



How FDA Regulates MRI Systems

Jana G. Delfino, Ph.D.

Biomedical Engineer

Division of Radiological Health

Office of InVitro Diagnostics and Radiological Health (OIR)

Center for Devices and Radiological Health (CDRH)

US Food and Drug Administration (FDA)



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Center for Devices and Radiological Health

Promote and protect the health of the public
by ensuring the **safety** and **effectiveness**
of medical devices and the **safety** of
radiation-emitting electronic products



How is MRI regulated by FDA?

FDA regulates manufacturers of the equipment and the equipment itself

- **LAWS** (legally binding requirements)
 - FD&C Act of 1938 (“The Act”)
 - Medical Device Amendments of 1976
- **REGULATIONS** (legally binding requirements)
- **GUIDANCES** (recommendations; typically not legally binding)



How is MRI regulated by FDA?

FDA’s regulation of magnetic resonance imaging equipment includes:

- Premarket requirements
- Postmarket requirements
- Requirements for investigational studies



Other State and Federal Agencies

Regulate use of magnetic resonance imaging devices through recommendations and requirements for:

- personnel qualifications
- institutional quality assurance programs
- facility accreditation



Safety and Effectiveness

Medical Device Amendments of 1976: Requires devices to be safe and effective

- **Safety:** Reasonable assurance, based on valid scientific evidence, that the *probable benefits to health from use of the device* for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, *outweigh any probable risks*.
- **Effectiveness:** Reasonable assurance, based on valid scientific evidence, that in a significant portion of the target population, the *use of the device for its intended use and conditions of use*, when accompanied by adequate directions for use and warnings against unsafe use, *will provide clinically significant results*.



Device Class and Pre-Market Requirements

Device Class	Controls	FDA Pre-market review process
Class I	General Controls	Most exempt
Class II	General Controls + Special Controls	510(k) clearance
Class III	General Controls + Pre-Market Approval	PMA approval



510(k) Premarket Notifications: How Is Substantial Equivalence Determined?

Submission from the manufacturer

- compares new device to predicate device(s)
- demonstrates that the new device is as safe and effective as predicate

Predicate = legally U.S. marketed device

Substantially equivalent (SE)

- same intended use AND same technological characteristics OR
- same intended use AND different technological characteristics (e.g., change in material, design, energy source, software) AND these differences do not raise different questions of safety and effectiveness

When do manufacturers need to submit a 510(k)?

- Introducing the device into commercial distribution for the first time
- Making a significant change to a currently marketed device
 - (i) that could significantly affect the safety or effectiveness of the device (e.g. a significant change or modification in design, material, chemical composition, energy source, or manufacturing process)
 - (ii) A major change or modification in the intended use of the device.

21 CFR 807.81

Role of FDA Guidance

- Guidance explains FDA's current thinking in a formal regulatory document
 - Useful to both industry and FDA reviewers
- Intended to increase transparency and consistency in the review process
- Most guidance documents do not establish legally enforceable responsibilities
 - Manufacturers can develop alternate methods of demonstrating substantial equivalence



Role of FDA Guidance

- FDA guidance document specific to MRI premarket submissions
 - “*Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (1998)*”
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073817.htm>



Role of Standards

- **Voluntary FDA-recognized standards**
 - Can simplify 510(k) submissions
 - CDRH Standards Program and liaisons
- CDRH recognized consensus standards relevant to MRI
 - IEC 60601-2-33
 - NEMA MS series
 - ASTM F2503, F2052, F2119, F2182, F2213



FDA's Post-market surveillance system: MedWatch

- FDA's nationwide adverse event reporting system, MedWatch, serves to monitor medical device performance after a device is approved or cleared for marketing.
- **Manufacturers, Consumers and User Facilities** (such as hospitals) report under MedWatch.
 - Alternative hospital-based reporting mechanism – MedSun
 - **Children's is a MedSun Hospital**
 - MedSun representatives are Jeff Hooper and Linda Matthews
- Database which stores reported events known as MAUDE. Publically available: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>



Postmarket Requirements Who has to report what and when?

- **Medical Device Manufacturers** must report:
 - Deaths
 - Serious injuries
 - Malfunctions to FDA
- **User Facilities** must report:
 - Deaths to FDA and to the manufacturer
 - Serious injuries to the manufacturer
 - Alternative mechanism for User Facilities is MedSun
- **Voluntary Reporting** at 1-800-FDA-1088



Reported problems occurring in MRI environment

- Adverse Event Reports received
January 1, 2006 – December 31, 2011.
- Broad search to capture all problems in the MR environment
 - *devices present in the MRI suite;*
 - *devices that accompany a patient;*
 - *items that are not medical device but may pose risk (jewelry, mops, etc.)*
- Keyword search for “MR” or “MRI,”
 - excluded “Mr.” “Mrs” or “MRSA”



Reported problems occurring in MRI environment

- Thermal-related issues
- Compatibility issues
- Projectile events
- Hearing issues
- Nerve stimulation/shocking

Thermal-Related Issues

Reported patient outcomes :

- Burns (second and third degree)
- Blisters
- Redness
- Heating or warmth

Most reported incidents attributed to:

- no padding or inadequate padding
- improper positioning
- accessory device on or with patient (e.g. electrodes, pulse oximeters, thermal blankets, t-shirt with silver threads)
- implanted device (e.g. rod, metal clip implant)

Compatibility Issues

Reported patient outcomes

- non-functional device after a scan was completed (e.g. infusion pump stalls)

Most reported incidents attributed to:

- Missing labelling
- MR Unsafe labelling, yet a scan was performed.
- Misunderstood labelling



Projectile Events

Reported patient outcomes:

- Death
- Crush injury or other blunt trauma

Most reported incidents are attributed to:

- site access issues
- product mislabeling as MR Safe/MR Conditional;
- labeling was not available;
- screening oversights



Hearing Issues

Reported patient outcomes:

- ringing in ears
- hearing loss (transient + permanent)

Most reported incidents attributed to:

- No hearing protection
- Faulty hearing protection

:



Nerve Stimulation/Shocking Events

Reported patient outcomes

- Peripheral nerve stimulation
- Shocking

Most reported incidents attributed to:

- associated with accessory or implanted devices



Reporting is Important

- **FDA needs to hear from you!**
 - Don't know about problems unless they are reported
- **Reporting by Consumers**
 - <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm>
- **FDA Guidance Document: Medical Device Reporting for Manufacturers**
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm>



Significant Risk/Non-significant Risk MRI Studies

- In general, FDA considers MRI studies to be non-significant risk provided the MRI equipment does not exceed specific operating conditions¹
- This includes the development of MRI coils, pulse sequences, and post processing algorithms
 - Such activity would be supervised by the local IRB

¹ FDA guidance document, "Criteria for Significant Risk Investigations of Magnetic Resonance Devices," 2003
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM072688.pdf>



Significant Risk Operating Conditions for MR systems

- **Static magnetic field**
 - >8T for adults, children and infants >1 month
 - >4T for infants <1 month
- **Specific Absorption Rate (SAR) above**

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	4
head	averaged over	10	3
head or torso	per gram of tissue	5	8
extremities	per gram of tissue	5	12

Significant Risk Operating Conditions for MR systems

- **Gradient Field Rate of Change**
 - Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation
- **Sound Pressure Level**
 - Peak unweighted sound pressure level >140dB
 - A-weighted rms sound pressure level >99dBA with hearing protection in place

Significant Risk/Non-significant Risk MRI Studies

- ...but, it is important to remember that the SR/NSR designation is assigned to a study protocol, rather than an individual device.
- Possible to have a SR study that involves an NSR MRI system (e.g. surgical procedure performed in 1.5T magnet or research software used to make patient care decisions)



Questions?

If you have questions about the level of risk in your study protocol:

- Submit a Risk-Determination request².
- Contact the Division of Radiological Health

Janine Morris, Division Director

(301) 796 – 5706

Janine.Morris@fda.hhs.gov

²http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#pre_ide



Thank you!

Jana.Delfino@fda.hhs.gov