Perspectives in MRI Safety for the Medical Physicist

Max Amurao, PhD, MBA

Relevant disclosure:
Member, American Board of Magnetic Resonance Safety

Outline

- **Engineering Controls**
  - MRI Safety Zones
  - MRI Safety and MR-Safe Equipment
  - Access Control
- **Administrative Controls**
  - MR Safety Training
  - Signs and Labels
  - MR Safety Committee
- **Procedural Controls**
  - MRI Safety Screening
  - Implants, Devices, Objects
  - Patient Positioning
  - Claustrophobia, Anxiety, Distress
  - Emergencies in the MRI Environment

Centers for Disease Control and Prevention (CDC)

The National Institute for Occupational Safety and Health (NIOSH)

- *Controlling exposures to occupational hazards is the fundamental method of protecting workers. Traditionally, a hierarchy of controls has been used as a means of determining how to implement feasible and effective control solutions.*[1]
- In this case, what's good for the worker is also good for the patient and the public.

Reference - https://www.cdc.gov/niosh/topics/hierarchy/

Engineering Controls

Facility Design – Construction and Shielding

- Fixed versus Mobile siting
- Static magnetic field shielding
- RF field and ELF shielding
- Vibrations
- Quench vent siting
- Room pressure relief
- Oxygen monitoring
  - Emergency power
  - Static build-up
  - Magnet co-siting
  - Noise levels
  - Room temperature
  - DC lighting

Engineering Controls

Facility Design – Construction and Shielding

Acceptance Testing: MRSafety-relevant elements (AAPM Report 100)

- Acoustic/Vibration Measurements
- RF Shielding Evaluation
- Magnetic fringe field mapping
- Mechanical system checks
  (table motion, ventilation, access control, etc.)
- Emergency system checks
  Emergency stops, quench button/vents, oxygen monitors, room pressure release panels, etc.
- Patient Monitoring, Drug Delivery, Gating, Sedation Systems

Reference: AAPM Report 100 (Dec 2010)

Engineering Controls

Facility Design – Construction and Shielding

4-MRI Safety Zone concept adopted by the Facility Guidelines Institute (FGI)

- Guidelines for the design and construction of Hospitals and Outpatient Facilities (2014)
- Applicable for Hospitals and Ambulatory Care (outpatient) Facilities

Zone I – Public Access
Zone II – MR Safety Screening
Zone III – Direct Supervision
Zone IV – MRI Suite

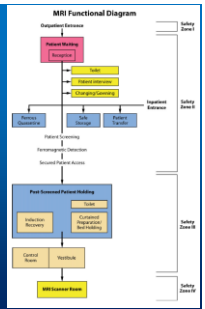
Zone III

- All access to Z3 should be physically restricted from general public access (e.g. key locks, passkey locking systems, proximity card, etc.)
- Access restriction should be able to differentiate between MR personnel and non-MR personnel.
- Only MR personnel can have reduced Z3 access restriction.
- All others in Z3 must be under the supervision of MR personnel.

- Z3 should be clearly delineated:
  - even in typically non-occupied areas (e.g. rooftops, quench vents)
  - Adjacent areas may be Z3 (above/below).
  - Access to non-occupied Z3 areas should be restricted for non-MR personnel. (e.g. facilities, construction, utilities)
- Specifically identified MR personnel (MRI Technologists) must ensure that MR safe practices are strictly followed for the safety of:
  - the patients
  - other non-MR personnel
  - equipment and property

Zone IV

- Z4 is the MR scanner magnet room itself.
- Z4 must always be located within Z3.
- Z4 should be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields.
- Z4 should have a lighted sign stating "The Magnet Is Always On" illuminated at all times (like emergency fire safety exit signs) to inform the public that the magnetic field is active even when power to the facility is deactivated.
- Direct visual observation and control by level 2 personnel (e.g. MR technologist) to access points into Z4 is required. Direct visual observation may be by line of site or by video monitors.
- Non-MR Personnel should be accompanied by, or be under the immediate supervision of and visual contact with, one specifically identified level 2 MR person for the entirety of their duration within Z3 or Z4 restricted regions.



Reference: ACR Guidance Document on MR Safe Practices (2013)
http://onlinelibrary.wiley.com/doi/10.1002/jmri.24011/pdf accessed: 29-Jul-2017

Engineering Controls

Access Controls

- Physical security and access restriction from all adjacent areas required for entry into Zone III and Zone IV.
- Independent access into Zone III must be limited to MR Personnel (appropriately trained).
- Access control to Zone II is optional.
- Patient holding area, screening area, and dressing area should all be in Zone II.
- What about MRI Trailers? (Zone II / III / IV)

Engineering Controls

Facility Design – MR Safety & MR-Safe Equipment

- Emergency Resuscitation and "Crash Carts"
- Handheld Test Magnets
- Oxygen Monitors
- Fire Extinguishers [Usually MR Conditional (know the conditions)]




Engineering Controls

Facility Design – MR Safety & MR-Safe Equipment

- Other Equipment – Wheelchairs
- Other Equipment – Patient Beds
- Other Equipment – Oxygen Tanks
- Other Equipment – IV Poles
- Other Equipment – Infusion Pumps & Devices
- Other Equipment – ECG Monitoring Devices
- Other Equipment – Ventilators
- Other Equipment – Patient Effects

Engineering Controls

Facility Design – MR Safety & MR-Safe Equipment

- Metal Detectors
  - Do not differentiate between non/ferromagnetic materials
  - 2013 ACR MR Safe Practices Guideline discourages it
  - Fixed Metal detectors at the entrance to Zone II? (for consideration)
- Ferromagnetic Detectors
  - Identifies ferromagnetic materials
  - 2013 ACR MR Safe Practices recommendation – adjunct to screening
  - Fixed ferromagnetic detectors in Zone III (for consideration)

Administrative Controls

- MR Safety Training
- Signs and Labels
- MR Safety Committee

Administrative Controls

- **MR Safety Training**
  - MR-Personnel versus non-MR-Personnel

    MR-Personnel – successfully completed and documented MR Safety training approved by the MR Medical Director (MRMD, or MRRD)

    Documentation of ongoing training (at least annual) required by ACR and TJC

    Non-MR-Personnel – no documented (or expired) training
  - Two levels of MR-Personnel

    Level 1 and Level 2 MR-Personnel may move freely about all zones.

Administrative Controls

- **MR Safety Training**
  - **Level 1 MR-Personnel** – successfully completed & documented minimal safety educational efforts to ensure their own safety as they work within Z3.
    - Non-MR Clinicians (Physicians, Nursing, Sedation & Anesthesia, etc.)
    - Non-Clinicians (Facilities, Security, Administrators, etc.)
  - **Level 2 MR-Personnel** – successfully completed & documented more extensive training and education in the broader aspects of MR safety issues.
    - Ensures their own safety and the safety of non-MR-Personnel.
    - MR Medical Director (MRMD) shall identify the necessary training as well as the individuals who qualify as Level 2 MR personnel
    - The MRMD should be Level 2

Administrative Controls

- **MR Safety Training - Content**
  - TJC annual training for MRI Technologists
    - Patient screening criteria that address ferromagnetic items, electrically conductive items, medical implants and devices, and risk for Nephrogenic Systemic Fibrosis
    - Proper patient and equipment positioning activities to avoid thermal injuries
    - Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional)
    - MRI safety response for patients who require urgent or emergent medical care
    - MRI system emergency shutdown procedures, such as MRI system quench and cryogen safety procedures
    - Patient hearing protection
    - Management of patients with claustrophobia, anxiety, or emotional distress

Reference: https://www.jointcommission.org/assets/1/18/AHC_DiagImagingRpt_MK_20150806.pdf HR 01.05.03.C25

Administrative Controls

Signs

- Signs should be provided at each initial point of entry to Zone II, Zone III, and Zone IV.
- Lighted sign indicating "**The Magnet Is Always On**" is required for each initial point of entry to Zone 4.
- Signal Words. Ref: 29 CFR 1910.145(f)(4)(ii)
  Signal words shall be readable at a distance of 5 feet
  - **Danger** – signal word for Zone IV
    [Ref: 29 CFR 1910.145(f)(5); 29 CFR 1910.145(d)(2)]
  - **Caution** – signal word for Zone III
    [Ref: 29 CFR 1910.145(f)(6); 29 CFR 1910.145(d)(4)]
  - **Notice** – recommended signal word for Zone II

Administrative Controls

Labels

- Document device/object MR Status
- Site testing with handheld magnet (~1000 G) or ferromagnetic detector
- Alterations on MR Safe/Unsafe/Conditional objects or devices may change the MR status/compatibility of the device. (e.g. replacement parts)
- A device or object demonstrated to be MR Unsafe may still be brought into Z3 under specific circumstances:
  - direct supervision of specifically designated 2 MR personnel;
  - device physically secured/restricted at all times while it is in Z3.
- ASTM F2503-13 – Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
  - International standard – applies to the practice of marking of items that might be used in the MR environment

Administrative Controls

Labels

- Based on the results of testing described in ASTM 2503-13 (Sec. 5), mark the item as
  - MR Safe; or
  - MR Unsafe; or
  - MR Conditional

colored

black & white

MR Safe
- electrically non-conductive
- non-metallic
- non-magnetic

MR Unsafe – An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment

Reference: https://www.astm.org/Standards/F2503.htm

Administrative Controls

Labels – MR Conditional

- an item with demonstrated safety in the MR environment within defined conditions
- At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields
- Additional conditions, including specific configurations of the item, may be required

Reference: https://www.astm.org/Standards/F2503.htm

Administrative Controls

Labels – MR Safe and MR Unsafe

- US FDA Guidance Document: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment. Guidance for Industry and Food and Drug Administration Staff. (December 11, 2014)

  A scientifically based rationale, rather than test data, may be sufficient to support identifying an implant as "MR Safe" or "MR Unsafe".
- For a passive implant to be labeled as "MR Safe" or "MR Unsafe", the FDA submission should include the scientific rationale or the testing described in the FDA guidance document. Testing results should address:
  - Magnetically induced displacement force (ref: ASTM F2052-14)
  - Magnetically induced torque (ref: ASTM F2213-06)
  - Heating by RF fields (ref: ASTM 2182-11a)
  - Image artifact (ASTM 2119-07)

Reference: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107708.pdf

Administrative Controls

The MR Safety Committee

- No generally accepted formal structure
- Possible structure following the Radiation Safety Committee format (NUREG 1516)
- The "Management Triangle" concept

Reference: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1516/sr1516.pdf Accessed 29-Jul-2017

Administrative Controls

The MR Safety Committee

- Executive Management
- MRMD/MRRD (Accountable)
- MRSO (On Site)
- MRSE (Technical Expert)
- MR Technologists
- Radiologists (Neuro, Body, MSK, Peds)
- Radiation Oncologists
- Medical Physicists / MR Scientists
- Other Personnel

  Nursing, Anesthesia, Respiratory, Code Team, Security, Housekeeping, Students, Researchers …

Procedural Controls

- MRI Safety Screening
- Implants, Devices, Objects
- Patient Positioning
- Claustrophobia, Anxiety, Distress
- Emergencies in the MRI Environment

Procedural Controls

- MR Safety policies and procedures are mandatory
- MR Safety P&P should be reviewed with any significant changes in safety parameters of the MR environment of the site.
  e.g. additional MR Scanner, significant software upgrades, faster or stronger gradients, advanced RF coils, etc.
- MR Safety P&P should include:
  - MRI safety screening
  - Implants, devices, objects
  - Patient positioning
  - Claustrophobia, anxiety, distress
  - Incidents, events, and emergencies

Procedural Controls

MR Safety Screening (documented)

- Required for all non-MR-personnel before entering Z3
- Only MR-personnel should perform an MR safety screening.
  - Roles of Level 1 and Level 2 MR Personnel
- Metal and Ferromagnetic detectors may be used as adjuncts
- Clothing and removable objects
- Risk / Benefit rationale should be provided in writing and signed by the authorizing radiologist.
- Screening form should be part of the patient medical record
- Sample MR Safety Screening Form from the 2013 ACR Guidance Document On MR Safe Practices: 2013

Procedural Controls

MR Safety Screening (documented)

- Unresponsive patients
  - Role of Level-2 MR Personnel
  - Roles of family or guardians
- Further investigation for history of metal/ferromagnetic objects
- Screening of non-MR personnel accompanying a patient in the MR suite, informed consent needed
- Acceptable methods of screening:
  - patient history
  - radiographic (plain X-ray) images
  - prior CT or MR studies of the anatomic area
  - written documentation on the type of implant/object

Procedural Controls

Implants, devices, objects

- Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device (ref: ISO/TS 10974:2012)
- Acceptable methods for identifying MR compatibility:
  - written records of the i/d/o formal testing results, pre-implantation*
  - product labeling regarding the i/d/o
  - peer-reviewed publications regarding MR compatibility and MR safety testing of the specific make, model, and type of the i/d/o
- MR safety testing records are valid only if:
  - i/d/o unaltered since such testing had been published; and
  - it is confirmed that the testing was performed on an i/d/o of precisely the same make, model, and type

Procedural Controls

Implants, devices, objects

- Variables that may have an impact on the MR Safety of an i/d/o:
  - static magnetic field strength
  - static magnetic field spatial gradient
  - orientation of the implant to the static B field or B-field gradient
  - rate of motion through the spatial static field gradient
- Risk assessment for MR imaging of i/d/o/ should consider:
  - mechanical risks
  - thermal risks
  - exposure of the device to the electromagnetic fields and related forces during imaging

Procedural Controls

Implants, devices, objects

- FDA required MR Safety information of MR Conditional devices include the following non-clinical testing parameters:
  - Static Magnetic Field
  - Maximum spatial field gradient
  - Maximum whole body averaged specific absorption rate reported by the MR system
  - Additional instructions – position of device outside/within the bore, restrictions on RF coil type, etc.
  - expected maximum temperature rise (in °C) after 15 minutes of continuous scanning
  - artifact caused by the device and extent of the artifact(in mm) for a specific static magnetic field strength and pulse sequence

Reference: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107708.pdf

Procedural Controls

Implants, devices, objects

- Prior MRI scan on the i/d/o is not sufficient evidence of compatibility – acquisition conditions may be very different!
- Informed consent required
- Who makes the final determination for scanning a patient with an object or implant?
  - Level 2 MR Radiologist or MR Medical Director
  - Non Level 2 trained physicians should not make the final determination of scanning a patient with an object or implant.
  - Predetermined criteria (set by MRMD) for scanning possible, with scan carried out by Level 2 Personnel.

Procedural Controls

Implants, devices, objects

- Ferromagnetic i/d/o – concern for translational or rotational displacement

  Non-ferromagnetic i/d/o –susceptible to displacement due to Lenz's forces
- Important resources:
  - Manufacturer Specifications for the Implant/Device
  - Reference Manual for Magnetic Resonance Safety, Implants, and Devices – 2017 ed. (Frank Shellock, PhD) (extensive list)
- What if – a ferromagnetic i/d/o/ is discovered during MRI?
- What if – patient monitoring is required?

Procedural Controls

Patient Positioning

- Critical for eliminating / reducing risk of thermal injuries & events
- MR Technologist must ensure that the patient's tissue(s):
  - do not directly come into contact with the scanner inner bore
  - do not form a conductive loop (arms, legs, hands, etc.)
  - do not have conductive loops from perspiration or liquids/gels
- Procedures that help
  - Use spacers
  - Clear patient instructions
  - MR Technologist verification

Procedural Controls

Claustrophobia, anxiety, distress

- The space in the magnet bore is restrictive or unpleasant, and worse with certain RF coils and MRI studies.
- It is worth spending time and effort to optimize patient comfort and ensure patient confidence.
- Continuously reassure the patient throughout the scan.
- An accompanying relative or attendant (appropriately screened, evaluated, and authorized) may be allowed to remain in the scan room in verbal (physical contact if necessary) with the patient
- Light or conscious sedation may occasionally be required
- Post sedation care must be provided after the exam

Procedural Controls

Claustrophobia, anxiety, distress

- Sedation and Anesthesia must follow appropriate guidelines:
  - American Society for Anesthesiologists (multiple guidelines)
  - ACR–SIR Practice Parameter for Sedation/Analgesia 2015
  - TJC Provision of Care, Treatment, and Services (PC) – Sedation and Anesthesia (multiple guidelines)
  - American Academy of Pediatrics and American Academy of Pediatric Dentistry: Guideline for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures (2011)

Procedural Controls

Emergencies, incidents, events

- Reporting of adverse events, MR safety incidents & near-incidents
  - Within institution/clinic
  - Used for Quality Improvement
  - If appropriate, report to the USFDA through the Medwatch program) https://www.fda.gov/safety/medwatch/
- Emergency Preparedness
  - MRI Emergency Switches – What do they look like? Where? What does it do?
  - Your facility HVA – which hazard is highest?
  - MRI Emergency Drill? (Fire, Active Shooter, Natural Events, Structural Damage)
  - Power Outage
    - Power needed for vacuum pump / cold head to keep cryogens liquefied.
    - Power loss → cryogen boil-off, freezing water/liquid → spontaneous quench

Procedural Controls

Emergencies, incidents, events –
Urgent and Emergent MRI Patient Conditions

- MRI Team – Technologist, Radiologist (MR-Level 2 trained)
- Clinical Teams: Radiation Oncology, Rapid Response (Code), Sedation, Respiratory, etc.
  - Equipment, emergency response and MR-Level 1 training
- Internal Security and Fire Safety Team
  - Equipment, emergency response and MR-Level 1 training
- **Stabilize and Evacuate***
  - For a medical emergency within Z4 requiring resuscitation or emergent medical intervention, initiate basic life support (as required) and simultaneously remove the patient from Z4 to a predetermined magnetically safe location.

Procedural Controls

Emergencies, incidents, events – Magnet Quench

- High risk for personnel, equipment, and physical facilities
- Initiate only after careful consideration (and planning)
- Quench SOP – Do you have one? Have you practiced it?
- Follow manufacturer recommendations
  - Controlled ramp down ideal
  - Quench with service engineer personal supervision
- Verify emergency exhaust systems
  - quench vents, pressure hatch, open doors: pressure relief
- Equipment
  - Thermal shock may cause permanent damage to superconducting magnet (~ $1MM/T). ~500°F temperature change within a few seconds
- Magnetic field does not instantly dissipate

Procedural Controls

Emergencies, incidents, events – Emergency Preparedness

- MRI Emergency Switches
  - What do they look like?
  - Where are they?
  - What do they do?
- Your facility HVA – which hazard is highest?
- MRI Emergency Drill?
  - Fire, Active Shooter, Natural Events, Structural Damage
- Power Outage
  - Power needed for vacuum pump / cold head to keep cryogens liquefied.
  - Power loss → cryogen boil-off, freezing water/liquid
  - Power loss → spontaneous magnet quench

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THANK YOU