MR Safety: Requirements and Practical Aspects

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Outline

- Requirements for MR Safety
  - Federal Regulations
  - Accreditation
    - Imaging
    - Institutional
- Practical Aspects of MR Safety
  - Setting up and maintaining a safety program
  - Device safety

Requirements for MR Safety – The Players

- Federal Government
- Radsite
- Intersocietal Accreditation Commission
- American College of Radiology
- The Joint Commission

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Federal Regulation

- Medicare Improvements for Patients and Providers Act (MIPPA)
- MIPPA calls for providers of Advanced Diagnostic Imaging services (CT, MR, PET, Nuc Med) that bill under Part B of Medicare to be accredited by Jan. 1, 2012, in order to receive payment for the technical component of these services.
- Currently applies only to private outpatient facilities, not to hospitals.

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Federal Regulation

- Facilities will receive an “unannounced” site visit by the accrediting body or CMS sometime during the 3 year accreditation cycle.
- Center for Medicare & Medicaid Services (CMS) has approved four national accreditation organizations – RadSite, ACR, TJC, IAC.
- All accreditation organizations have quality standards that address safety of equipment, patients and staff.

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Radsite

- RadSite MAP Accreditation Standards Version 2 (MAP v 2.1) (Request from http://www.radsitequality.com /cms-accreditation-requirments)
- Imaging Provider shall implement a patient and personnel safety program; must submit a key policy supporting this safety program which includes elements listed in Standard 6.2.1
- Personnel responsibilities to ensure compliance with policies and procedures pertaining to imaging system safety
- No items described explicitly for MR Safety

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Intersocietal Accreditation Commission

- The IAC Standards and Guidelines for MRI Accreditation (http://www.intersocietal.org/mri/standards/IACMRIStandards2014.pdf)
- Personnel training in MR Safety
- Written policies and procedures must exist to ensure patient and personnel safety. Safety policies must be enforced, reviewed and documented annually by the Quality Improvement committee or the Medical Director

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Intersocietal Accreditation Commission

- Policy to educate, train and screen facility staff
- Mechanism in place to screen all patients, personnel and visitors
- Method to continuously monitor patient
- Procedure to identify patients who suffer incidents or complications
- Acoustic noise protection
- RF burn prevention
- Policies addressing contraindications

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Intersocietal Accreditation Commission

- Must include policies regarding emergencies
  - Medical emergency response
  - Quench
- Appropriate equipment and supplies (MR Safe or Conditional) must be available to manage emergencies and critically ill or high risk patients

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- MRI Accreditation Program Requirements (http://www.acr.org/~/media/ACR/Documents/Accreditation/MRI/Requirements.pdf)
  - Supervising Physician responsibilities - Develop, implement and enforce policies and procedures in compliance with the ACR White Paper on MR Safety
  - Medical Physicist responsibilities to be familiar with principles of MR Safety for patients, personnel and the public.

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American College of Radiology

- Safety guidelines, practices, and policies must be written, enforced, reviewed, and documented at least annually by the MR supervising physician.
- The annual medical physics / MR scientist performance evaluation must also include an assessment of the MRI safety program (signage, access control, screening procedures and cryogen safety) as well as an inspection of the physical and mechanical integrity of the system.

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- ACR Accreditation Facility Tool Kit
  - Site Information
  - Personnel documentation for Physicians, Medical Physicists, Technologists
  - Performance evaluations, QC, inspections
  - Policies and procedures review
  - Physician peer review program
  - Patient report evaluation
  - Image labeling evaluation

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  - Image labeling evaluation

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ACR Accreditation Facility Tool Kit

- MR Policies and Procedures review
  - Unforeseen ferrous objects in MR scan room
  - Thermal burns and SAR
  - Response of personnel during and after a quench
  - Reporting of MR accidents to FDA via Medwatch Program
  - Hearing protection for patients/persons in MR scan room
  - Documentation of medical director / MR safety officer's name and responsibilities
  - Screening of visitors or other personnel in MR scan room

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ACR Accreditation Facility Tool Kit

- MR Policies and Procedures Review (cont.)
  - Screening patient's renal status before contrast administration
  - Crash cart, location, check
  - How to handle emergencies/codes in Zone IV
  - Educating MR staff, non-MR staff and emergency personnel
  - Ongoing education
- Refer to ACR Guidance Document on MR Safe Practices: 2013 for assistance on policies and procedures

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MR Safety Related Guidance Documents

- ACR Guidance Document on MR Safe Practices: 2013
- The Joint Commission: Sentinel Event Alert, Issue 38, Feb. 14, 2008
  - Preventing accidents and injuries in the MRI suite
  - Risk reduction strategies
  - TJC recommendations
- Gilk T, Kanal E. Interrelating Sentinel Event Alert #38 With the ACR Guidance Document on MR Safe Practices: 2013. An MRI Accreditation Safety Review Tool. JMRI 37:531-543 (2013)

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The Joint Commission – Imaging Accreditation

- Seeking Imaging Center Accreditation (http://www.jointcommission.org/accreditation/ahc_seeking_imaging_centers.aspx)
- Special Accreditation Option: Advanced Diagnostic Imaging for Freestanding Imaging Centers
  - Fulfills requirements for MIPPA
  - In order to meet CMS' requirements for advanced imaging, TJC has added three new elements of performance (EP) to the environment of care (EC) chapter.

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The Joint Commission - Hospital / Ambulatory Care Center Accreditation

- Revised Requirements for Diagnostic Imaging Services (http://www.jointcommission.org/assets/1/6/PREPUB-12-20-2013-DiagImaging_AHC.pdf)
- Environment of Care (EC) Standards
  - Chapters
    - Environment of Care (EC)
    - Human Resources (HR)
    - Provision of Care, Treatment, and Services (PC)
  - Elements of Performance (EP)
- New Standards effective July 1, 2014!

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New and Revised TJC Standards Related to MR Services and Safety

- Standard EC.02.01.01
  - EP: A14
  - EP: A16
- Standard EC.02.04.03
  - EP: A20
- Standard HR.01.05.03
  - EP: A25
- Standard PC.01.02.15
  - EP: A10

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New and Revised TJC Standards Related to MR Services and Safety

- Standard EC.02.01.01
  - EP: A14 (safety risks – patients, ferromagnetic objects, acoustic noise)
  - EP: A16 (safety risks - restricting access)
- Standard EC.02.04.03
  - EP: A20 (annual performance evaluation)
- Standard HR.01.05.03
  - EP: A25 (ongoing technologist training)
- Standard PC.01.02.15
  - EP: A10 (correct patient, imaging site, position)

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Standards Changes for Organizations Providing Diagnostic Imaging Services (continued)

Continued from page 5

New and Revised Requirements for Diagnostic Imaging Services

Standard	EP	Ambulatory Care		Critical Access Hospital		Hospital	
		New	Revised	New	Revised	New	Revised
EC.02.01.01	14		X	X		X	
	16	X		X		X	
EC.02.02.01	17	X		X		X	
EC.02.04.01	7		X	X		X	
EC.02.04.03	15		X	X		X	
	17		X		X		X
	19	X		X		X	
	20	X		X		X	
	21	X		X		X	
	22	X		X		X	
	23	X		X		X	
EC.02.06.05	4	X		X		X	
	6	X		X		X	
HR.01.02.05	19	X		X		X	
	20	X		X		X	
HR.01.05.03	14	X		X		X	
	25	X		X		X	
MM.06.01.01	13	X		X		X	
PC.01.02.15	5		X		X		X
	6		X		X		X
	7		X (deleted)		X (deleted)		X (deleted)
	10	X		X		X	
	12	X		X		X	
PC.01.03.01	25	X		X		X	
	26	X		X		X	
PI.01.01.01	46	X		X		X	
	47	X		X		X	
PI.02.01.01	6	X		X		X	

= includes MR services / safety related items

= This is the only revised EP for the MR related items

Joint Commission Perspectives®, January 2014, Volume 34, Issue 1

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Standard EC.02.01.01, EP: A14

- For organizations that provide MRI services: The organization manages safety risks in the MRI environment associated with the following:
  - Patients who may experience claustrophobia, anxiety, or emotional distress
  - Patients who may require urgent or emergent medical care
  - Patients with medical implants, devices, or imbedded foreign objects (such as shrapnel)
  - Ferromagnetic objects entering the MRI environment
  - Acoustic noise

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Standard EC.02.01.01, EP: A16

- For organizations that provide MRI services: The organization manages safety risks by doing the following:
  - Restricting access of everyone not trained in MRI safety or screened by MRI-trained staff from the scanner room and the area that immediately precedes the entrance to the MRI scanner room.
  - Making sure that these restricted areas are controlled by and under the direct supervision of MRI-trained staff.
  - Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI unit, by its design, can have its magnetic field routinely turned on and off by the operator.

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Standard EC.02.04.03, EP: A20

- For organizations that provide MRI services: At least annually, a diagnostic medical physicist or MRI scientist conducts a performance evaluation of all MRI imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics:

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Standard EC.02.04.03, EP: A20 (cont.)

- Image uniformity for all radiofrequency (RF) coils used clinically
- Signal-to-noise ratio (SNR) for all coils used clinically
- Slice thickness accuracy
- Slice position accuracy
- Alignment light accuracy
- High-contrast resolution
- Low-contrast resolution (or contrast-to-noise ratio)
- Geometric or distance accuracy
- Magnetic field homogeneity
- Artifact evaluation

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Standard HR.01.05.03, EP: A25

- The organization verifies and documents that technologists who perform MRI examinations participate in ongoing education that includes annual training on safe MRI practices in the MRI environment, including the following:
  - Patient screening criteria that address ferromagnetic items, medical implants and devices, and risk for nephrogenic systemic fibrosis (NSF)
  - Proper patient positioning activities to avoid burns
  - Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional)*

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Standard HR.01.05.03, EP: A25 (cont.)

- MRI safety response procedures for patients who require urgent or emergent medical care
- MRI equipment emergency shutdown procedures
- Patient hearing protection
- Management of patients with claustrophobia, anxiety, or emotional distress

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Standard PC.01.02.15, EP: A10

- For [critical access] hospitals that provide diagnostic computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), or nuclear medicine (NM) services: Prior to conducting a diagnostic imaging study, the [critical access] hospital verifies the following:
  - Correct patient
  - Correct imaging site
  - Correct patient positioning
  - (other for CT)

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Practical Aspects of MR Safety

- Setting up and maintaining a safety program
  - ACR white paper information
  - Zones
  - Required training
  - Site design

ACR Guidance Document on MR Safe Practices: 2013 M. Kanal et. al, J. Magn. Reson. Imaging 2013;37:501–530.

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Practical Aspects of MR Safety: Safety Program

- All sites should maintain MR safety policies.
- Policies should be reviewed and updated with new equipment and new recommendations (national or international). Annual review may be warranted.
- Name a MR medical director to ensure that MR safe practice guidelines are established and maintained.
- Procedures to ensure timely reporting of all adverse events and incidents (Medical Director, Medwatch) and used for continuous quality improvement efforts.

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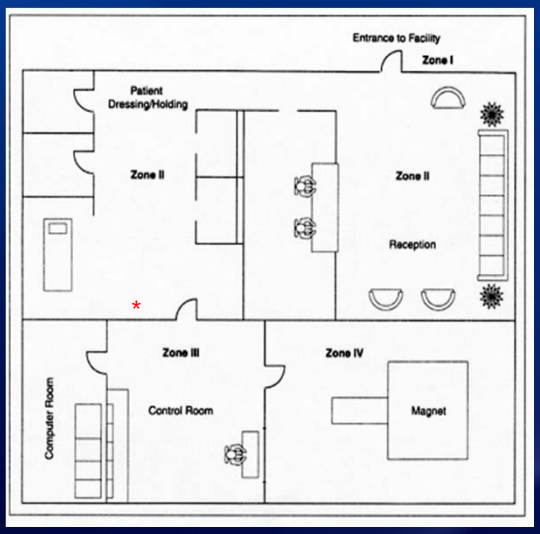
Practical Aspects of MR Safety: Zones



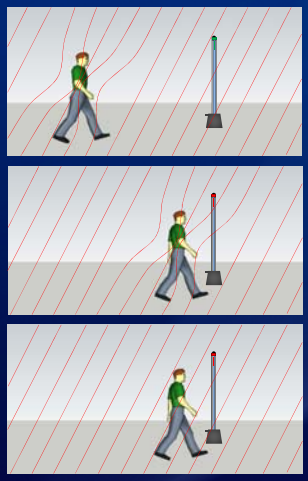
*Ferromagnetic detector (FD) placement

Practical Aspects of MR Safety: Required Training

- Annual MR safety training for MR personnel (approved by Medical Director)
  - Level 1: passed minimal safety training to ensure their own safety as they work (within Zone III)
  - Level 2: Extensively trained in MR safety issues, including, the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, and ferromagnetic attraction. (all zones, including Zone IV)
  - No MR Safety Training : Non MRI personnel (Zone 2 or less, else chaperoned)

Ferromagnetic Detection

- Ferromagnetic materials perturb the local magnetic field.
- Field perturbations follow the object as it moves.
- A high sensitivity magnetic gradiometer senses the environmental field gradient.
- Ferroguard is sensitive only to changing magnetic field gradients.
- A moving field perturbation triggers a visual/audible alarm.



No Alarm

Alarm

No Alarm (no FM object being carried)

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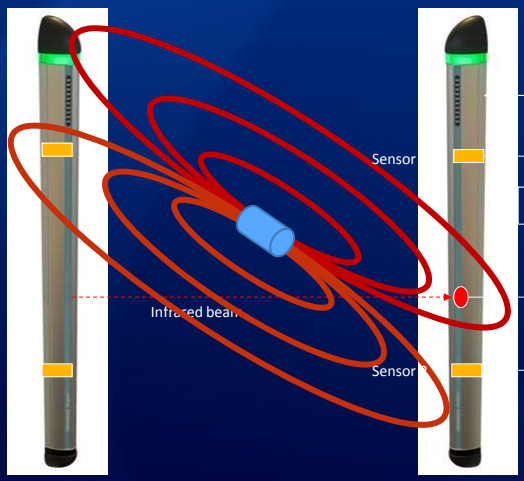
Slide provided by Metrasens

How Ferroguard Works



Magnetic Gradiometer technology in a patented configuration.

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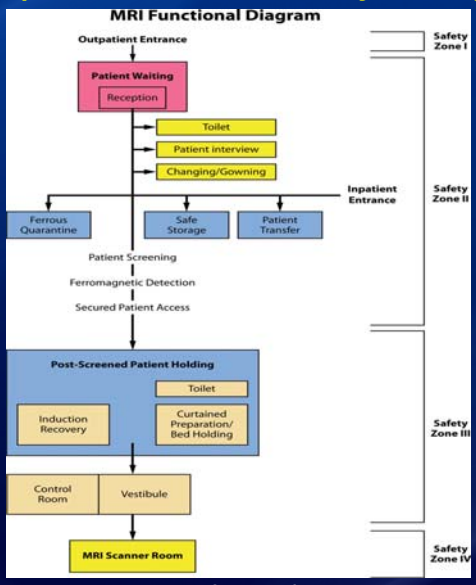
Slide provided by Metrasens

Practical Aspects of MR Safety: FD placement

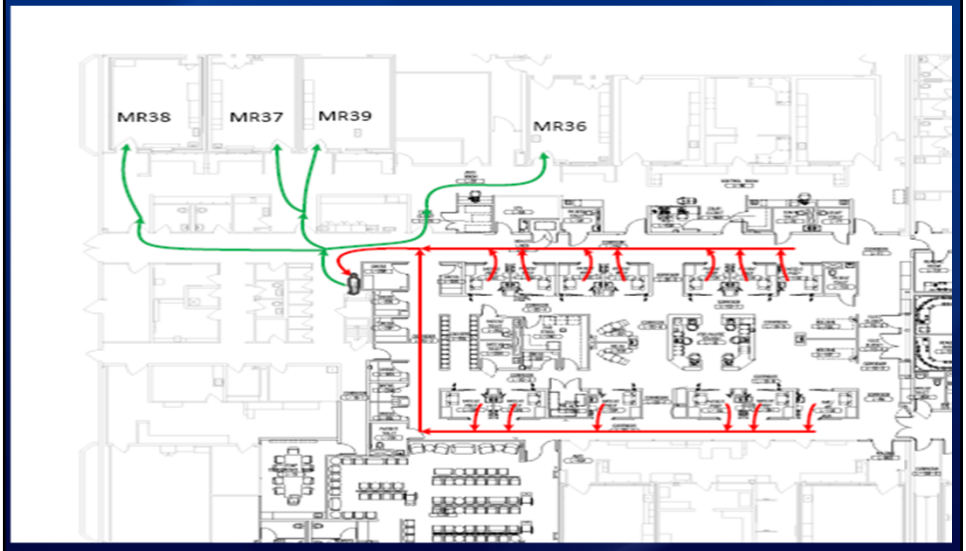


ACR Guidance Document on MR Safe Practices: 2013 M. Kanal et. al, J. Magn. Reson. Imaging 2013;37:501–530.

Site planning aspects to ensure safety

- Safety Design includes:
  - Technologist work flow
    - Screening (worksheet)
    - FD screening (patient, staff)
    - Verbal screening
  - Patient entry
    - Clothing change
    - Screening
  - Barriers

Practical Aspects of MR Safety: Site Design



Patient and staff flow with FD screener

Set up and Maintain Safety Program

- Role of Ferromagnetic Detectors (FD)
  - Detect metal that could be attracted into magnet
- Role of metal detectors
  - Detect metal location after FD detection
- FD Difficulties
  - Also detects moving ferrous metal in environment
- FD Placement within site (Zone II)
  - Must control what is behind walls, radius when using FD for screening

Procedure For Patient Safety in MRI

- Patients should be asked to change into gowns appropriate for MR scanning.
- Exceptions to this should be reviewed and approved by Radiologist (very few exceptions).
- Patients should be screened before Zone 3
- Any ferrous objects held by the patient after leaving Zone 2 should be placed in bins or held by the technologist.
- Patient is free of ferrous material prior to FD
- Family members (of children) screened too.

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Other Site Design Criteria

Placement of:

Ferrous Wheel chairs, walkers, crutches

screening areas (verbal, physical)

lines of sight during patient care (Zones III, IV)

Emergency resuscitation equipment (Zones II, III)

Signs:

- Zone III
- Zone IV
- Magnet is on!

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Site Design: Signs

Meets regulation, but could add “entering magnetic field area”

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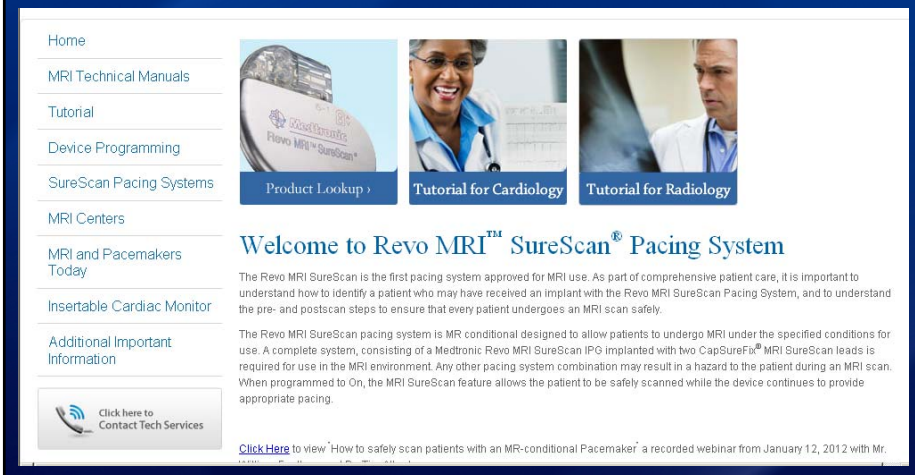
Site Design: Signs

Nice signs but ACR and new JC requirement "Magnet is always on"

Site Design: Signs

Meets regulations, but a bit cluttered and eventually can become invisible to staff

MRI Conditional Pacemakers (Revo, Advisa; Sure Scan pacing system)



Patients will present with what they call MRI Safe device!

MRI Conditional Pacemakers

- Device safety - MRI Conditional Pacemaker (s)
  - New conditions for imaging
    - Normal mode
    - No thorax limitation
- Radiology personnel training (required)
- Cardiology personnel training (required)
  - Monitoring during scanning (required)
  - Device placed in MRI mode prior to MR imaging (by Cardiology, required)
    - Test for diaphragm stimulation
  - Return device to original settings post MRI

MRI Conditional Pacemakers

- Training at:
- http://www.medtronic.com/mrisurescan-us/
- Certificate provided at the end of training
- Trained personnel must be present during MRI
- Different from previous Revo design:
  - Normal mode
  - No thorax limitation

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Steps to take when faced with new device in MRI

- Must know
  - Manufacturer
  - Model
  - Serial Number or lot number (if possible)
- Device card (if present, review and use information)
- Contact Manufacturer – MRI safety sheet available?
- Web tools (MRI safety sites)
- Team approach (Risk/Benefit)
- When in doubt, don't scan!

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Summary

- New JC requirement affects MRI
- New FD can be used to screen patients/staff
- Site safety includes site design and routine personnel training and physicists play a central role
- Conditional devices in MRI
  - require correct data, device assessment, and team review prior to MRI
  - Note: MR Conditions must always be met before scanning

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References

- ACR Guidance Document on MR Safe Practices: 2013 , JMRI 37:501–530 (2013)
- Medtronic Documentation
  - http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/pacemakers/revo-mri-pacing-system/education-and-training/index.htm
  - http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/pacemakers/revo-mri-pacing-system/mri-safety/index.htm
  - http://www.medtronic.com/mrisurescan/

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Example Policies and Procedures

- The following example MR Safety related policies and procedures are provided for educational purposes only and are not intended to represent current or final P&P at my institution.
- Use of any of the content of the following should only be done after careful review by local expert MR Safety personnel.

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Unforeseen Ferrous Object in MR Scan Room Procedure

Content Applies To

[Facility]

Scope

MR

Purpose

- To provide steps if an unforeseen ferrous object is taken into the MR scan room (Zone 4).
- To provide steps if an MR Conditional Device is placed too close to the magnet and is attracted toward the strong magnetic field.

Definitions

- **Unforeseen ferrous object:** An object that has a magnetic property that produces a strong and powerful attraction between the object and the center of the magnet. It is an item that has mistakenly been taken into the MR environment and is attracted toward the strong static magnetic field. Also defined as an “MR Conditional” device in which the required separation distance
- **MR Conditional Device:** Portable devices that have been demonstrated to pose no known hazards in an MR environment with specified conditions of use. The device has undergone testing to demonstrate that it is safe or it is made from materials that are considered to be safe if certain distance requirements are met
- **Quench (Emergency Shutdown):** A rapid boiling off of liquid helium.

Procedure

1. Ferrous object or MR conditional device is pulled up to or into the magnet.
    a. If a person (employee or patient) is pinned by a ferrous object in the scanner, and it is considered to be a harmful or life threatening situation, press the STOP button to quench the magnet and call Code Blue.
    b. If a ferrous object or MR conditional device is pulled up to or into the magnet and there is no immediate danger to a person (employee or patient), quench is NOT needed.

2. Do not attempt to remove object.

3. Remove patient from scan room.

4. Secure room to prevent further personal injury or damage.

5. Notify the following personnel/Departments:
    a. MR Physicist
    b. MR Physics Assistant
    c. MR Technologist Supervisor
    d. Radiation Safety Officer
    e. Risk Management
    f. MR Safety Committee Chair

6. Place service call to magnet vendor.

7. Reschedule patients to other scanners.

8. Fill out Safety report and Incident report.

Related Documents

References

Radio Frequency Warming Procedure

Content Applies To

[Facility]

Scope

MR

Purpose

- To prevent excessive heating and burns associated with Magnetic Resonance Procedures.
- To ensure that patients receive the proper treatment in the event of radio frequency warming during scanning.

Definitions

- 1st degree burn - damage is largely limited to the epidermis.
- 2nd degree burn - lead to the formation of blisters.
- 3rd and 4th degree burn - result in deeper lesions.
- Cross points - when a cable crosses another cable, loops across itself, or touches the patient or the sides of the magnet bore.
- General warming - Patient feels warming sensation but no pain involved.
- Localized heating - Patient feels heating that exceeds pain threshold at a localized site and is a definite cause for concern to the patient.
- Radio Frequency (RF) warming/heating: MR systems require the use of RF pulses to create the MR signal. The RF energy is transmitted readily through free space from the transmit RF coil to the patient. When conducting materials are placed within the RF field, the result may be a concentration of electrical currents sufficient to cause warming or excessive heating and tissue damage.

Procedure

Prevention of Warming

1. Follow all MR safety criteria for external and internal implants and devices made from electrically conductive materials.

2. Use only MR devices, monitoring equipment, and accessories that have been thoroughly tested and determined to be safe.
3. Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing blankets, sheets, or towels between the conductive material and the patient.
4. Keep electrically conductive materials (ECG leads, cables, wires, etc.) that must remain within the bore of the MR system from forming conductive loops or cross points.
5. Position all cables and wires so that they exit as close as possible to the center of the table.
6. Place pads between the patient's arms and the bore walls on every body-coil transmit scan. Place a towel under the arm pit or any other sites where there is skin to skin contact to reduce the possibility of patient burns.
7. When restricting movement of legs for pelvic imaging, always place a spacer between the feet so the toes and calves are not touching.
8. Follow all instructions for the proper operations of physiologic monitoring or other similar electronic equipment provided by the manufacturer of the device.
9. Remove all ECG electrodes that are used for inpatient purposes prior to MR imaging. Only use MR approved electrodes for monitoring. Ensure electrodes are placed appropriately to avoid air gaps. Prep area and remove excess hair.
10. Suggested imaging techniques for decreasing Specific Absorption Rate (SAR):
    a. Stay at lower level of SAR when pre-scanning
    b. Turn magnetization transfer (MT) OFF
    c. Turn spatial saturation pulses OFF (SAT Band)
    d. Turn fat sat off if acceptable within the imaging requirements
    e. Reduce the number of slices per acquisition in 2D exams
    f. Reduce the flip angle in gradient echo and TRU FISP exams
    g. Increase TR (if this will not affect image contrast)
    h. Confirm the use of "Low SAR Pulse" located on the Siemens sequence tab

When a Patient Complains of Heating

1. Refer to the Radio Frequency Warming Checklist
2. Stop scanning and assess patient.
3. Identify type of patient warming complaint.
    a. General warming (Normal)

i. MR Technologist and RN to evaluate site.
ii. Follow steps for prevention of warming. Adjust cables, add pads, change imaging techniques to reduce SAR, etc.
iii. Remind patient to squeeze ball if warming persists.
iv. Technologist will communicate with patient prior to each scan.
v. If warming continues, consult Radiologist to evaluate the site, and to either abort, or alter protocol.
vi. Post Exam
    1. Technologist and RN to evaluate site.
    2. Technologist to complete Safety report and contact Quality Control.
    3. RN or Technologist to document an MR Clinical Note in the EMR, give discharge instructions, and follow up with a phone call next day to patient.

b. Localized heating
i. MR Technologist and RN to evaluate site.
ii. If reddening, have Radiologist evaluate site.
iii. Establish level of pain using numerical pain scale
iv. Radiologist to determine if exam to be aborted.
    1. Radiologist consults with ordering MD and determines another imaging modality.
v. Post Exam
    1. RN to observe patient's site for >15 minutes.
    2. RN or Technologist to document an MR Clinical Note in the EMR, give discharge instructions, and follow up with a phone call next day to patient.
    3. Technologist to complete Safety and Incident Report and contact Quality Control.
    4. Remove RF coil if applicable until tested by quality control.
    5. If serious burn occurs, close the scanner until assessed by vendor equipment service.

When a Patient is Unable to Communicate

1. Follow all steps in procedures for preventing RF warming.
2. Avoid all bore-coil skin contact.
3. Use large bore scanner if bore skin contact is a concern.

4. Inspect sites of MR ECG leads post examination.

Related Documents

References

Shellock FG. Radiofrequency-induced heating during MR procedures: A review. Journal of Magnetic Resonance Imaging 2000; 12:30-36

Knopp MV, Metzner R, Brix G, van Kaick G. Safety considerations to avoid current-induced skin burns in MRI procedures. (German) Radiologe 199838; 759-63

Lange S, Nguyen QN. Cables and electrodes can burn patients during MRI. Nursing. 2006; 36:18.

Karoo RO, Whitaker IS, Garrido A, Sharpe DT. Full-thickness burns following magnetic resonance imaging: a discussion of the dangers and safety suggestions. Plast Reconstr Surg. 2004; 114:1344-1345

Magnet Quench Procedure

Content Applies To:

[Facility]

Scope

MR

Purpose

To provide guidelines in the event of a MR magnet quench

Procedural Statements

1. A quench occurs when a superconducting magnet suddenly loses its field and the helium supply rapidly boils off. A quench can occur spontaneously or intentionally by pushing the "magnet stop" button. A magnet may be intentionally quenched in an emergency situation, such as a person being pinned to the bore by a ferromagnetic object.

2. Typically, almost all the helium will escape safely through the quench pipes to the outside air, and the quench presents no serious danger. But if there is a blockage or failure of the venting system, the helium may accumulate in the scan room, which is an EMERGENCY situation. Helium itself is colorless, odorless and tasteless. Helium vapor is extremely cold, and causes water condensation, which looks like steam. Prolonged exposure to helium vapor can result in asphyxiation or frostbite.

3. An Escape Respirator is used to provide oxygen to staff and patients in the scan room when an emergency occurs.

4. MR Technologists are required to complete a quench specific competency yearly.

Equipment

1. MR Compatible Oxygen Escape Respirator

2. Instrument to break an radio frequency window

Procedure

1. MR Technologist
    a. Stay calm
    b. Instruct the patient to remain calm
    c. Open all the doors
    d. Secure the scan room door open
    e. Before entering the MR suite put on an MR-compatible oxygen "Escape Respirator" hood per instructions on the oxygen tank.
    f. Enter scan room and immediately remove patient from the scan room.
    g. If the scanner door cannot be opened, that could indicate a pressure increase in the room due to improper helium venting.
        i. In the very rare event that a person is trapped inside the scan room and scan room door won't open, then break a scanner room window to relieve the pressure.
    h. Contact the following personnel after any quench:
        i. MR Supervisor
        ii. Scanner Service Personnel
        iii. Physicist and/or Radiology Quality Control Department
    i. Evacuate the area for at least twenty minutes. The area must be cleared by facilities, A Radiology Physicist, and a Scanner Service Personnel before returning.
    j. Complete a service report.

Related Documents

References

Equipment/Safe Medical Devices Act

Content Applies To

[Facility]

Scope

Inpatient and Outpatient Practices

Purpose

To provide guidelines for the handling of medical equipment that may have malfunctioned and for reporting medical device-related problems in accordance with the Safe Medical Devices Act (SMDA).

Definitions

Device-Related Event: Device-related events are those events occurring as a result of a failure, malfunction, improper or inadequate design, manufacture, labeling, or user error.

Medical Device: A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is used in medical practice and is not a drug or biologic.

User: A user is an individual who uses a medical device for its intended purpose in the course of their duties at the Hospital or the Clinic.

Serious Illness or Injury: A serious illness or injury is an injury or illness that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, or requires medical or surgical intervention to preclude such permanent impairment or permanent damage.

Procedure

1. Report occurrence immediately to Risk Management. Contact the On-Call Risk Manager through the hospital operator.

2. If a reusable device malfunctions, the device should be removed from service immediately and tagged to alert others to not use it until an inspection has been made by Biomedical Engineering. If a PCA pump is involved, Legal will also be notified

immediately (On-Call Pager:) and that PCA pump should be sequestered until it can be safely transported to either Risk Management or Legal Department.

3. If a non-reusable device malfunctions, all parts should be sequestered and the Risk Manager notified.

4. Contaminated devices will be bagged and labeled as biohazardous.

5. The Risk Manager investigates reported SMDA event(s) and, if indicated, bring the information to the attention of the Risk Management Committee for review under the SMDA.

6. Risk Management submits mandatory reports within ten days of occurrence to the FDA and manufacturer pursuant to SMDA. Risk Management submits annual report to FDA as required.

Related Documents

References

Approved By

MR Hearing Protection Policy

Content Applies To

[Facility]

Scope

MR

Purpose

To provide guidelines for the use of hearing protection for all MRI patients, family members and personnel in the magnet room during procedures

Policy Statements

1. Every patient must be given earplugs and/or headphones to wear to deter the possible risk of hearing loss due to the high decibel of noise created by certain scans. In addition, ear plugs and/or headphones shall be worn by all individuals in the magnet room during a procedure.

2. If the patient refuses to wear the earplugs and/or headphones they must be made aware of the possible risk of damage to their hearing due to the high decibel of noise from certain scans.

3. If the patient still refuses after being told the risks, this should be documented in RIS and/or the Electronic Medical Record (EMR).

Related Documents

References

MR Safety Assessment for Patient and Family Members Policy

Content Applies To

[Facility]

Scope

MR

Purpose

- To minimize the risk of complications or life threatening hazards within the MR Suite (Zone 4) for patients and/or patient family members.

Policy

Patients

- Patient Screening Form (PSF) or MR Patient Screening Documentation must be completed each and every time the patient undergoes an MR diagnostic test or an MR surgical procedure.
    - Information should be given by the patient whenever possible.
    - A family member, a credible/reliable source, or a nurse caring for the patient may assist if the patient is unable to give reliable information.
    - If unable to obtain reliable information, radiographs of head, chest, & abdomen may be obtained (at the radiologist's discretion) to rule out any contraindications.
    - Inpatients:
        - The nurse caring for the patient will complete the PSF with patient or representative assistance and sign the form.
    - Outpatients:
        - Will be reviewed and signed by a technologist or PSS staff member in the sub-wait area
- Prior to being exposed to the static, gradient, or radio-frequency electromagnetic field of the MR system, the qualified MR technologist will complete the following:
    - Review the PSF or MR Patient Screening Documentation with the patient for completeness and accuracy and sign the form.
    - Complete a mini-examination pause, which includes:
        - Identifying the patient using two patient identifiers.
        - Verifying the correct examination is being performed in accordance with the indication, including the correct body part, side (if applicable) and imaging protocol.

        - Verifying the patient about to be imaged is the same patient entered in the imaging equipment system.
    - Visually inspects the patient for contraindicated devices.
    - Check gown pockets for any hidden hazards.
    - Any contraindications must be brought to the attention of the performing Radiologist and if necessary, for resolution with the ordering physician.
- The patient may undergo the MR procedure if:
    - Review of the PSF or MR Patient Screening Documentation is negative for contraindications.
    - When all contraindications have been resolved.
- Completed PSF is sent to HIMS to be scanned into the EMR.

Family Members

- Patient Screening Form (PSF) or MR Patient Screening Documentation must be completed each and every time the family members requests to enter the MR suite.
- Prior to being exposed to the static, gradient, or radio-frequency electromagnetic field of the MR system, the PSF will be reviewed with the patient for completeness and accuracy, and signed by a qualified MR technologist.
    - Family members **with** contraindications will only be allowed in the MR sub-wait area (Zone 2).
        - Family members that have pacemakers can accompany the patient to the MR sub-wait area (Zone 2), but must be instructed to wait in that area for the patients to return from their procedures.
        - If needed, and to insure their safety in the MR sub-wait area (Zone 2), a nurse or tech assistant may be made available to watch the family member.
    - Family members **without** contraindications will be allowed to accompany patients into the MR Suite (Zone 4).
- The family member must change into a patient gown and pants to ensure all ferrous belongings have been removed.

Related Documents

References

Patient Screening Form Magnetic Resonance Imaging (MRI)

Patient Identification

Patient's Weight _____kg	Patient's Height _____cm	Claustrophobia ☐ Yes ☐ No	Latex allergy ☐ Yes ☐ No

Some of the following items may be hazardous to your safety and some can interfere with the MRI examination. Please check the correct answer for each of the following.

1. Have you ever had a MRI before? ☐ Yes ☐ No If yes, when was your previous MRI scan? _____
2. Do you have a history of cancer? ☐ Yes ☐ No If yes, what type of cancer? _____
3. Have you had previous back surgery? ☐ Yes ☐ No If yes, when _____
4. Have you had previous brain surgery? ☐ Yes ☐ No If yes, when _____
5. Do you have a Deep Brain Stimulator, Codman-Hakim, Stratta, or programmable shunt? ☐ Yes ☐ No
6. Have you ever had an injury to the eye involving a metallic object (e.g., metallic slivers, shavings, foreign body)? ☐ Yes ☐ No
   If yes, please describe _____

Do you have any of the following?

☐ Yes ☐ No Cardiac pacemaker/or defibrillator (Stop and Inform Staff)
☐ Yes ☐ No Aneurysm clip(s) in the head (Stop and Inform Staff)
☐ Yes ☐ No Insulin or infusion pump (Stop and Inform Staff)
☐ Yes ☐ No Implanted drug infusion device (Stop and Inform Staff)
☐ Yes ☐ No Bone growth/fusion stimulator (Stop and Inform Staff)
☐ Yes ☐ No Pessary (Stop and Inform Staff)
☐ Yes ☐ No Internal pacing wires
☐ Yes ☐ No Heart valve/stent prosthesis (Need card)
☐ Yes ☐ No Intravascular stents, filters, or coils
☐ Yes ☐ No Swan-Ganz catheter and temp probe
☐ Yes ☐ No Shunt (spinal or intraventricular)
☐ Yes ☐ No Pill cam

☐ Yes ☐ No Cochlear, or ear implant (Need card)
☐ Yes ☐ No Hearing aid (Remove before MRI)
☐ Yes ☐ No Any type of prosthesis (limb, eye, penile, etc.)
☐ Yes ☐ No Transdermal drug delivery system (Nitro)
☐ Yes ☐ No Tattooed makeup (eyeliner, lips, etc.)
☐ Yes ☐ No Any metal fragments (bullet/shrapnel/BBs)
☐ Yes ☐ No Pregnant/breast feeding
☐ Yes ☐ No Breast expanders
☐ Yes ☐ No Any implant held in place by a magnet

Comments

Prior to your MRI scan, you will be asked to remove all clothing and change into a gown and pants for your exam. Again, most metallic objects cannot be brought into the scan room. This includes: shoes, bra hooks or under wires, hairpins, watches, hearing aids, wigs, hairpieces, back/pelvis/knee support brace, safety pins, earrings, and removable dental braces.

GLASSES AND DENTURES MAY BE REMOVED INSIDE THE SCAN ROOM
YOU WILL BE REQUIRED TO WEAR EARPLUGS OR EARPHONES DURING THE MRI EXAMINATION

_____ Date____/____/_____ Time_____
Signature of Person Completing Form

Form completed by ☐ Patient ☐ Relative ☐ Other_____

Reviewed by ☐ PSS (Initials)_____ ☐ RN (Initials)_____ ☐ MRI Technologist _____
Signature
Date____/____/_____ Time_____

Official Use Only	
Unique	

MR Medical Emergency Response Procedure

Content Applies To

[Facility]

Scope

MR

Purpose

- This procedure will be activated when the MR technologist has a medical emergency in the MR suite. Due to precautions that must be taken in the presence of a strong magnetic field, special emergency procedures must be followed.

Definitions

- IMRI: Intraoperative Magnetic Resonance Imaging

Procedure

Medical Emergency within the Diagnostic MR suite

1. Initiate Code Blue
    a. By pressing 'Code Blue' button on wall, or
    b. Dial 911 and give appropriate information to operator

2. Immediately move patient from the scan room to Radiology Recovery

Medical Emergency with Anesthesia in Diagnostic Suite

1. Anesthesia staff will instruct MR Technologist to initiate Code Blue on Anesthesia Call Box in control room

2. Patient will be moved from scan room to Zone 3

3. MR technologist will secure Zone 4

4. Anesthesia personnel will facilitate the code

Medical Emergency within the IMRI Surgical Suite

1. Anesthesia personnel will facilitate the Code Blue
2. MR Technologist will retract the scanner from the surgical suite by either remote control or by the manual backup process
3. Close the doors behind the magnet
4. Once the doors have been closed, the crash cart can enter the OR suite

Related Documents

References

MR Fire and Electrical Emergency Response Procedure

Content Applies To

[Facility]

Scope

MR

Purpose

- This procedure will be activated when the MR technologist has a fire and/or electrical emergency in the MR suite. Due to precautions that must be taken in the presence of a strong magnetic field, special emergency procedures must be followed.
- It is important to remember that this is a coordinated response to any fire emergency as well as any mechanical or electrical emergency between Safety and Security, Facilities Services and Clinical Engineering.

Definitions

- Electrical Emergency: When fire, smoke, or sparking noises are present within the MR scan room or the surgical suite.
- Electrical Emergency Shutdown: Removes all electrical power to the scanner (fire and voltage)
- Escape Respirator: Used to provide oxygen to staff and patients in the scan room when an emergency occurs.
- Ferromagnetic Material: Any object that can be attracted by a magnet. There are varying degrees of attraction.
- IMRI: Intraoperative Magnetic Resonance Imaging
- Magnet Stop Button: Used to “quench” the magnet, reducing the magnetic field. (ex: Patient pinned to the magnet)
- Table Stop Button: Stops the table and disengages the electrical brake of the table making it possible to move the table manually.

Procedure

Within the MR Suite

1. Remove patient from scan room

2. After the patient is removed from the scan room, close and lock the scan room door to contain the fire.

3. Initiate an Electrical Power Off (EPO)
    a. The MR Technologist will determine if there is an electrical emergency.
    b. Pressing the “electrical kill” button to stop electrical power to the scanner and control, does not quench the magnet

4. Call 911

1. Call a Code Red and give the Operator the following information;
    i. Name
    ii. Location
    iii. Type of emergency (fire, smoke or electrical)

5. Activate the nearest fire alarm pull station, if available.

1. Extinguish the fire, if safe to do so, using a MR safe fire extinguisher.

6. Evacuate all persons including non-essential staff from area.

7. Prevent inadvertent entry of any ferromagnetic material into the scan room.

8. For fire safety in an MR room, refer to page 8 of the Comprehensive Emergency Management Plan:

9. Contact the following and advise them of the situation
    a. MR Supervisor or Lead
    b. Radiology Physicist and/or Assistant
    c. Facilities
    d. MR Vendor Support Services

Related Documents

References

MR Card Access Procedure

Content Applies To

[Facility]

Scope

MR

Purpose

To identify a process by which staff members can apply for card access into the MR suite.

Definitions

- MR card access permits access to restricted Zones 3 and 4 within the MR suite.
- Levels of access include
    - Access into diagnostic MR scanners
        - Persons who have a need to enter the MR suite on a daily basis and have mastered the annual MR safety test.
            - MR Technologists
            - Additional Radiology staff
            - Security
            - Facilities
    - Access to the IMRI Surgical Suite
        - Persons who have a need to enter the IMRI suite on a routine basis and have mastered the required prerequisites, which includes annual MR safety.
            - MR technologists
            - OR Staff
            - Anesthesia Staff
            - Outside Vendors
            - Security
            - Facilities

Procedure

5. All individuals requesting an MR card access must
    c. Master the MR safety post-test on an annual basis
    d. Have no physical contradictions to entry of a magnetic field
    e. Should have supervisor/manager apply for photo card access through the MRI Safety website.
    f. Once completed the form will be sent for approval/denial.
        vi. MR personnel will confirm that the individual has mastered the MR safety exam via Transcript.
    g. Once approved Security will provide card access remotely

Related Documents

References