MAYO CLINIC

# Implanted Devices Evaluation

Anshuman Panda, PhD

AAPM Annual Meeting 2019
San Antonio, TX

No Conflict of Interest to Declare




## List of Active and Passive Devices

- **Active Implanted Medical Devices**
  - Cardiac (pacemakers, ICD, CRT-D, loop recorders)
  - Stimulators (deep brain, vagal nerve, spinal, bone and bl
  - Programmable Shunts and Pumps (pain, drug, in
  - Cochlear implants
- **Passive implanted devices &** **gn objects**
  - Neurological (aneurysm
  - Orthopedic and D **oods, screws, braces)**
  - Cardiovas **valves, stents, coils & filters)**
  - GI **, tube, Pill Cam, magnetic sphincter)**
  - **, tissue expanders)**
  - **oreign objects (metal in orbits, BBs, bullet fragments)**
- **ternal objects and devices**
  - Medication patches, Glucose Monitor, Hearing aids
  - Permanent makeup, tattoos, piercings
  - Immobilization, temporary fixation, patient comfort (blankets)




AAPM Summer School



## Implanted Devices MR Safety Labeling


MRI Safe: The item is safe for **nder all conditions.


MRI Unsa **s not safe for use in MRI unde **ons.

**RI Conditional: The item is safe for use in MRI only under certain conditions.

NO Label: The item has not been evaluated for MR safety.

Please Do Not Use 'MR Compatible'



## Absolute Contraindication Implants for MRI?

- 10 years ago – most active implanted device and many passive
  - **Cardiac (pacemakers, ICD, CRT-D, loop recorders)**
  - **Stimulators (deep brain, vagal nerve, spinal, bone and bladder)**
  - **Pain Pumps**
  - **Cochlear implants**
- 5 years age – majority active implanted devices
  - **Stimulators (deep brain)**
  - **Pain Pumps**
  - **Cochlear implants**
- Today
  - ?

## Typical Implanted Device Evalution Call

- Patient is in the waiting room
- Does not have any information on implanted device
- Claims had MR at another site (most likely it was CT)
- There is no prior history or images in PACS
- Can we safely scan this patient?
  - Also can you please give me an YES and NO answer in 5 mins, we are running 30 minutes behind schedule
- Hmm…it Depends!



## Implants in MRI: Challenges


- Rapid growth of patients with implants
  - Increased number of MR conditional implants
  - Multiple implants and retained implants
  - Poor documentation in patient EMR
  - Direct vendor patient marketing as "MRI conditional"
  - Evolving and retroactive MR conditional labeling
- Rapid growth of MRI systems
  - High field (7T) and Low Field (<1T MR-Linac)
  - Hybrid Systems (PET-MR, Hybrid MR-OR)
  - Advanced procedures with high end hardware (fast gradients, multichannel transmit, scan parameter complexity)



## Complexity vs Clarity


- Opportunity for physicists to step in and assert our role in clinical practice as MRSE
- Radiation safety framework
  - Leverage Radiation Safety model as a analogy
  - Radiation Safety Committee
- We are all in the same boat – lean on each other
  - Interpersonal – Call a friend
  - Departmental – MR Safety Task Force
  - Institutional/Enterprise – MR Safety Committee
  - Professional Communities – AAPM and ISMRM Safety Committees

## Objectives

- How to operationalize implanted device evaluation and expand scope of our practice as MR Safety Experts
  1. Operational framework for device evaluation (evolving)
  2. Review relevant resources and guidelines (evolving)
  3. MRSE device evaluator starter guide (evolving)



## Safety Concerns – MR Conditional Devices

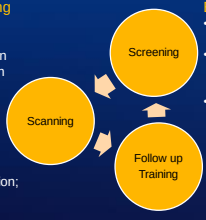
- Static Field (B0)
- Radio Frequency Field
  - SAR
  - B1+ rms
  - Duration of single series or entire scanning session
- Type of coil
- Spatial Gradient
- Identify
- Find vendor guidance
- Time-Varying Gradient Slew Rate
- Acoustic Noise
- Positioning/Landmarking/Centering
- Patient height, weight
- Location of device implantation
- Immbolization: external, comfort
- Patient monitoring
- Additional implants
- Artifacts



## Operationalize Implanted Devices Evaluation

**Evaluation Checks Pre/During**

- Verbal, visual, physical screening
  - Evaluation; interpretation and communication plan
  - Escalation process MRSO, MRSE, MRMD)
- Scan coordination
  - Inter/Intra departmental
  - Vendors
- Safe execution
  - Positioning; coils selection; monitoring;
  - Pulse sequences and parameters (Ultra low SAR protocols)




**Evaluation Checks Before**

- Institutional Framework
  - Patient EMR
- Departmental Framework
  - Schedulers MRSO
  - Guidelines and Policies
- Patient Framework
  - Screening Form

**Post Scan**

- Reporting
  - Internal and external (FDA MAUDE)
- Education and Training
- Safety committee review
  - Guidelines and policy update

## Operationalize Implanted Devices Evaluation


### Evaluation Checks Before

- Institutional Framework
  - Patient EMR
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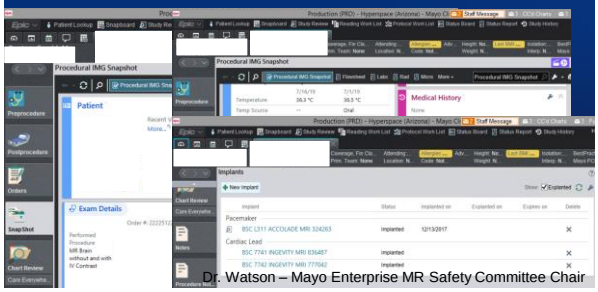
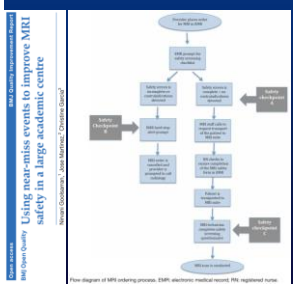
## Institutional Framework – Patient EMR

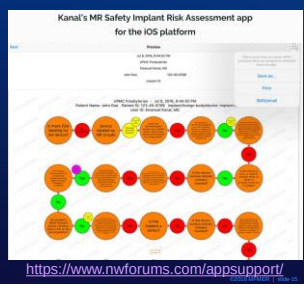



Dr. Watson – Mayo Enterprise MR Safety Committee Chair

## Departmental Framework – Schedulers, MRSOs

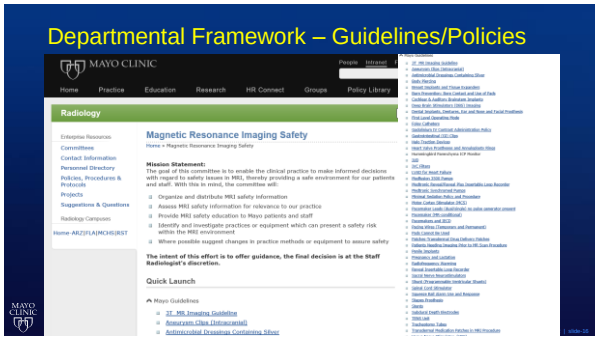


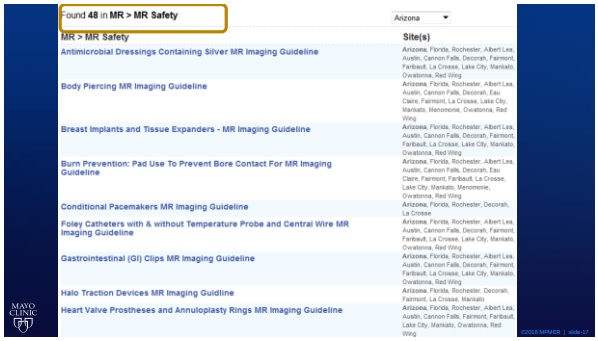


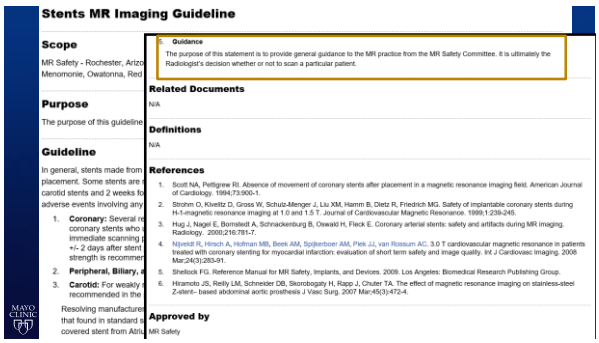




https://www.nwforums.com/appsupport/

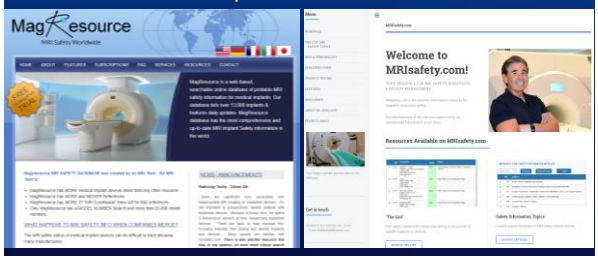
## Departmental Framework – Guidelines/Policies



## Guidelines Development Resources




http://magresource.com/ http://www.mrisafety.com/

## Blanket Policies - "All Stents are Safe"

- Use caution when using blanket safety statements in guideline

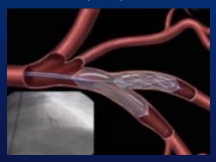
Aorfix AAA Flexibel Stent Graft

MR Conditional

Spanner Prostatic Stent

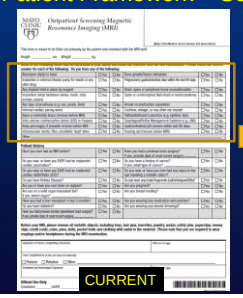
MR Unsafe

Coronary Artery Stent

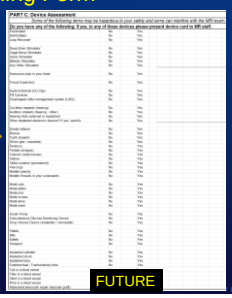


Multiple overlapping stents represent a potential thermal risk at higher fields due to shorter wavelength

## Patient Framework – Screening Form



CURRENT



FUTURE

## Operationalize Implanted Devices Evaluation

### Evaluation Checks Pre/During

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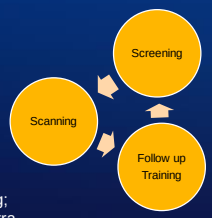





## Screening: Verbal, Visual, Physical

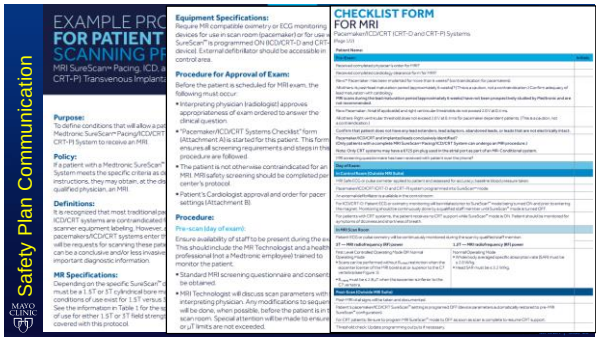


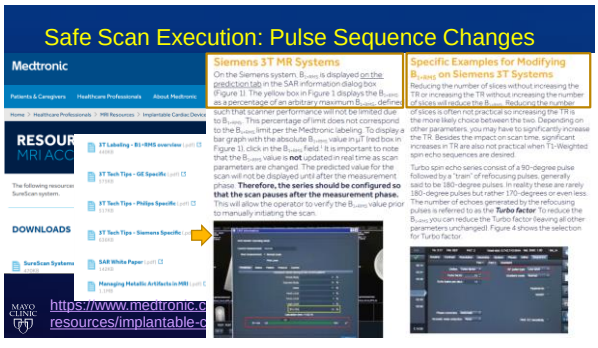

## Escalation Process: MRSO → MRSE → MRMD


- MRSE clearly communicate technical nuance on risks in MRI environment to aid in making effective patient management decisions
  - Low SAR scanning protocols; off-label scanning; positioning; monitoring; coils; pulse sequences and parameters
- Does not make medical decisions
  - Does advise on technical conditions for scanning on label
  - May be asked to advise on approaches to scanning off label and associated risks

| Safety Concerns - Evaluation | Device | Field | | |
|---|---|---|---|---|
| | Impact | Static | Grad | RF |
| **Lead Heating**<br>**Conductive lead acts as an antenna, picking up RF energy. A portion of this energy is dissipated as heat in cardiac tissue near tip of the electrode.** | Heat and electrical shock by concentrating RF energy; myocardial stimulation; tissue damage may affect therapy. | | | ● |
| **Unintended Stimulation/ heating**<br>**Gradient and RF fields induce voltages in leads that will be applied to the lead electrodes. Large voltage pulses may directly stimulate the heart. Electrical currents may be induced on the conductive surface of the case.** | May lead to a single or intermittent stimulation from oversensing or undersensing; sustained tachycardia; thermal tissue damage near the case | | ● | ● |
| **Device Interactions/Vibration**<br>**Static field will act on ferromagnetic material producing a translation or rotation of the device or lead.**<br><br>**Gradient and RF fields can induce electrical currents on conductive surfaces of device components. Interaction with static field may result in components to vibrate.** | Pacemaker or defibrillator movement, patient discomfort, malfunction or failure (asynchronous pacing). | ● | ● | ● |

Adapted from: http://www.medtronic.com/



August 2015, Volume 205, Number 2

Residents' Section
Frequently Asked Questions

« Previous Article | Next Article »

## What MRI Sequences Produce the Highest Specific Absorption Rate (SAR), and Is There Something We Should Be Doing to Reduce the SAR During Standard Examinations?

Jerry Allison[1] and Nathan Yanasak[1]

There are several approaches for managing SAR. Most SAR reduction approaches have associated imaging consequences. These approaches are as follows:

- Increase the TR, which can lead to longer scanning times.
- Reduce flip angles (for FSE sequences, use 60–130° refocusing pulses rather than 180° refocusing pulses), which can alter image contrast-to-noise ratio or signal-to-noise ratio.
- Reduce the number of slices in an acquisition, which can lead to longer scanning times.
- Reduce the number of echoes in multiecho sequences, which can lead to longer scanning times.
- Control the scanning room temperature and humidity (follow manufacturer specifications), which may affect comfort for lightweight patients.
- Dress the patient in light clothing, which may affect patient modesty.
- Take breaks between high SAR acquisitions or interleave high SAR and low SAR acquisitions to allow patient cooling, which can lead to longer scanning times.
- Be sure the patient ventilation system in the scanner is turned on.

## Cardiac MRI Exams with Very Low SAR (0.1 W/kg) for Patients with Active Implantable Medical Devices

Jessica A. Martinez[1,2], Kévin Moulin[3], Ashley Prosper [2], Daniel B. Ennis [3]
[1] Department of Bioengineering, University of California Los Angeles, CA, USA
[2] Department of Radiological Sciences, University of California Los Angeles, CA, USA
[3] Radiological Sciences Lab, Department of Radiology, Stanford University, Stanford, CA, USA

RSL Radiological Sciences Laboratory Stanford Medicine

UCLA Magnetic Resonance Research Labs

**I. Specific Absorption Rate (**

Scanner reported SAR is th
estimated to be absorbed by th
but it can be reduced by modify

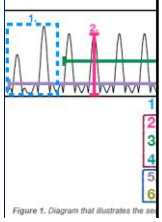


*Figure 1. Diagram that illustrates the se*

**II. Workflow**

Modifying sequence parameters without care can substantially compromise image quality. A workflow has been proposed to modify MRI protocols to meet a SAR target[2] (**Figure 2**).

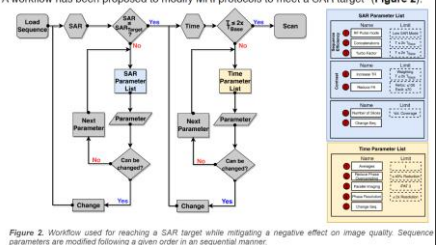
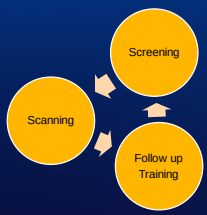



*Figure 2. Workflow used for reaching a SAR target while mitigating a negative effect on image quality. Sequence parameters are modified following a given order in an sequential manner.*

## Operationalize Implanted Devices Evaluation




### Post Scan

- Reporting
  - Internal and external (FDA MAUDE)
- Education and Training
- Safety committee review
  - Guidelines and policy update

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## Reporting – Internal

Safety

SERF

SAFETY EVENT REPORTING FORM

- SERF Reporting (Patient)
- Midas Incident Reporting (Patient) (ILA | MGHS | BSI)
- Incident Reporting (Employee)
- Severity Scale

**Resources**

Education Sessions:
1: The "Why, Who, & What"
2: The "When & Where"
3: Foundations & Form Introduction
4: How To's and Training Link
5: Manager Info

Radiology SERF Q & A Mailbox

SERF Help Ticket

Accreditation: The Joint Commission/Centers for Medicare and Medicaid Services

MRI Safety

| Event Information | |
|---|---|
| Event Type & Date | ACCIDENTAL INJURY & 07/14/2017 1:00:00 AM |
| Event Level, Group, Location & Where Occured | ACTUAL EVENT, MRI, MCH & EXAM ROOM |
| Severity, Triage & Sentinel | 2, NO & NO |
| Event Documents | |
| Body Part Imaged | ABDOMEN & PELVIS |
| Department Involved | RADIOLOGY |
| Division Flag | MR BODY |
| Event Description Summary | POSSIBLE 1ST DEGREE BURN POST MRI. PATIENT HAD A MR ABDOMEN/PELVIS WITHOUT INCIDENT. THE NEXT MORNING, SHE WOKE UP AND NOTICED REDNESS AROUND HER LOWER ABDOMEN/PELVIS REGION. DESCRIBED IT AS A SUN BURN; A DIME SHAPED AREA AND A COUPLE STRIPED AREAS OF REDNESS. WHEN SHE CALLED, THE REDNESS HAD GONE AWAY. SHE THOUGHT IT MIGHT BE RELATED TO HER UNDERWEAR. THE LABEL STATED 96% POLYESTER, 2% SPANDEX, 2% OTHER FIBER. SHE WILL FOLLOW UP WITH HER PROVIDER AS NEEDED. |
| Injury & Description | YES, AREA OF REDNESS ACROSS LOWER ABDOMEN/PELVIS. 1 DIME SHAPED AND 2 OR 3 STRIPE-LIKE AREAS. |

## Reporting – External FDA MAUDE


https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

## FDA MAUDE Database Search


- Product Codes LNH (Nuclear Magnetic Resonance systems, 892.1000)
- MOS (coil Magnetic Resonance, 892.1000).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

## MAUDE - Manufacturer and User Facility Device

### MAUDE Adverse Event Report: GE MEDICAL SYSTEMS, LLC 3.0T SIGNA HDX MR SYSTEM NUCLEAR MAGNETIC RESONANCE IMAGING

FDA Home | Medical Devices | Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

**GE MEDICAL SYSTEMS, LLC 3.0T SIGNA HDX MR SYSTEM NUCLEAR MAGNETIC RESONANCE IMAGING** Back to Search Results

**Event Date** 05/28/2019
**Event Type** Injury
**Manufacturer Narrative**

Unique identifier: udi not required there are no additional device identification numbers. Ge healthcare's investigation is ongoing. A follow up report will be submitted once the investigation has been completed. Device evaluation anticipated, but not yet begun.

**Event Description**

It was reported that a ge healthcare field engineer (fe) was servicing an mr system and brought a ferrous table motor into the scan room. While still in the field engineer's left hand, the motor was attracted to the magnet and impacted the rear of the system. The field engineer injured his hand and was diagnosed with a minor fracture to the left radial styloid in his wrist and an abrasion to his left thumb. The fe received a plaster cast as well as oral pain killers and antibiotics as treatment for the injury.

Search Alerts/Recalls

## MAUDE Adverse Event Report: SIEMENS MEDICAL SOLUTIONS USA, INC. SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING

FDA Home | Medical Devices | Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
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**SIEMENS MEDICAL SOLUTIONS USA, INC. SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING** Back to Search Results

**Event Date** 04/29/2019
**Event Type** Malfunction
**Event Description**

Patient presented with three distinct burns on right distal calf, ankle and 5th digit following mri. Parents were getting a patient dressed when they noticed an area under the patient's cotton sock and pulled the sock off. The area on the 5th digit and ankle were focal blisters; the lesion on the right lateral calf was approximately 6-8 cm long with 2 cm extending outside of the patient's sock. The patient had a cotton sock on the other foot and there was no lesion on that side. The machine was evaluated to see if there was any source of focal heating. No item was identified. The sheet, sock, and patient id which was on the right ankle was retained. None of them appear to have been a conductive risk. Our medical physicist and credentialed mr safety expert was contacted to evaluate the delivery of radiofrequency radiation. Evaluation of the sar values for each sequence is being done currently. The radiology team has notified Siemens of incident. At this point, there is no known cause for these burns.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

**Type of Device** SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING
**Manufacturer (Section D)** SIEMENS MEDICAL SOLUTIONS USA, INC.

## Closing the Loop: MR Safety Committee

- Radiologist (MRMD)
- Technologist (MRSO)
- Physicist (MRSE)
- Administrators (Supervisors and Managers)

1. Training and Education
2. Guideline and Policy Updates

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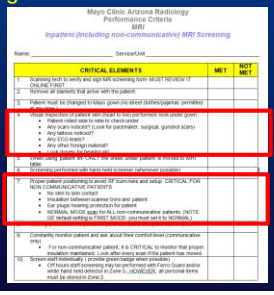
## Training and Education – MR Tech Level 2



Mayo Clinic Arizona Radiology
Performance Criteria
MRI
*Inpatient (including non-communicative) MRI Screening*

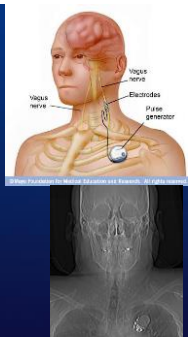
Name: _____ ServiceUnit _____

| | CRITICAL ELEMENTS | MET | NOT MET |
|---|---|---|---|
| 1 | Scanning tech to verify and sign MR screening form MUST REVIEW IT ONLINE FIRST | | |
| 2 | Remove all elements that arrive with the patient | | |
| 3 | Patient must be changed to Mayo gown,no street clothes/pyjamas permitted | | |
| 4 | Visual inspection of patient skin (head to toe) performed- look under gown<br>• Piercings inside mouth? Unable to check under<br>• Any scars noticed? (Look for pacemaker, surgical, gunshot scars)<br>• Any tattoos noticed?<br>• Any ECG leads?<br>• Any other foreign material? | | |
| 5 | Verbal using patient ID- ONLY the sheet under patient is moved to MRI table | | |
| 6 | Removing communicate hand held (cellphone/ personal pocket) | | |
| 7 | Proper patient positioning to avoid RF loam-loks and wetap; CRITICAL FOR NON COMMUNICATIVE PATIENTS<br>• No skin to skin contact<br>• Insulation between scanner bore and patient<br>• Ear plugs hearing protection for patient<br>• NORMAL MODE scan for ALL non-communicative patients. (NOTE: GE default setting is FIRST MODE you must set it to NORMAL) | | |
| 8 | Constantly monitor patient and ask about their comfort level (communicative only)<br>• For non-communicative patient, it is CRITICAL to monitor that proper insulation maintained. Look after every scan if the patient has moved. | | |
| 10 | Screen staff individually ( provide green badge when possible)<br>• Off hours staff screening may be performed with Ferro Guard and/or wide hand held detector in Zone 3, HOWEVER, all personal items must be stored in Zone 2 | | |



## Policy and Guideline Updates

- VNS – Brain w/wo
  - Pt scanned at 1:00 pm
    - VNS identified (pt disclosed) and noted in the screening form; VNS turned OFF, set to 0 mA.
    - Non TR coil used ; TR coil was not identified correctly
  - Pt rescanned at 3:00 pm
    - VNS missed (pt did not disclose)
    - TR coil not used
- Patient screening form must be reviewed and signed each and every time any patient presents for an exam






## TR Coil Labels

## Operationalize Implanted Devices Evaluation

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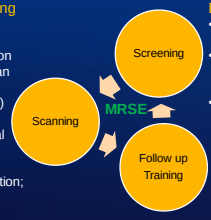


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**Post Scan**

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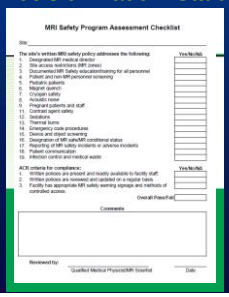
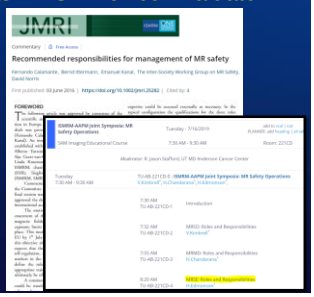
## Tools of Trade – Start as MRSE Device Evaluator


MRI Safety Program Assessment Checklist


JMRI

Recommended responsibilities for management of MR safety

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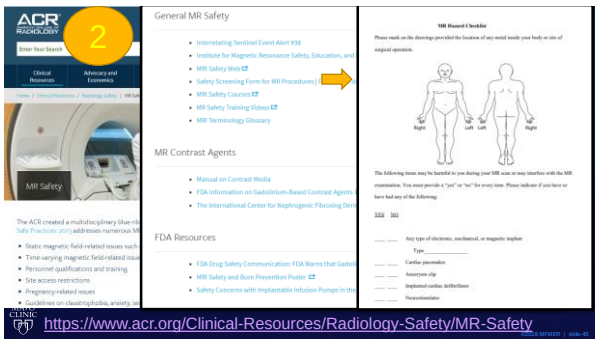
## Tools of Trade – Start as MRSE Device Evaluator

**MR Safety Reference Documents**

- A Closer Look at the Thresholds of Thermal Damage: Workshop Report by an ICNIRP Task Group (2016) (pdf)
- ACR Addresses FDA Gadolinium Safety Concerns (2016)
- ACR contrast media manual (2018)
  - American College of Radiologists guidelines for contrast media
- ACR Guidance Document on MR Safe Practices: 2013 (2013)
  - American College of Radiologist's MR guidelines
- AHRA: Emergency Preparedness for Imaging Service Providers
- British Heart Rhythm Society: Safe use of MRI in people with cardiac implantable electronic devices (2015)
  - British Cardiology guidance document on the use of Pacemakers in MR scanners
- CAR Standard for Magnetic Resonance Imaging (2011)
  - Canadian Association of Radiologists MR guidelines
- EU Directives on MR safety (2013)
  - European Union MR safety guidelines
- FDA Guidance on "Assessment of RF-Induced Heating in the MR Environment for Multi-Configuration Passive Medical Devices" (2016) (pdf)
- FDA site for reporting adverse events (website last updated 2016)
  - A link to the Federal Drug Administration's' data base for reporting all adverse events
- FDA MR Safety Alert (2014)
  - MRI Safety: FDA Safety Communication
- FDA Safety Alert on Gadolinium (2015)
  - Gadolinium-based Contrast Agents for Magnetic Resonance Imaging (MRI): Drug Safety Communication - FDA Evaluating the Risk of Brain Deposits With Repeated Use
- Gadolinium Retention Updates & Resources (2016)
  - Compiled for the SMRT by Greg Brown, A.Dip.Rad.Tech.
- GE Healthcare: Class I Recall (2015)
  - MRI Systems with Magnet Rundown Unit by GE Healthcare: Class I Recall - Potential Disabling of the Magnet Rundown Unit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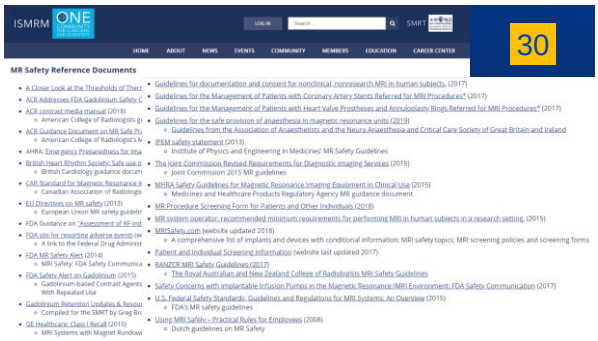
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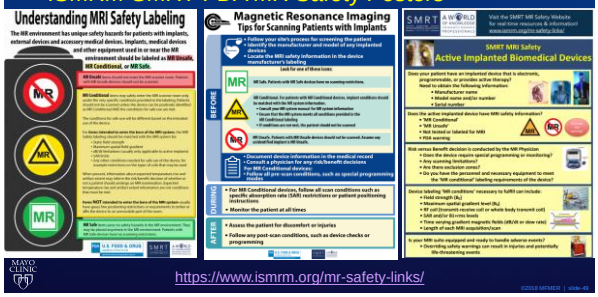
MR Safety Reference Documents

## ISMRM-SMRT-FDA MR Safety Posters

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