

MAGNETIC RESONANCE (MR) SAFETY

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive outlines policy and procedures to ensure patient, visitor, trainee, and employee safety in the Magnetic Resonance (MR) environment or area.
- 2. SUMMARY OF MAJOR CHANGES:** Major changes include:
 - a. Revising and converting VHA Handbook 1105.05 Magnetic Resonance (MR) Safety to a directive to comply with VHA Directive 6330, Controlled National Policy/Directives Management System, dated June 24, 2016.
 - b. Including Level 1 and 2 Magnetic Resonance (MR) Personnel definitions and delineations.
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** The National Director, Radiology Program, Diagnostic Services (10P11D) is responsible for the contents of this directive. Questions may be referred to 919-384-8593.
- 5. RESCISSION:** VHA Handbook 1105.05, Magnetic Resonance Imaging Safety, dated July 19, 2012, is rescinded.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of May 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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MAGNETIC RESONANCE (MR) SAFETY

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy and procedures for preventing injuries in the magnetic resonance (MR) environment. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

The MR environment may present a risk of injury to patients, visitors, trainees, and employees. Injuries 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). **NOTE:** *Additional and more in-depth background information may be found in Appendices A-H.*

3. DEFINITIONS

a. **Ferromagnetic.** Metals including, but not limited to, iron, steel, and cobalt, which are strongly attracted to a magnetic field or can become magnetized by the magnetic field.

b. **Ferromagnetic Detector.** A device or system that detects ferromagnetic materials.

c. **Magnetic Resonance and Magnetic Resonance Imaging (MRI).** MR and MRI terms may be used differently when it comes to the imaging exam (i.e., MRI) versus compatibility issues in the magnetic environment (i.e., MR). Although the terms are somewhat interchangeable, they refer to one of two things:

(1) **MRI.** A technique to visualize internal organs that employs a powerful magnetic field as well as radiofrequency electromagnetic fields.

(2) **MR.** A characteristic of the powerful magnet that can be associated with the environment, equipment, and/or personnel.

d. **MR Conditional.** MR Conditional refers to pacemakers and other implants which pose potential patient hazards in the MR environment; therefore, these devices and objects have been deemed appropriate in the MR environment with very specific restrictions and conditions as set by the manufacturer. Deviating from the restrictive conditions removes the manufacturer's conditional status and therefore may render them unsafe. **NOTE:** *Alterations performed by a facility on MR Safe, MR Unsafe, and MR Conditional equipment or devices may alter the compatibility properties of the device, which has the potential to cause damage to the device/object or anyone near the device/object.*

e. **MR Personnel.** Individuals who have had basic and advanced safety training for the MR environment.

(1) **Level 1 MR Personnel.** Individuals who receive basic MR safety training. These individuals frequent the MR area, such as those who transport patients, those who clean the area, support assistants who help the Level 2 MR Technologists with getting patients on/off the table, and/or those who respond to emergencies in Zones III and IV of the MR area. **NOTE:** For a definition of Zones III and IV, see the definition on “MR Zones” below.

(2) **Level 2 MR Personnel.** Individuals who receive advanced MR safety training. These individuals are MR Technologists, Radiologists, or other individuals as designated by the Radiology Service Chief.

f. **MR Safe.** MR Safe refers to objects or devices that are known to be nonmagnetic and not electrically conductive. MR Safe items can be indwelling items as well as external items in the MR environment. Indwelling items are those that have been implanted into an employee or patient’s body and have been deemed MR Safe by the manufacturer. External items are objects that are known to be nonmagnetic and not electrically conductive and should have an “MR Safe” label affixed to them.

g. **MR Unsafe.** MR Unsafe objects or devices have been tested and have been found to be attracted to a magnetic field and must not enter Zone IV. If external MR Unsafe devices are necessary for patient care in Zone III and are not fixed to the facility structure, they must be tethered or secured to prevent accidental entry into Zone IV. **NOTE:** For a definition of Zones III and IV, see the definition on “MR Zones” below.

h. **MR Zones.** The MR area is set up with four Zones to facilitate patient, guest, and employee safety. The Zones are designated as I through IV and each progressive Zone has more stringent safety requirements.

(1) **Zone I.** The area where the general public and other health care team members move freely about. This is the area where the MR environment is accessed by outpatients and visitors.

(2) **Zone II.** The area that forms the interface between Zone I and Zone III. Zone II is utilized for greeting the patients, checking them in for their respective exams, and screening for hazardous MR devices or implants. Zone II is the designated location where patients and other Non-MR personnel (defined below) change their attire for MR safe clothing. Zone II may be designated as the entry point for inpatients.

(3) **Zone III.** A restricted access area that forms the interface between Zone II and Zone IV. This area is controlled by MR personnel and typically known as the control area where Level 2 MR personnel operate the MRI machine.

(4) **Zone IV.** A highly restricted area that is only accessible through Zone III. This area is controlled by Level 2 MR personnel and is the location of the MRI machine.

i. **Non-MR personnel.** Non-MR personnel are patients, visitors, or facility staff who do not meet the criteria of Level 1 or Level 2 MR personnel.

j. **Personal Identity Verification Card.** Personal Identity Verification (PIV) Card refers to the requirements set in VA Directive 710, Personnel Security and Suitability Program, dated June 4, 2010, and VA Handbook 6510, VA Identity and Access Management, dated January 15, 2016, which binds the identity of the individual to the respective card. This card, with recognized security measures, can control access to specific areas and generate reports that identify users who entered these controlled areas.

k. **Quench.** A quench is an intentional or accidental loss of the superconducting magnetic field. A quench can result from a critically low level of cryogenics, or can be induced by increasing the resistivity of the magnet wires. A quench results in the heating and rapid boiling off of cryogenics. There are potential risks to a quench (e.g., asphyxiation, frostbite, fire hazards) and generally associated costs to get the MRI system operational again. **NOTE:** For more information on cryogen risk, see Appendix G.

4. POLICY

It is VHA policy to ensure patient, personnel, and visitor safety in all clinical and research MR areas that image humans.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring compliance with this directive.

b. **Deputy Under Secretary of Health for Operations and Management.** The Deputy Under Secretary of Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each Veterans Integrated Service Network (VISN) Director.

(2) Ensuring that each VISN Director has the resources required to support the fulfillment of the terms of this directive in all the VA medical facilities within that VISN.

(3) Providing oversight of VISNs and working with National Radiology Program Office to assure compliance with this directive.

(4) Responding to and taking appropriate action on reports of noncompliance with this directive.

c. **Director, National Radiology Program Office, Diagnostic Services.** The Director, National Radiology Program Office, Diagnostic Services, is responsible for:

(1) Providing policy and programmatic guidance on MR safety.

(2) Providing consultative services and education on MR safety and safe practices.

(3) Serving as point of contact for issues of noncompliance with this directive and coordinating with the Deputy Under Secretary of Health for Operations and Management and other VHA leaders when further action is necessary.

d. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring proposals for restructuring, reduction, or augmentation of MRI comply with VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016.

(2) Ensuring MR/MRI operations meet the requirements in this directive.

e. **VA Medical Facility Director.** VA medical facility Director is responsible for:

(1) Ensuring compliance with this directive in all research and clinical MR areas.

(2) Ensuring the imaging suites of MRI machines are constructed so the MRI operator can observe a patient in the magnet while having an unobstructed view of persons approaching the Zone IV door and can readily intercept any unauthorized person or unsafe object from entering Zone IV.

(3) Developing procedural guidelines to ensure risk assessments and minutes of the MR Safety Committee are submitted to the appropriate Facility Quality Management Service or other designated committee.

(4) Identifying the positions within the organization that frequent MR on an ongoing and consistent basis and ensure these individuals accomplish Level 1 MR safety training initially and on an annual basis. Examples may include: ward/unit nurses and physicians who monitor patients or respond to emergencies, any personnel who will assist in lifting/moving patients, cleaning and environmental staff working in MR, as well as police, fire, and other safety officers. **NOTE:** *For information on training, see paragraph 6 – “Training” – below.*

(5) Ensuring the facility develops processes or procedures to comply with this directive. These may include, but are not limited to, safety screening of patients/personnel requiring access to Zones III and IV, continuous monitoring of patients in Zone IV, safe administration of contrast to MRI patients, sedation of MRI patients (if sedation is available), procedures for emergencies in the MR area (e.g., cardiac arrest, a contrast reaction, a patient pinned in the magnet by a metal object, a fire, quench, disruptive patient), and policies for pacemakers and MR Conditional devices.

(6) Ensuring that when routinely scheduled patients or research subjects are present in Zones II through IV, there will be a minimum number of MR personnel in Zones III through IV to assure safe operation and adequate access control. The minimum number of MR personnel is calculated as follows:

(a) For a facility that functions with one MR machine per Zone III/IV, there will be a minimum of two MR personnel in Zones III through IV, and at least one of these personnel will be designated as Level 2 MR Personnel. **NOTE:** *Temporary exception is made when MR personnel are interviewing the patient/research subject or retrieving the patient/research subject from waiting/changing areas.*

(b) For a facility with two or more MR machines that share a single Zone III area where both machines are in use at the same time, there will be a minimum of one Level 2 MR Personnel for each machine and a minimum of one additional MR personnel, i.e., two machines during scheduled hours will require two Level 2 MR personnel and an additional Level 1 or 2 MR personnel. When only one machine is in use, e.g. during lunch or an evening shift, there will be a minimum of two MR personnel in Zones III through IV, and at least one of these personnel will be designated as Level 2 MR Personnel. **NOTE:** *Facilities must prepare and plan to deal with emergencies that occur after normal business hours, e.g., fire, power outages, or water leaks, in the MR area.*

f. **Radiology Service Chief.** The Radiology Service Chief is responsible for:

(1) Serving as or designating an MR Director.

(2) Designating an MR Safety Officer. **NOTE:** *The MR Director can also serve as the MR Safety Officer.*

(3) Establishing an MR Safety Committee and appointing a Chair of the Committee (e.g., the MR Director or MR Safety Officer).

(4) Reviewing and concurring on MR Safety Committee minutes, incident reviews, and risk assessments.

(5) Establishing processes or procedures for safe operation in the MR area. These processes or procedures must address devices that are MR Conditional, MR Safe, and MR Unsafe, as well as appropriate clothing for those who enter Zones III and IV.

(6) Establishing processes or procedures that address pacemakers in the MR environment and when Level 2 MR personnel may proceed with an MRI. **NOTE:** *Processes or procedures for MR Conditional pacemakers must be vetted by the facility cardiology staff, or relevant staff, to ensure a cohesive process is established.*

(7) Establishing processes or procedures to address visitors and service animals in Zones III and IV, if not addressed in other policies.

(8) Delineating who and how cleaning of Zone IV will be completed.

(9) Delineating which Level 1 MR personnel have permission to respond to emergencies in Zone IV.

(10) Defining which individuals are Level 2 MR trained personnel and ensuring

safety training is accomplished initially and on an annual basis.

(11) Ensuring MR Safety Screening questionnaire is completed for all individuals who enter Zones III and IV. In general, this is completed prior to each entry into Zone III. **NOTE:** *MR personnel who regularly enter Zones III and IV must complete screening questionnaire at least annually, to be kept on file, and to be updated as health conditions change that would affect their safety.*

(12) Ensuring the individuals within the Radiology Service who are designated as Level 1 and Level 2 MR personnel have the appropriate competencies if applicable for their jobs in the MR environment.

g. **MR Director.** The MR Director is a radiologist/physician who is designated as Level 2 MR personnel and understands the complexity of MRI. They must possess requisite skills to be the subject matter expert for the facility when devising MRI protocols. The MR Director is responsible for:

(1) Serving as the Chair or as a member of the MR Safety Committee.

(2) Working closely with and directing the MR Safety Officer to ensure safe operation of the MR areas.

(3) Ensuring adherence to MRI and contrast protocols.

(4) Collaborating with the MR Safety Officer and others to devise facility-specific imaging protocols. Imaging protocols must address risks, including those associated with patients who may experience claustrophobia, anxiety or emotional distress, and those with implanted devices, shrapnel, etc.

h. **MR Safety Officer.** The MR Safety Officer is an individual who has been designated as Level 2 MR personnel and is well-versed in the knowledge of MRI protocols and MR safety (typically a working MR Technologist). The MR Safety Officer is responsible for:

(1) Working closely with all Level 1 and 2 MR personnel to ensure safe operation of the MR areas.

(2) Serving as the Chair or as a member of the MR Safety Committee.

(3) Participating in and overseeing the annual processes of emergency drills that include: cardiac arrest, contrast reaction, fire, entrapped patient/employee/quench, and disruptive patient. These emergency drills must be documented in the MR Safety Committee meeting minutes. **NOTE:** *It is not necessary nor is it allowed to actually perform a quench when performing these emergency drills.*

(4) At a minimum of a quarterly basis, testing and documenting call systems and intercoms between patients and technologists. **NOTE:** *For more information, see Appendix C.*

(5) Assisting the Service Chief or MR Director in the development of MRI Safety policies and MRI procedures.

(6) Reporting or overseeing the reports from close call or adverse events. **NOTE:** For more information about what constitutes close calls or adverse events, see VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

(7) Working closely with the MR Director and MR Safety Committee to devise methods to mitigate close calls and adverse events. **NOTE:** For more information about what constitutes close calls or adverse events, see VHA Handbook 1050.01.

(8) Ensuring all items that are utilized in Zone IV are properly labeled for safe use in the MR environment

i. **Level 1 MR Personnel.** Level 1 MR personnel are responsible for:

(1) Prior to entry into Zone III, reporting to the MR Safety Officer or a Level 2 MR personnel any procedure or surgery they undergo where a device with ferromagnetic properties has been introduced in or on them. This allows their screening questionnaire to be updated for safety purposes.

(2) Adhering to guidelines regarding access to the different Zones, notably:

(a) Level 1 MR personnel are permitted unaccompanied access throughout Zones I through III.

(b) Level 1 MR personnel must have permission from a Level 2 MR personnel before they can enter Zone IV. **NOTE:** An important difference between Level 1 and Level 2 MR personnel is that Level 1 personnel have unrestricted access through Zone III, but must have permission before entering Zone IV. Level 2 MR personnel may screen and authorize Level 1 and Non-MR personnel into Zone IV, and have unrestricted access throughout all Zones.

(c) Level 1 MR personnel may be permitted to accompany Non-MR personnel into and throughout Zone III as long as a Level 2 MR personnel is present. Level 1 MR personnel cannot directly admit and cannot be responsible for Non-MR personnel in Zone IV.

j. **Level 2 MR Personnel.** Level 2 MR personnel are responsible for:

(1) Overseeing the day-to-day safe operation of the MR environment. This includes:

(a) Ensuring safety screening questionnaires are completed for all individuals prior to their entry into Zone III. **NOTE:** Patients and research subjects must fill out a screening questionnaire at each visit.

(b) Granting access to individuals to Zone IV.

(c) Remaining in Zone III or IV if a patient or research subject is in Zone IV.

(2) Following established product MR Conditional labeling and safety guidelines carefully and precisely, applying them to the static magnetic field strengths at which they had been tested.

(3) Supervising Non-MR personnel still within Zone III or IV until such supervision has been formally transferred to another of the facility's Level 2 MR personnel, e.g., in the event of a shift change or lunch break.

(4) Accompanying or immediately supervising Non-MR personnel for the entirety of their duration within Zone III or IV. **NOTE:** *It is acceptable for Non-MR personnel to remain in a changing room or restroom in Zone III without visual contact as long as the personnel and the patient can communicate verbally with each other.*

(5) Performing the second screening with written MR safety screening questionnaire on all nonemergent patients who will enter Zone IV. Level 2 MR personnel must then review these completed questionnaires orally with the patient, surrogate, or research subject in their entirety before permitting the patient or research subject to be cleared into Zone III. At least one Level 2 MR personnel must sign the second screening questionnaire, along with the patient, surrogate, or research subject, and the form must be incorporated into the respective patient's electronic health record. Level 2 MR personnel must clarify and document blank, adverse, or ambiguous answers from the screening questionnaire before allowing the individual into Zone III.

(6) Adhering to guidelines regarding access to the different Zones, notably:

(a) Level 2 MR personnel can move freely through all Zones without the need for prior approval.

(b) Level 2 MR personnel can admit all others into Zone IV by following locally established screening and monitoring procedures.

(7) Undergoing a screening annually, or as conditions change due to the individual's respective health changes, e.g., surgery with implanted devices. Records for their annual screening must be kept by the organization and made available upon request. **NOTE:** *An important difference between Level 1 and Level 2 MR personnel is that Level 1 personnel have unrestricted access through Zone III, but must have permission before entering Zone IV. Level 2 MR personnel may screen and authorize Level 1 and Non-MR personnel into Zone IV, and have unrestricted access throughout all Zones.*

k. **Chair, MR Safety Committee.** The Chair of the MR Safety Committee is responsible for:

(1) Meeting, at least quarterly, and as appropriate for a close call or adverse event. Minutes of meetings shall be prepared for the Facility Quality Management Service. **NOTE:** *For more information about what constitutes close calls or adverse events, see VHA Handbook 1050.01.*

(2) Ensuring proper zoning of the facility with the necessary signage. **NOTE:** For a diagram of MR zones, see Appendix A.

(3) Ensuring MR Safe or Conditional monitoring and transport devices have been established for patient care.

I. **Ordering Provider.** The ordering provider is responsible for submitting the facility-specific screening questionnaire at the time the MRI order is placed. This ensures that patient education has been established and the initial screening process has been conducted by the respective health care provider before the exam has been scheduled. **NOTE:** For an example of the ordering provider's screening questionnaire, see Appendix B.

6. TRAINING

a. **Level 1 MR Safety Training.** Level 1 training is specific to those individuals who have been designated as Level 1 MR personnel. VHA MR Safety Training Level 1 is available on TMS course # 9696 or equivalent locally developed training. In the event of extenuating circumstances, personnel whose normal duties do not require level 1 training can receive "just-in-time" training. All Health Professions Trainees will be designated as Level 1 MR personnel and only require MR Safety Training through the TMS Mandatory Training for Trainees (MTT) course #3185966 or MTT Refresher course #3192008. **NOTE:** The facility must identify a process in writing to indicate who or which positions within the facility need Level 1 training, and ensure those individuals take the course annually.

b. **Level 2 MR Safety Training.** Level 2 training is specific to those individuals who have been designated as Level 2 MR personnel. Suggested Level 2 training programs are available at VHA Radiology Web Page for MR Level 2 Training. Locally developed training should encompass education in the broader aspects of MR safety issues; i.e., issues related to the potential for thermal burns, direct neuromuscular excitation from rapidly changing gradients, and how to respond to emergencies in the MR environment. **NOTE:** For information on how to access this web page, see Appendix H.

c. **Emergency Training.** Level 2 MR personnel and those Level 1 MR personnel who respond to emergencies in the MR area should anticipate and train for emergencies in or near Zone IV annually, as such emergencies pose a special danger because responding personnel may bring unsafe objects with them, such as crash carts, fire axes, and police service weapons. Records for these training events must be kept in accordance with local facility policies and procedures and be made available upon request. **NOTE:** For additional details pertaining to emergencies, see Appendix F.

7. REFERENCES

- a. Title 38 United States Code (U.S.C.) 7301(b).
- b. VA Directive 710, Personnel Security and Suitability Program, dated June 4, 2010.
- c. VA Handbook 6510, VA Identity and Access Management, dated January 15, 2016.
- d. VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016.
- e. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.
- f. Office of Construction & Facilities Management Design Guides (OCFM). (2008). MRI Design Guide. Retrieved from <https://www.cfm.va.gov/til/dGuide/dgMRI.pdf>.
- g. ACR Guidance Document on MR Safe Practices: 2013. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1002/jmri.24011/pdf>.

PHYSICAL SECURITY AND ACCESS

VA medical facilities must adhere to this directive and follow the standard approaches of MR Safety as outlined by the American College of Radiology (ACR).

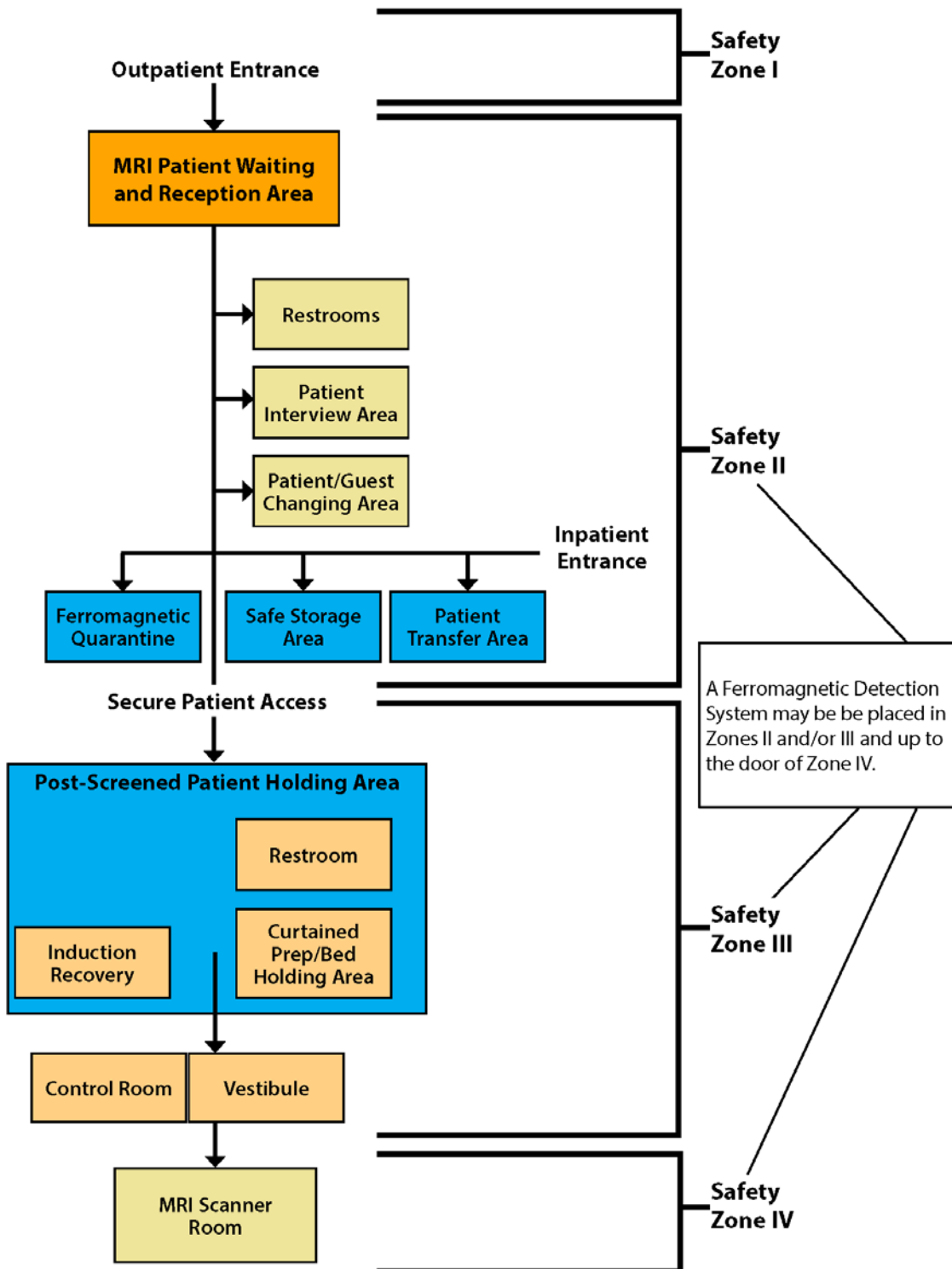
NOTE: *The most recently updated ACR Guidance can be found at:*

<https://www.acr.org/Quality-Safety/Radiology-Safety/MR-Safety>.

1. Description of Zone Diagram

The Magnetic Resonance (MR) area is set up with four Zones to facilitate patient, guest and employee safety. The picture diagram indicates that outpatients and visitors will walk into Zone I where they can move about freely. From Zone I, outpatients and visitors may enter Zone II of the MR area where they are greeted by a receptionist who will request they sit in the adjacent waiting area or move to the designated private area so they can change into a patient gown/MR safe clothing in preparation for their MR exam. A patient or visitor toilet is typically located in the Zone II area for use by patients and guests. Zone II is also the designated area where inpatients and hospital employees enter the MR area. MR Technologists have designated areas in Zone II to speak with MR patients which allows the safety screening to be performed, quarantine of any unsafe items, and transferring of inpatients to MR stretchers. Patients and employees may then proceed to Zone III which is a restricted area and accessible only be designated employees who have the necessary keys or badge swipe access. This Zone III area may have a toilet, and small waiting area for those patients who are about to have their MR exam performed. Zone III is also the area where the MR Technologist sits to operate the sophisticated controls of the MR machine. The last area on the diagram is Zone IV; this is area where the MR machine is situated and access to Zone IV typically has only one entrance through the Zone III area. If the facility opts to use a Ferromagnetic Detection System, it should be placed according to the manufacturers specifications between Zone II and the door to Zone IV.

2. Zone Diagram



- a. The essential elements of this plan are that outpatients and visitors must first enter a reception area where they are greeted, then 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 Zone IV through interior controlled space. The entrance to Zone IV is near the operator's console so the technologist may readily intercept unauthorized persons or unsafe objects. Anyone approaching the Zone IV door must be clearly seen by the technologist. The 5-gauss magnetic field line should not enter adjacent spaces that are not supervised by the MR operator. If the 5-gauss line extends beyond the confines of the building, the area must be cordoned off and delineated by signage to prevent access to the area.
- b. The door to Zone III and Zone IV must be locked whenever Level 2 MR personnel are not present in those areas or are unable to control zone IV access. Placing a ferromagnetic detector with an audible alarm according to the manufacturer's guidelines provides an additional level of safety. **NOTE:** *A ferromagnetic detector supplements patient screening but does not replace it.*
- c. Establishing physical security for a mobile MR van presents special challenges because the door to Zone IV may enter directly from an uncontrolled space at the side of van which cannot be seen by the technologist. For mobile units that have direct lift access to Zone IV, ramps or decks built at the side of the van must include a lockable gate that controls access Zone IV, while continuing to allow personnel access via the control room door.
- d. Prominent magnetic field hazard signs with hazard icons must be posted at all approaches to Zone IV and mobile MR vans. Signs near the Zone IV door must say "the magnet is always on" and "you must ask the technologist for permission to enter," or equivalent language. All items that are utilized in Zone IV must be properly labeled for safe use in the MR environment as noted by the current ACR Guidance Document on MR Safe Practices. **NOTE:** *For additional information, see the Responsibilities section for the MR Safety Officer.*
- e. A handwashing sink should be located in Zone III near the control room. Alternative methods such as alcohol-based solutions may be explored as a temporary measure. **NOTE:** *This is a requirement for new construction and renovations.*
- f. It is recommended that wall oxygen be installed during renovations in Zone IV and the gurney transfer area so that oxygen tanks do not enter Zone IV. While MR Safe oxygen tanks are available, these tanks can be confused with regular steel tanks. If MR Conditional oxygen tanks are used, they must be clearly labeled along with the tank regulator and stand in which they rest. **NOTE:** *MR Unsafe Oxygen cylinders are not allowed in Zones III and IV.*
- g. Items that are located in Zone III and not physically secured (e.g., fire extinguishers and items that may be used in Zone IV) must be MR Safe or Conditional and readily identifiable by their labeling.

h. New construction to MR areas must:

(1) Add controlled access to Zone III by Personal Identity Verification (PIV) access or similar secure access.

(2) Add installation of a ferromagnetic detector with an audible alarm according to the manufacturer's guidelines.

(3) Add a handwashing sink in Zone III. This ensures proper hand hygiene throughout the patient care experience and throughout the work day.

(4) Add wall oxygen in Zone IV. This mitigates accidents involving ferromagnetic oxygen tanks that can become projectiles in Zone IV.

(5) Include tethering points built into the design. This ensures equipment such as MR Conditional ventilators have secure fastening points during use in Zone IV. Crash carts and other items stored in Zone III must have tethering points as appropriate to prevent them from entering Zone IV.

(6) Include quench safety features that mitigate suffocation risks to patients, visitors, and employees, i.e., blow out door and quench pipe do not affect patient care areas or waiting rooms.

SAFETY SCREENING

1. PROCESS: All nonemergent patients who enter Zone IV must be screened twice prior to reaching Zone III using form(s) approved by the Radiology Service Chief.

a. **First or Initial Screening.** The initial screening determines if patients have unsafe pacemakers, aneurysm clips, shrapnel, etc., and minimizes the possibilities of patients traveling for an exam and not receiving one due to contraindications that could have been identified earlier. The initial screening must be performed by the ordering clinician or their staff and must be available in the electronic health record prior to scheduling the exam. Screening questions can also be incorporated in the computerized order entry dialogue of Computerized Patient Record System (CPRS), which facilitates ease of use for the ordering provider. If the initial screening form was not completed and the ordering provider is not available to complete the initial screening, one Level 2 and an additional signature by a Level 1 or 2 trained staff member signatures are required to sign and date this form to avoid any delays in care.

EXAMPLE SCREENING QUESTIONS FOR THE ORDERING CLINICIAN TO USE

1. Have you ever had an MRI? Was there a problem?
2. Have you ever had surgery in your entire life, including childhood?
3. Have you had any metal devices or implants placed in your body for any reason?
 - a) Do you have a pacemaker or defibrillator? Model_____
 - b) Do you have any aneurysm or brain clips? Model_____
 - c) Do you have a cochlear implant?
 - d) Do you have any shrapnel in your body? Where and when did this occur_____
 - e) Do you have any stents, cardiac or vascular? Model_____
 - f) Do you have a heart Valve? Model_____
 - g) Have you had any implanted orthopedic hardware? Where_____
 - h) Are you a machinist or welder or have you ever had metal in your eyes?
4. Are you claustrophobic? (Patient may need open MRI or Sedation.)
5. Are you pregnant? If so, elective procedures may be delayed until after delivery.
6. Do you have a history of High Blood Pressure? (Lab values will be required for contrast exams.)
7. Do you have kidney disease, poor kidney function, kidney tumor, or have you had a kidney transplant? (Lab values will be required for contrast exams.)
8. Are you diabetic? (Lab values will be required for contrast exams.)
9. Are you on dialysis?

10. Are you allergic to MRI contrast or have you had any previous reaction to MRI contrast?

b. **Second Screening.** The second screening is performed by Level 2 MR personnel. Conscious, nonemergent patients and research subjects must complete a written MR safety screening questionnaire before entering Zone III. Surrogates may provide the written MR safety screening questionnaire for those patients who are unresponsive or cannot reliably provide their own medical histories. These completed questionnaires are then to be reviewed orally with the patient, surrogate, or research subject in their entirety before permitting the patient or research subject to be cleared into Zone III. The second screening questionnaire must be signed by the Level 2 MR personnel, patient, surrogate, or research subject and must be incorporated into the respective patient's electronic health record. Blank, adverse, or ambiguous answers from the screening questionnaire must be clarified and documented by the Level 2 MR personnel before allowing the individual into Zone III. Screening questionnaires of non-patient/Non-MR personnel (i.e., those who accompany patients to comfort them and access Zone III and/or IV) should be kept in a secure location until no longer needed for safety or quality assurance purposes. For safety purposes, these non-patient individuals may be screened once providing it is done by Level 2 MR personnel.

2. RESOLUTION OF CONTRAINDICATIONS

If a potential contraindication is found during a Level 2 MR screening, and the Level 2 MR personnel, in concert with the supervising radiologist, makes a decision to proceed with the MRI exam, resolution of this contraindication must be documented on the screening questionnaire. To alleviate future delays and MR Safety concerns, the same information and resolution could be placed in an MRI note via CPRS for the respective patient. If the safety of a device is unknown, the manufacturer may be contacted directly to provide a letter or written safety statement. If a medical device is investigated and it is determined the patient should not be imaged while the device is in place, the contraindication should be documented in the electronic health record. Likewise, any complications in MRI resulting from a device must be documented in the respective patient's health record. The technologist will keep a file of all manufacturer safety documents, web pages and correspondence that are used to determine the safety of a device. It is recommended that the facility create a standard CPRS note title such as MRI SAFETY NOTE so this information can be found quickly. **NOTE:** *For a list of Web sites and printed manuals that reference the safety of implants and devices, see Appendix H for Additional Resources.*

3. UNOBTAINABLE HISTORY

If patients cannot give a history, the radiologist must be consulted. If no history is available, the supervising physician must clearly document in the respective patient's electronic health record that the potential benefits outweigh the risks or the procedure should be cancelled. Performing radiographic images may provide additional information.

4. SPECIFIC DEVICES

Specific external and implanted devices must be reviewed at the time of or prior to the MRI exam. This ensures the most up-to-date information is reviewed from the respective manufacturer. The supervising radiologist, the MR Director, or Level 2 MR personnel determine whether to scan the patient. If there are questions about an implant, device, foreign body, etc., the supervising radiologist or MR Director makes the final determination before proceeding with the exam. **NOTE:** *Resolution to contraindications must be documented.*

5. EXAMPLE OF SECOND SCREENING QUESTIONNAIRE

The use of MRI Screening via iMed (electronic informed consent/ patient decision making process) in the electronic health record is highly recommended. **NOTE:** *An example of the second screening questionnaire used by Level 2 MR personnel may be found at the ACR's web page for MR Safety, listed in Appendix H.*

PATIENT PREPARATION

1. Patients must be thoroughly questioned about any potentially hazardous objects and devices prior to their exam. It is recommended that patients be changed into a hospital-provided gown, scrubs, or other MR Safe clothing during their exam. In cases of patients for whom changing is not possible or desired, the use of ferromagnetic detectors may help to mitigate safety concerns. The MR technologist should inquire about any special clothing items like silver impregnated athletic underwear garments or clothing containing nonferrous metallic threads, which may heat up during the exam and cause skin burns. Either the patient or the healthcare team should remove and replace (as appropriate) external devices that are MR Unsafe or interfere with the MRI exam. Patients, if not ambulatory, should be transported into Zone III using an MR Safe wheelchair or gurney. Prior to entry into Zone IV, patients should be screened by an automatic ferromagnetic detector system (see Appendix A regarding new activations and renovations). A sheet or blanket should be offered for patient comfort.

2. Objects that must be removed before the patient enters Zone IV include, but are not limited to: wallets, money clips, credit cards and other cards with magnetic strips, electronic devices such as beepers or cell phones, hearing aids, metal jewelry, watches, pens, paper clips, keys, coins, hair barrettes and hairpins, shoes, belt buckles, safety pins, and any article of clothing that has a metal zipper, buttons, snaps, hooks, underwires, and metal threads. A visual inspection of the patient's ears for hearing aids and piercings is highly suggested. A ferromagnetic detector system may be used to augment the examination but is not an adequate screening by itself.

3. Infusion or external pumps that are not designed for the MR environment must be switched to an MR Safe or Conditional pump, converted to gravity drip, or heparin lock under the direction of a physician.

4. Monitoring equipment and cardiac leads must be replaced with MR Safe or MR Conditional monitoring equipment. When electrocardiogram (EKG) electrodes are used, the leads must be kept from touching the patients during the scan. Patients who are unconscious, sedated, or anesthetized but require EKG monitoring must be examined after each imaging sequence with potential repositioning of the EKG leads and any other electrically conductive material that contacts the patients skin. Cold compresses or ice packs could be placed on all electrically conductive material that touches the patient during the exam. Distortion of the EKG within the magnetic field can make interpretation complex and unreliable. Routine monitoring of the patient's heart rate and rhythm may be accomplished using MR Safe or Conditional pulse oximetry, which would eliminate the risks of thermal injury from EKG leads. Wires from MR Conditional leads should be placed in the center of the bore whenever possible.

5. Sandbags used to hold patients in specific positions must be replaced with MR Safe bolsters. **NOTE:** *Sandbags may contain steel shot which is strongly attracted by the magnet. Even if they are filled with sand, the sand may contain enough iron to cause imaging artifacts.*

6. Regular oxygen cylinders and regulators must be exchanged with MR Safe equipment or, preferably, wall oxygen while ensuring the flow rate is unchanged from the patient's previous setting.

7. Drug delivery patches may contain metallic foil and may have associated risks for thermal injury. Since removal may interfere with the delivery of medications, the patient's prescribing physician may need to be consulted. Level 2 MR personnel should alert the radiologist if the metallic foil patch is positioned on the patient so that it is in the volume of excitation of the transmitting radio frequency coil.

8. A set of ear plugs and/or MR Safe headset must be made available to the patient to attenuate noise from the magnet gradients. The manufacturer's recommendations for hearing protection must be followed for each respective MRI machine.

9. The patient should be positioned so as not to form a loop where the distal portions of the limbs touch together (e.g., when the knees are held apart but the feet touch each other). It is recommended that patients be instructed not to cross their arms or legs. Sponges or non-conductive padding can be used to hold limbs apart and away from each other as well as away from the bore of the MRI machine.

10. Patients who have claustrophobia or who 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 the bore they will be placed, and be reassured that they will be removed as quickly as possible upon pressing the panic button. It is helpful to speak to them and encourage them between each imaging series.

11. Patients must be offered a panic button which allows them to signal the Level 2 MR personnel that they require immediate attention or wish to be removed from the magnet. The panic button should be checked with each patient to ensure it is functional. A panic button may not work for patients who are paralyzed, sedated or obtunded; these patients should be checked between each imaging series to ensure their safety and comfort.

12. Pregnancy has not been proven to be a risk for the MRI scan. However, it is common practice to delay elective MRI exams until after delivery. If delay is not possible, the supervising physician should clearly document in the respective patient's electronic health record that the potential benefits outweigh the risks. It is further recommended that signature consent be obtained for the imaging procedure; however, for pregnant patients needing gadolinium administration signature consent is required. Although it is permissible for MR personnel to work in the MR environment, pregnant employees and other Non-MR personnel should not remain in Zone IV during the image acquisition portion of the exam.

PATIENT MONITORING

1. The Zone IV door must never be locked while a patient is in the room.
2. All cases requiring sedation must be approved by a radiologist. Sedation will be administered by appropriately privileged providers using MR Safe equipment. **NOTE:** *For more information, see VHA Directive 1073, Moderate Sedation by Non-Anesthesia Providers, dated December 30, 2014.*
3. If a patient attempts to remove an imaging coil during the course of a study, the study will be terminated and the radiologist notified. If a patient attempts to remove an imaging coil, it may result in patient injury and/or damage to the imaging coil.
4. 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 each imaging series to ensure their safety and comfort.

OVER-RIDING FOOD AND DRUG ADMINISTRATION LIMITS

1. The rate at which radio frequency (RF) energy is absorbed by the body is controlled by Food and Drug Administration (FDA) regulation to avoid excessive heating of the patient. The upper limit of the specific absorption rate (SAR) can only be exceeded under direction of the radiologist, if the radiologist first confirms that the patient does not show signs of heating. **NOTE:** *SAR is a measure of how quickly the body heats up when exposed to RF electromagnetic fields.*

2. The time rate of change for the magnetic field beyond FDA levels is password-protected on the MR machine and cannot be exceeded without an approved human research protocol. Exceeding the FDA limit may result in painful peripheral nerve stimulation. The research protocol must be removed from the MR console when the research study has concluded and all subject testing is finalized.

INTRAVENOUS GADOLINIUM ADMINISTRATION

Intravenous gadolinium administration may be necessary during MRI examinations. To evaluate and mitigate risks, all gadolinium administration must follow current local protocols, ACR, FDA, and VHA guidelines. **NOTE:** *See Appendix H for additional resources.*

EMERGENCIES

1. Emergencies in or near Zone IV pose a special danger because responding personnel may bring unsafe objects with them, such as crash carts, fire axes, and police service weapons. Level 2 MR personnel and those Level 1 MR personnel who respond to emergencies in the MR area should anticipate and train for emergencies in or near Zone IV on an annual basis. Records for these training events must be kept in accordance with local facility policies and procedures and be made available upon request. Crash carts and other MR Unsafe devices that are stored in Zone III must be tethered to the floor or wall to prevent accidental entry into Zone IV. The facility must have facility procedures or guidelines to ensure controlled access to Zone IV is maintained in the emergency setting to mitigate safety hazards. Annual drills must include the following: cardiac arrest, contrast reaction, fire, entrapped patient/employee/quench, and disruptive patient.

2. If a patient experiences a cardiorespiratory or other emergency during their exam, the technologist should remove the patient from Zone IV, transport the patient by MR Safe gurney to a safe location outside of Zone IV, and close the Zone IV door. To the greatest practicable extent, this task must be completed before the code team arrives. Once the Zone IV door has been secured, temporary unrestricted access to Zone III may be permitted for the duration of the emergency.

3. Under certain circumstances it may be necessary to manually quench the MRI magnet using the quench button. These circumstances include when a patient, employee, or family member becomes trapped against the magnet by a metal object, or when a fire occurs in Zone IV. 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 process, which may further delay restoring the magnetic field.*

ADDITIONAL BACKGROUND AND RISKS OF THE MR ENVIRONMENT

1. STATIC MAGNETIC FIELD RISK

The magnetic field of an MRI machine is exceptionally strong, invisible, and always on. The field attracts certain metals and draws them to the magnet with uncontrollable force. These objects can strike and injure a patient or employee, or may damage the magnet. Ferromagnetic metals (most commonly iron containing alloys and some forms of steel) are most strongly attracted to magnets. Some other metals, such as cobalt, nickel, chromium, and certain alloys, may be attracted to a much lesser degree. Examples of objects that may become attracted to and lodged to the magnet include gurneys and beds, 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 or cause intraocular/orbital hemorrhage. Non-MR Conditional pacemakers and other medical devices (e.g., insulin infusion pumps, ventilators, etc.) may be damaged, reprogrammed or turned off. Pagers, cell phones, and hearing aids may be damaged. Analog watches may become magnetized, which prevents the hands from moving. Credit cards with magnetic strips may be erased by magnetic field exposure.

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 may also induce currents in electrically conductive materials, such as wires that are lying on the patient or 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, gradient switching may cause biological effects, such as contraction of peripheral muscles or perceived flashes of light from the retina. Potentially, extreme gradient switching could induce seizures or arrhythmias.

4. CRYOGEN RISK

Cryogen is a gas, usually helium, cooled until it becomes a liquid. MR magnet windings are cooled by cryogenics, which causes the wires to have a very low resistance to electricity, a phenomenon called superconductivity. During an unplanned loss of magnetic field, cryogen in the magnet may evaporate or leak suddenly. This gas is normally directed to the exterior of the building by large pipes. In the event that helium leaks into Zone IV, it may displace the oxygen in the room, which could lead to asphyxiation.

5. PATIENT BURNS

(DATE)

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APPENDIX G**

The RF field in the MR environment may induce currents in electrically conductive materials such as wires that are lying on the patient, which may cause skin burns. Burns may also be caused by direct skin contact with the inner bore of the MRI machine, imaging coils, as well as skin to skin contact. These situations can be mitigated by using sponges or non-conductive padding to protect the patient's skin.

ADDITIONAL RESOURCES

The following serves as additional resources for individuals who work in the MR environment:

1. VA Directive 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012.
2. VA Directive 6550, Pre-Procurement Assessment for Medical Device/Systems, dated February 20, 2015.
3. VA Handbook 6510, VA Identity and Access Management, dated January 15, 2016.
4. VA Handbook 5005/77, Staffing, Qualification Standard for the Appointment of Diagnostic Radiologic Technologist, GS-647, Part II, Appendix G25, Diagnostic Radiologic Qualification Standard, dated June 26, 2014.
5. VA Handbook Directive 710, Personnel Security and Suitability Program, dated June 4, 2010.
6. VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016.
7. VHA Radiology Web Page for MR Level 2 Training:
http://vaww.va.gov/RADIOLOGY/Useful_Links.asp.
8. American College of Radiology (ACR) MR Safety web page:
<https://www.acr.org/Quality-Safety/Radiology-Safety/MR-Safety>.
9. ACR Guidance Document on MR Safe Practices: 2013. Retrieved from
<http://onlinelibrary.wiley.com/doi/10.1002/jmri.24011/pdf>.
10. ACR Manual on Contrast Media (2017). Retrieved from
<https://www.acr.org/Quality-Safety/Resources/Contrast-Manual>.
11. The Joint Commission (JC). (2017). Strong MRI safety programs prevent safety events. Retrieved from
<https://www.jointcommission.org/issues/detail.aspx?Issue=6dpbAlmR1zpPoUU4fiB3tRhNfB%2BISAD7bH1rPIUGvRg%3D>.
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18. U.S. Food & Drug Administration (FDA). (2014). MRI Safety: FDA Safety Communication. Retrieved from <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm135362.htm>.

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