-safe equipment must have high impedance or fiber optic leads to minimize the possibility of skin burns. Lead wires need to be directed straight out of the magnet away from the walls of the bore and without forming a loop or contacting the patient so as not to induce electrical currents which can result in patient burns.

e. All cases requiring sedation must be approved by a radiologist. Sedation must be administered by appropriately-privileged providers using MRI-safe equipment.

f. If a patient attempts to remove an imaging coil during the course of a study, the study must be terminated and the radiologist called. Such patients may be shocked by high voltages or may cause expensive damage to the coil.

g. Patients who are insensate, sedated, or obtunded may not know that they are being burned by currents induced in a cable, pulse oximeter, or other device. Patients who are unable to speak may not be able to communicate the fact that they feel pain. These patients must be examined between imaging sequences in order to detect skin burns early before they progress.

13. OVERRIDING FOOD AND DRUG ADMINISTRATION (FDA) LIMITS

a. FDA regulation places limits on allowable human exposure to radiofrequency electromagnetic fields during MRI studies. The upper limit of the SAR can only be exceeded under direction of the radiologist, if the radiologist first confirms that the patient does not show signs of heating.

b. The time rate of change of the magnetic field beyond FDA levels is password protected and cannot be exceeded without an approved human research protocol. Exceeding the FDA limit may result in painful peripheral nerve stimulation. The limit must be restored when the research study is completed.

14. INTRAVENOUS GADOLINIUM ADMINISTRATION

a. High risk patients include those with moderate or severe kidney disease or kidney failure projected by the eGFR less than 30 milliliters per minute per 1.73 meters squared (eGFR < $30 \text{ mL/min/1.73m}^2$), those with prior severe allergic reaction to a gadolinium contrast agent requiring treatment, and those with Nephrogenic Systemic Fibrosis (NSF). Signature consent is required when administering intravenous gadolinium to these patients, in accordance with VHA Handbook 1004.01. Signature consent is required when administering gadolinium to a patient who is pregnant; however, there is no evidence gadolinium causes injury to fetus.

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b. An MDRD-eGFR must be obtained within 6 weeks of anticipated gadolinium injection in patients who might have reduced renal function, including any patients with a history of renal disease (including a solitary kidney, renal transplant, or renal neoplasm), anyone over the age of 60, and patients with a history of hypertension or diabetes mellitus.

c. In patients with eGFR < 45 mL/min/ $1.73m^2$, gadolinium must be limited to the lowest dose necessary. Gadodiamide (Omniscan®), gadopentetate dimeglumine (Magnevist®), and gadoversetadmide (OptiMARK®), which are the agents most commonly associated with NSF, must be avoided.

d. Patients with $eGFR < 30 \text{ mL/min}/1.73\text{m}^2$ should not receive intravenous gadolinium contrast material. If use of gadolinium is thought to be unavoidable, the decision to image these patients must be made in conjunction with the Nephrology service. The Radiologist, Nurse, or other registered caregiver must administer the lowest dose that will allow a diagnosis. Gadodiamide, gadopentetate dimeglumine, and gadoversetadmide must not be used. Although the effectiveness of dialysis in preventing NSF is unclear, it is nevertheless recommended that hemodialysis be performed immediately after a MRI study in which gadolinium is given to a patient who requires routine dialysis.

e. If use of gadolinium is unavoidable in a patient who has had a prior allergic reaction to gadolinium, pre-treatment with corticosteroids is recommended.

f. If a nurse or physician determines a contrast reaction was allergic, the event must be entered in the Veterans Health Information Systems and Technology Architecture (VistA) Adverse Reaction Tracking Package by the practitioner. The event must be subsequently identified for entry into the national VA Adverse Drug Event Reporting System (ADERS) by health care personnel designated by the medical facility as VA ADERS reporters. *NOTE: Headache and vomiting are not by themselves allergic symptoms.*

15. EMERGENCIES

a. Emergencies in or near the magnet room pose a special danger because responding personnel may bring unsafe objects with them, such as crash carts, fire axes, and service weapons. MRI personnel need to anticipate and train for such emergencies.

b. During an emergency that may affect the MRI suite, a trained person must be stationed to control access to the magnet area.

c. A procedure needs to be established by the MRI Section Chief to grant escorted access for urgent entry to the magnet room during off-hours. This could be provided, for example, by the MRI technologists on-call.

d. The code team, behavioral intervention team, safety, or emergency officers and police must be Level-1 trained.

e. If a patient arrests while being studied, the technologist must remove the patient from the magnet, transport the patient by gurney to a safe location outside of the magnet room, and close the magnet room door. Ideally this task must be completed before the code team arrives.

f. Crash carts or oxygen tanks in the resuscitation area must be chained to the wall, unless they are MRI-safe.

g. Under certain circumstances it may be necessary to manually quench the magnetic field using the quench button. These circumstances include a patient who is trapped in the magnet by a metal object, a fire in the magnet room, or a patient who must be resuscitated on the magnet table. It may take several minutes for the magnetic field to be completely dispersed. *NOTE: Restoring the magnetic field may be expensive and may take several days. The MRI machine or quench pipe may be damaged by the quench.*

16. REFERENCES

a. ACR Guidance Document for Safe MR Practices: 2007 http://www.acr.org/SecondaryMainMenuCategories/quality_safety/MRSafety/Safe_mr07.aspx

b. ACR Manual on Contrast Media v7 http://www.acr.org/secondarymainmenucategories/quality_safety/contrast_manual.aspx

c. Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging: A Report by the American Society of Anesthesiologist Task Force on Anesthetic Care for Magnetic Resonance Imaging http://journals.lww.com/anesthesiology/Fulltext/2009/03000/Practice_Advisory_on_Anesthestic_Care_for_Magnetic.9.aspx

d. FDA Alerts and Notices on MRI Safety http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm135362.htm

e. Joint Commission Sentinel Event Alert, Issue 38 http://www.jointcommission.org/assets/1/18/SEA_38.PDF

f. Institute for Magnetic Resonance Safety, Education, and Research. List of safe devices. <u>http://www.mrisafety.com/</u>

g. VHA's Patient Safety Alerts and Advisories <u>http://vaww.ncps/Guidelines/alerts/Docs/MRIgenalert.doc</u>

h. VHA National Center for Patient Safety's MR Hazard Summary http://vaww.ncps.med.va.gov/Initiatives/Hazards/mrihazardsummary.html

i. Brown TR, Goldstein B, Little J, Severe burns resulting from magnetic resonance imaging with cardiopulmonary monitoring. Risks and relevant safety precautions. American Journal of Physical Medicine and Rehabilitation (Am J Phys Med Rehabil) 1993;72:166-7.

POTENTIALLY HAZARDOUS DEVICES AND OBJECTS

1. Devices may be classified as MRI-safe, conditionally safe, and unsafe.

a. Conditionally safe devices are those that may be imaged under special conditions and precautions specified by the manufacturer. These precautions might include disconnecting the device, using certain types of imaging coils, imaging only certain parts of the body, avoiding certain body positions, avoiding higher-field strength, keeping a device a certain distance from the magnet, checking for lead integrity, reprogramming the device before and after the procedure, an increased level of vital sign monitoring, and having resuscitation equipment standing by.

b. Cardiac pacemakers, neurostimulators, and intracranial aneurysm clips are examples of device classes in which the ability and protocol to safely image varies depending on the make and model. Before imaging a patient with any of these devices it is necessary to establish the identity of the device from operative records. For patients who are also seen in outside hospitals, this may be challenging.

c. Considering the potential for injury if a device is misidentified and is actually unsafe, and considering that alternative imaging strategies are almost always available, many MRI services have concluded that all pacemakers, neurostimulators, and aneurysm clips must be considered a contraindication. If one decides to proceed with a conditionally safe device, it is important to document the model of the device and secure a copy of the manufacturer's safety statement. *NOTE:* A list of device models and their safety classification may be found at *www.MRISafety.com*.

2. Devices which may be a contraindication to MRI. include:

a. **Pacemakers and Implantable Cardioverter-defibrillators.** Pacemakers and Implantable Cardioverter-defibrillators are generally a contraindication for MRI. Some older models built before 2000 stop functioning after exposure to the magnetic field, necessitating surgical replacement. Most new models are also not safe. Problems include reprogramming, rapid pacing, failure to capture, and induced currents in leads. For conditionally safe devices, follow the manufacturer's instructions. A cardiology consult is recommended.

b. **Intrathoracic Cardiac Leads and Catheters Containing Leads.** Intrathoracic Cardiac Leads and Catheters Containing Leads such as thermodilution pulmonary artery catheters (e.g., Swan-Ganz catheter) may cause excitation of myocardium. They have been known to melt in the patient.

c. **Balloon Pumps and LV Assist Devices.** Balloon Pumps and LV Assist Devices are a contraindication to imaging.

d. **Neurostimulators.** Neurostimulators are generally a contraindication for MRI. Some devices are safe if the manufacturer's instructions are followed.

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e. **Neuroprostheses.** Implanted neuroprostheses and functional electrical systems for walking, grasping, or micturition are a contraindication.

f. **Deep Brain Stimulators.** MRI of Deep Brain Stimulators is controversial. If imaging is done, follow manufacturers' instructions.

g. Conductive Halos, Head-frames, and External Fixation Devices. Some nonconductive models of Conductive Halos, Head-frames, and External Fixation Devices are MRI safe.

h. **Stents.** While some types of stents are attracted by the magnet, these implants are not known to dislodge. However, some manufacturers place conditions on imaging. Note that stents cause significant field artifacts. For example, an abdominal aortic stent can cause severe distortion of lumbar spine images.

i. **Aneurysm Clips.** While many new models of Aneurysm Clips are MRI safe, Radiology must not image unless the make and model are known and confirmed to be safe by the manufacturer.

j. **Shrapnel.** Some shrapnel, shotgun pellets, and bullet casings are ferromagnetic, while others are not. In general, if the fragments are small, are in a noncritical location such as muscle, and have been in the body long enough to be encapsulated by fibrosis, then imaging is safe. If fragments are in a soft tissue such as a lung, the brain, or near the eye or spinal cord, imaging must be avoided.

k. **Metal in Eye.** If a patient reports an ocular injury by a metallic foreign body, the ordering Physician must obtain orbit films to screen for retained metal. Occupational exposure without injury (e.g., a machinist) is not sufficient cause for screening.

l. **Tattoos.** Dark pigment tattoos and eyelid tattoos may cause mild burns. Recently applied tattoo pigment may migrate in the skin, causing the tattoo to appear smudged.

m. Devices Containing Magnets. Devices Containing Magnets are a contraindication.

n. **Cochlear Implants.** Regarding Cochlear Implants, It may be necessary to surgically remove an internal magnet before the procedure. Consult the manufacturer.

o. **Surgical Skin Staples.** Regarding Surgical Skin Staples the patient may feel discomfort or burning. Heating may be relieved by ice packs.

p. Internal Pumps. Internal Pumps are usually a contraindication.

q. Penile Implants. While most models of Penile Implants are safe, several are not.

3. Devices which are not usually considered to be a hazard.

a. Artificial Heart valves and Annuloplasty Rings. Artificial Heart valves and Annuloplasty Rings may be weakly attracted by the magnetic field, but the force is much less than normal hydrodynamic forces.

b. **Vascular Access Ports.** Vascular access ports are implantable ports used for patients who require long-term, infrequent or intermittent central venous access.

c. **Retained Epicardial Pacing Wires.** Retained Epicardial Pacing Wires pose a hypothetical risk, but in practice the disconnected wires are commonly imaged without complication.

d. **Orthopedic Implants.** Stainless steel Orthopedic Implants are not attracted by the magnet. However they may results in local imaging artifacts.

e. **Radioactive Seed Implants.** Radioactive seed implants are a form of radiation therapy for prostate cancer, also known as brachytherapy or internal radiation therapy.

4. Pregnancy is not known to be a risk either to MRI or to gadolinium administration. However, it is common practice to delay elective MRI until after delivery. If delay is not possible, the physician must write a note stating why the study must be performed. It is further required that signature consent be obtained for gadolinium.

EXAMPLE QUESTIONS THAT CAN BE USED FOR SAFETY SCREENING BY THE ORDERING SERVICE

1. Have you ever had an Magnetic Resonance Imaging (MRI)? Was there ever a problem?

2. Have you ever had surgery in your entire life, including childhood? Have you had any metal devices or implants placed in your body for any reason?

a. Usually unsafe: Cardiac pacemaker or implantable cardioverter-defibrillator (ICD), intracranial aneurysm clip, neurostimulator.

b. Usually safe: Most shrapnel, stents, orthopedic implants, heart valves, brachytherapy seeds.

3. Have you ever had metal in the eye, either from an accident or your occupation? If patient has not had a prior MRI, get orbit films.

4. Are you claustrophobic? If so, may need open MRI, pre-medication, or sedation. Sedation will require special scheduling.

5. Are you pregnant? If so, elective procedures may be delayed until after delivery.

For contrast studies:

6. Do you have any kidney problems such as poor kidney function, a kidney tumor, kidney transplant or single kidney? Are you diabetic? Are you 60 or older? If so, order creatinine. If eGFR is less than 30, patient cannot receive contrast.

7. Have you ever had a reaction to gadolinium contrast? If so, what type of reaction did you have? Depending on severity of reaction, radiologist might recommend premedication with corticosteroids, or non-contrast study.