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MR Safety: Rules and Regulations

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Disclosures

- None

Outline

- Equipment MR Safety
  – Manufacturer requirements
- Responsible Organization MR Safety
  - Federal Regulations
  - State Regulations
  - Accreditation
    - Imaging
    - Institutional

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Manufacturer Requirements

- 510(k) premarket applications to the FDA concerned with multiple aspects of MRI Safety
- Magnetic Resonance Diagnostic Devices - Class II device
- FDA Guidance for Industry: Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (issued November 14, 1998)
  - Elaboration of general requirements of 21 CFR 807.87
  - Recognizes other standards:
    - IEC 60601-2-33 – 3.1 "Particular requirements for the safety of magnetic resonance equipment for medical diagnosis"
    - NEMA Standards

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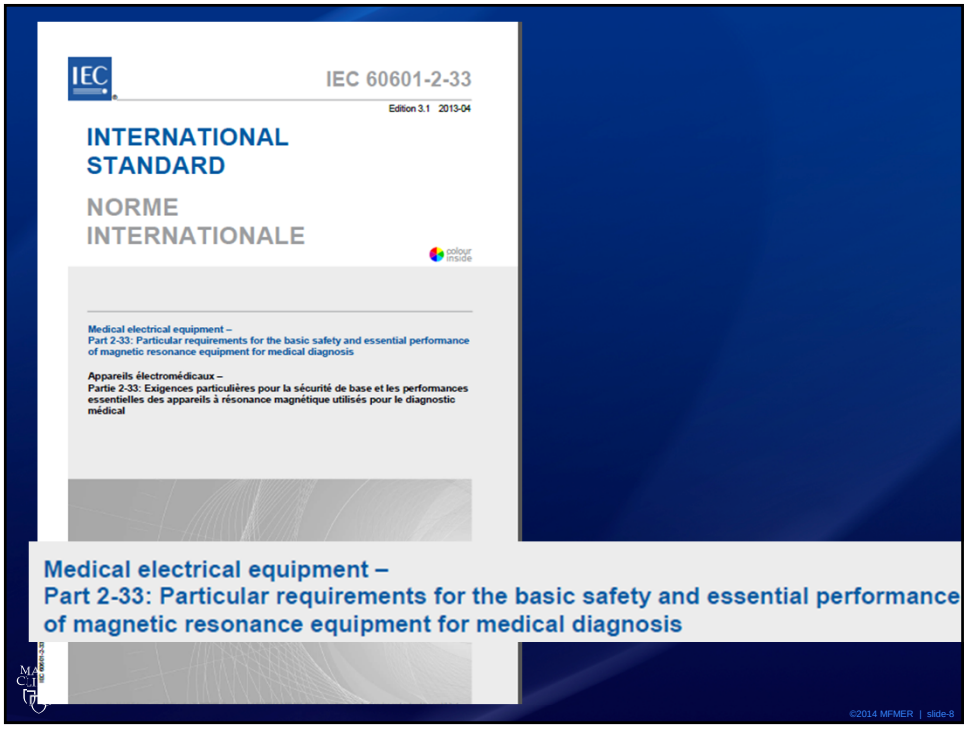
FDA Guidance for Industry: Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

- Attachment A – Recommended Safety Characteristics
  - Static Field
  - Acoustic Noise
  - Operating Modes (RF and dB/dt)
  - Emergency Shutdown

FDA Guidance for Industry: Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

- Attachment B – Recommended User Instructions
  - Screening
  - Level of Supervision
  - Emergency Procedures
  - Excessive Noise
  - Controlled Access Area
  - Liquid Cryogens
  - Operating Modes
  - Auxiliary Equipment
  - Emergency Shutdown
  - Fire Precautions
  - Prescription use
  - Recommended training
  - Quality Assurance
  - Maintenance



IEC 60601-2-33 (Ed. 3.1)

- Safety of patients examined with MR systems
- Safety of MR workers
  - Operators (technologists)
  - MR workers in development, manufacturing, installation and servicing
- Organizational aspects of safety
  - Operating modes
  - Limits for PNS/SAR/Static Field
  - Sound pressure limits
  - Instructions for use of MRI Scanner (Prescreening, medical supervision, emergency medical procedures, excessive acoustic noise, controlled access areas, cryogens, operating modes…)

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IEC 60601-2-33 (Ed. 3.1)

Establishes and defines three operating modes:

- Normal Operating Mode
  Considered safe for all patients, regardless of patient's condition
- First Level Controlled Operating Mode
  Operating parameters may cause physiological stress
- Second Level Controlled Operating Mode
  May produce significant risks for patients

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NEMA Standards recognized by FDA for MR Diagnostic Devices

- "Describe standard measurement methods… not… acceptable levels of performance or safety"
- MS 1 - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images

  MS 2 - Determination of Two-dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images

  MS 3 - Determination of Image Uniformity in Diagnostic Magnetic Resonance Images

  MS 4 - Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices

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NEMA Standards recognized by FDA for MR Diagnostic Devices (continued)

MS 5 - Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

MS 6 - Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images

MS 7 - Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Magnetic Resonance Imaging Systems

MS 8 - Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

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FDA also calls out

- IEC 60601-1
  Medical Electrical Equipment, Part 1: General Requirements for Safety
- UL2601-1
  UL version of IEC 60601-1
- UL94
  Tests for flammability of Plastic Materials for Parts in Devices and Appliances (Pads, coil enclosures)
- DICOM
- 21 CFR Subchapter J – Radiological Health

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FDA regulates the manufacturers, but generally not the use

- Exception: **Guidance for Industry and FDA Staff: Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices**
  - Designates operation conditions outside of the designed usage of the FDA-approved device
  - If exceeding these limits, the *user* is required to apply for an Investigational Device Exemption (IDE)

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Requirements for MR Safety – The Players
Responsible Organization MR Safety

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

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Federal Regulation

- The Safe Medical Devices Act of 1990
  - Requires health-care professionals to report death or injuries caused or suspected to have been caused by a particular medical device to the FDA or the product's manufacturer.
  - Must file report within 10 working days after event is determined to be reportable
  - Broad definition of medical devices, ranging from gauze sponges to implanted devices

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Federal Regulation

- Medicare Improvements for Patients and Providers Act (MIPPA) of 2008
  - 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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American College of Radiology

- 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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- 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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American College of Radiology

- 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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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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State Regulations

- States may also regulate use
- E.g. – licensure of radiologic technologists
- MN Statute 144.1225 – requires accreditation within 6 months of commencing operations for reimbursement from any source
  - Revised to only apply to imaging facilities that are not a licensed hospital

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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)
- Release of new standards has been postponed, planned for 2015

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Proposed 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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Proposed 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

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Proposed 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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Proposed 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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Proposed 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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Proposed 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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Proposed 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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Proposed 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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Proposed 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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Thank-you