

MRI Safety Standards

Tobias Gilk - Sept 28, 2022

 2022 Dubai Advanced MRI Safety Seminar

MRI Safety Standards

Outline

MRI Safety Standards

- Intro
- MRI Machine Safety Standards
- Physical Environment & Clinical Practice MRI Safety Standards
- Ionizing vs. MRI Safety Accreditation
- Organizational Structure For MRI Safety
- Q & A

MRI Machine Safety Standards

IEC 60601-2-33

MRI Machine Safety Standards

IEC 60601-2-33

- International Electrotechnical Commission (IEC)
 - Establishes standards for electrical products (including medical)
 - Just published ed. 4.0 of MRI safety standard (for manufacturers)

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

Physical & Clinical MRI Safety Standards

Physical & Clinical MRI Safety Standards

Physical Environment

Design Standards

- FGI Guidelines (USA)
- VA MRI Safety Directive (USA)

Best Practices

- MRI Facility Safety Design Guidelines (appendix 2 in ACR 2020 Manual on MR Safety)
- VA Imaging Services Design Guide
- Metrasens MRI Planning Guide
- MHRA MRI Safety Guidelines

Physical & Clinical MRI Safety Standards

Clinical Care

Clinical Care Standards

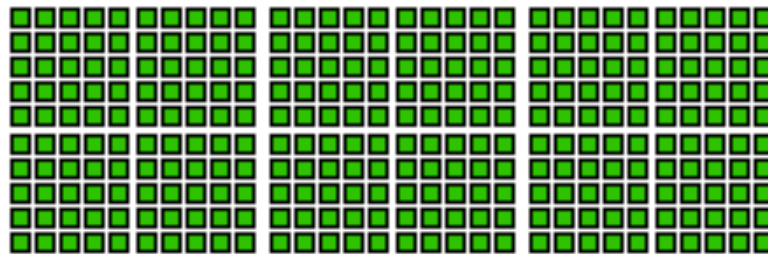
- ACR 2020 Manual on MR Safety

Best Practices

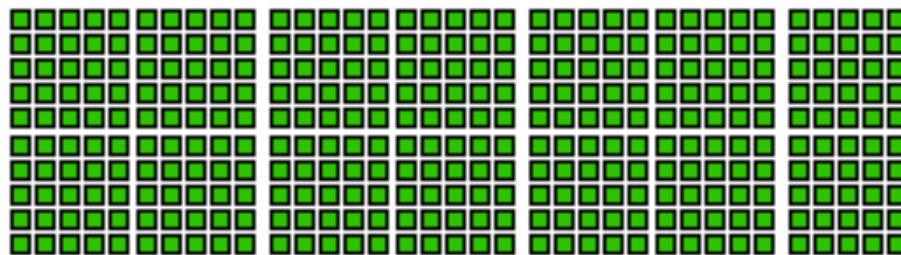
- ACR 2020 Manual on MR Safety
- MHRA MRI Safety Guidelines

Ionizing Radiation vs. MRI

Ionizing Radiation vs. MRI



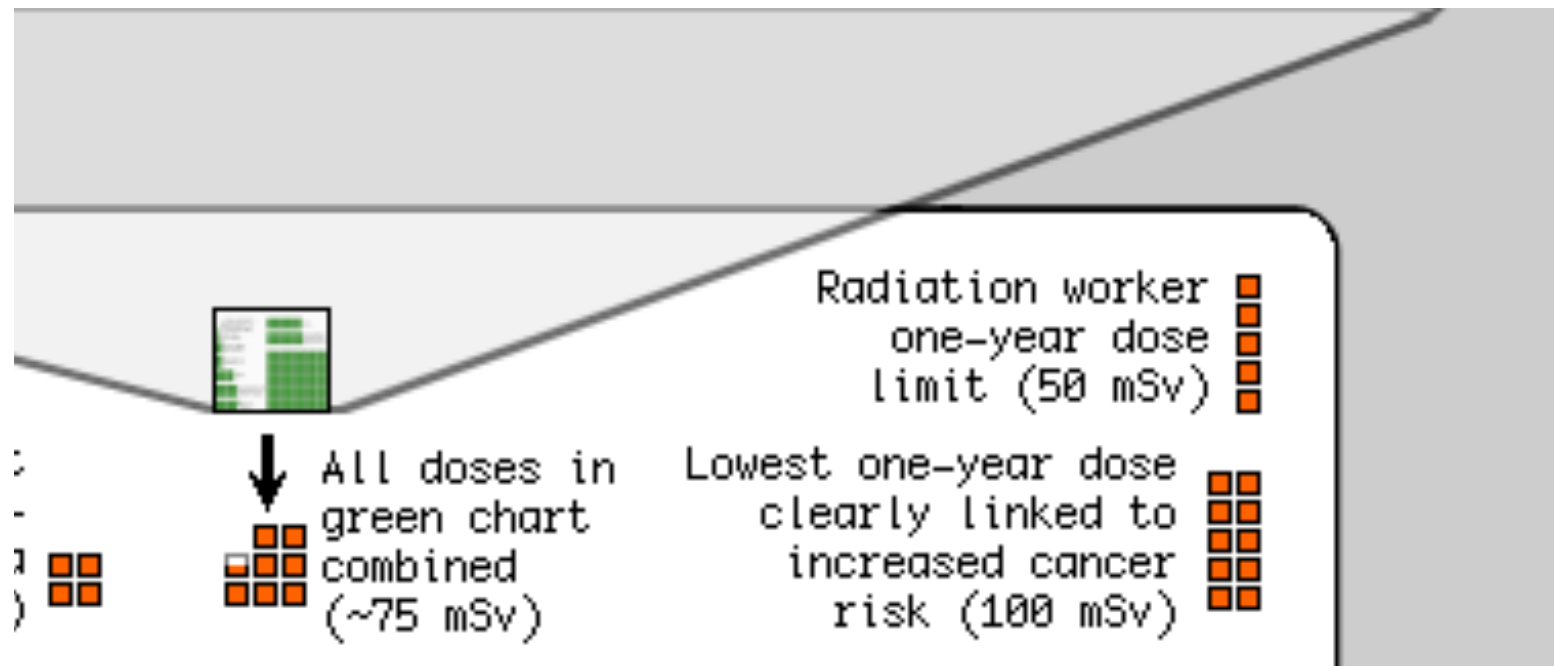
Dose from spending an hour on the grounds at the Chernobyl plant in 2010 (6 mSv in one spot, but varies wildly)



Chest CT scan (7 mSv)

<https://xkcd.com/radiation/>

Ionizing Radiation vs. MRI



<https://xkcd.com/radiation/>

Ionizing Radiation vs. MRI

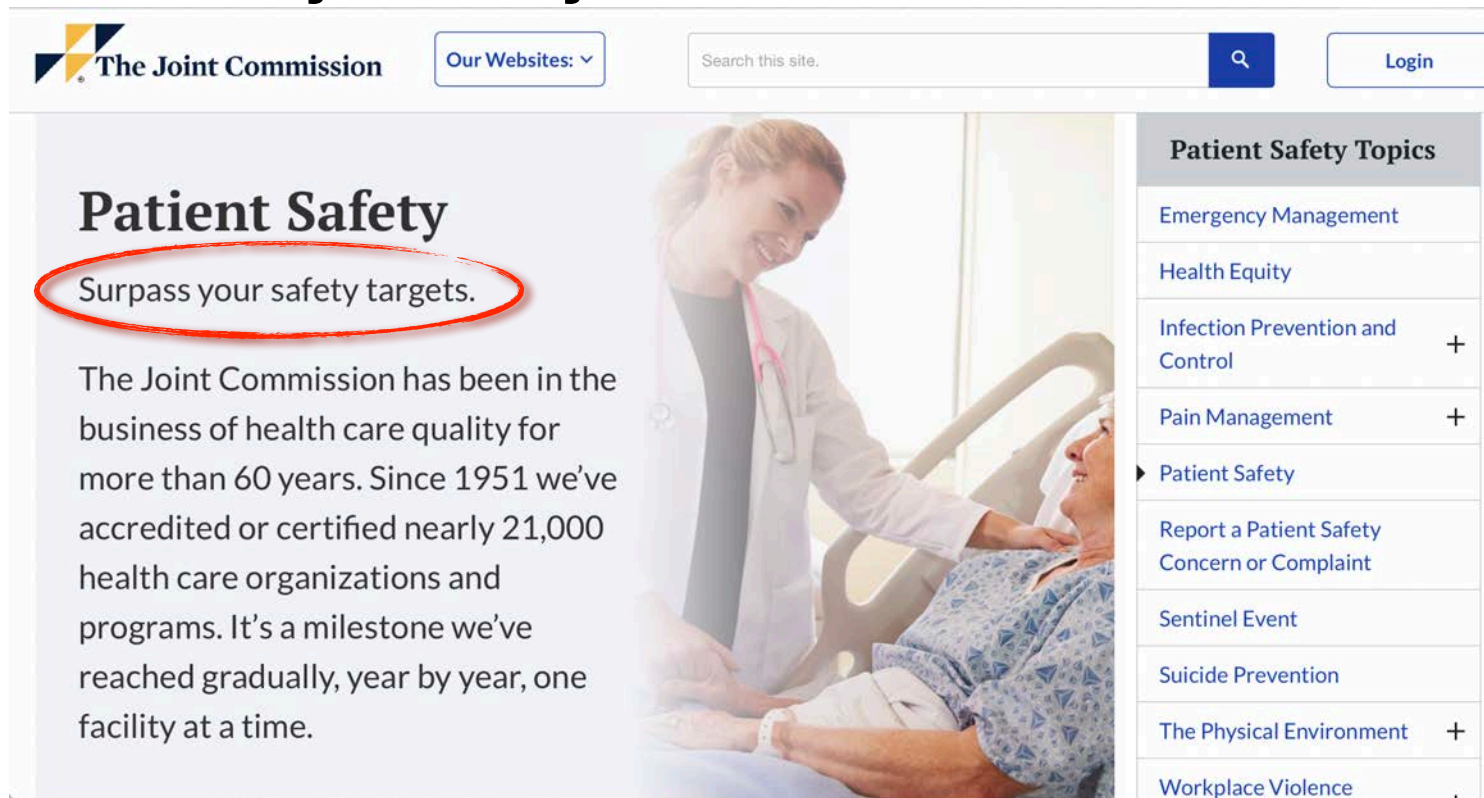
Risk = Likelihood x Consequence

LIKELIHOOD	almost certain	Moderate	Major	Critical	Critical	Critical
	likely	Moderate	Major	Major	Critical	Critical
	possible	Moderate	Moderate	Major	Major	Critical
	unlikely	Minor	Moderate	Moderate	Major	Critical
	rare	Minor	Minor	Moderate	Moderate	Major
		insignificant	minor	moderate	major	critical
		CONSEQUENCE				

MRI Safety In Accreditation

MRI Safety In Accreditation

Promise of Quality & Safety



The screenshot shows the top navigation bar of The Joint Commission website. It includes the logo, a dropdown menu for "Our Websites", a search bar, and a "Login" button. The main content area features a "Patient Safety" section with a red circle around the text "Surpass your safety targets." Below this is a paragraph about the organization's history. To the right is a "Patient Safety Topics" sidebar with a list of categories, including "Patient Safety" which is expanded to show sub-topics like "Report a Patient Safety Concern or Complaint", "Sentinel Event", "Suicide Prevention", "The Physical Environment", and "Workplace Violence".

The Joint Commission Our Websites: ▾ Search this site. Login

Patient Safety

Surpass your safety targets.

The Joint Commission has been in the business of health care quality for more than 60 years. Since 1951 we've accredited or certified nearly 21,000 health care organizations and programs. It's a milestone we've reached gradually, year by year, one facility at a time.

Patient Safety Topics

- Emergency Management
- Health Equity
- Infection Prevention and Control +
- Pain Management +
- ▶ Patient Safety
 - Report a Patient Safety Concern or Complaint
 - Sentinel Event
 - Suicide Prevention
 - The Physical Environment +
 - Workplace Violence

MRI Safety In Accreditation

Promise of Quality & Safety

Contact:
Name
Title
Phone Number
E-mail



For Immediate Release

(Facility Name Here) Earns ACR Accreditation

(City, State) — (Facility Name), has been awarded a three-year term of accreditation in magnetic resonance imaging (MRI) as the result of a recent review by the American College of Radiology (ACR). MRI is a noninvasive medical test that utilizes magnetic fields to produce anatomical images of internal body parts to help physicians diagnose and treat medical conditions.

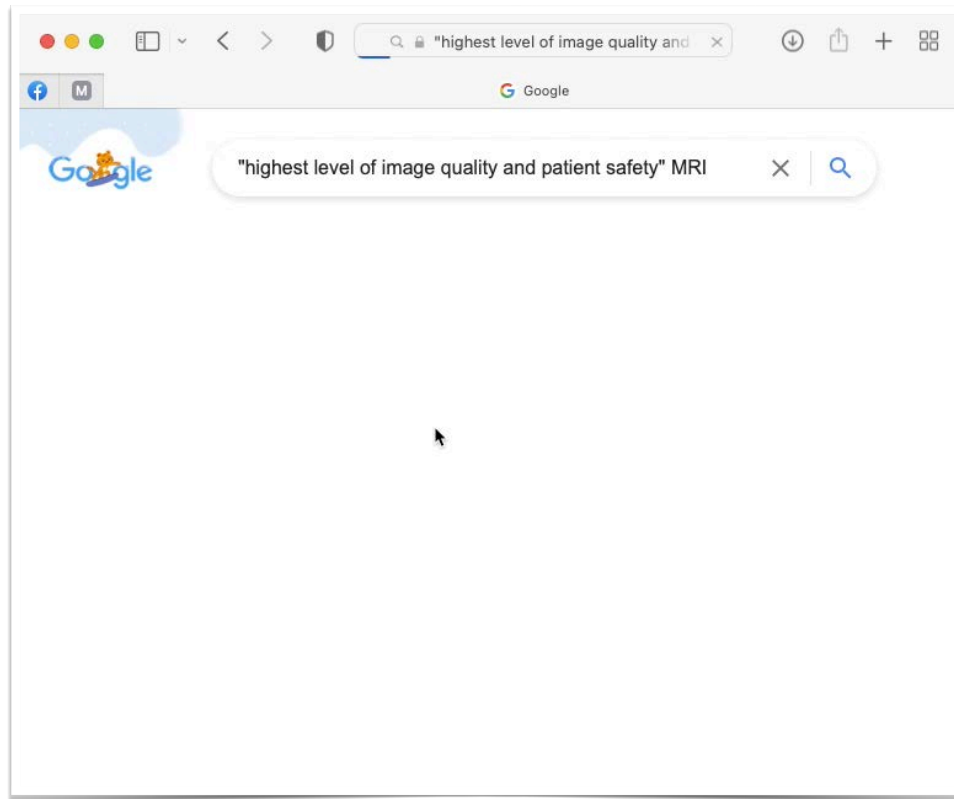
The ACR gold seal of accreditation represents the highest level of image quality and patient safety. It is awarded only to facilities meeting ACR Practice Guidelines and Technical Standards after a peer-review evaluation by board-certified physicians and medical physicists who are experts in the field. Image quality, personnel qualifications, adequacy of facility equipment, quality control procedures, and quality assurance programs are assessed. The findings are reported to the ACR Committee on Accreditation, which subsequently provides the practice with a comprehensive report they can use for continuous practice improvement.

The ACR is a national professional organization serving more than 34,000 diagnostic/interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists with programs focusing on the practice of medical imaging and radiation oncology and the delivery of comprehensive health care services.

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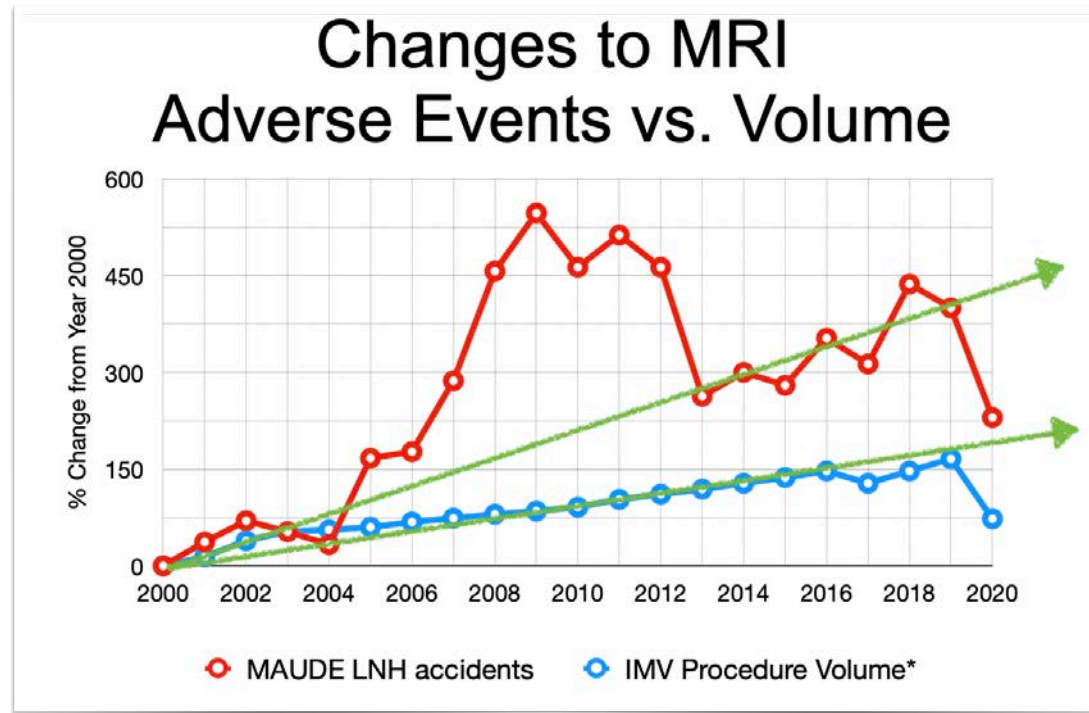
MRI Safety In Accreditation

Promise of Quality & Safety



MRI Safety In Accreditation

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<https://gilkradiologyconsultants.com/blog/the-mri-accident-chart-2000-2020/>

MRI Safety In Accreditation

Joint Commission International (JCI)

Radiology and Diagnostic Imaging Services

Standard AOP.6

Radiology and diagnostic imaging services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.

Standard AOP.6.1

A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services.

Standard AOP.6.2

Individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results.

Standard AOP.6.3

Radiation safety program is in place, followed, and documented, and compliance with the facility management and infection control programs is maintained.

Standard AOP.6.4

Radiology and diagnostic imaging study results are available in a timely way as defined by the hospital.

Standard AOP.6.5

All equipment and medical technology used to conduct radiology and diagnostic imaging studies is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.

Standard AOP.6.6

X-ray film and other supplies are regularly available.

Standard AOP.6.7

Quality control procedures are in place, followed, and documented.

Standard AOP.6.8

The hospital regularly reviews quality control results for all outside sources of diagnostic services.

MRI Safety In Accreditation

Joint Commission (USA)

Environment of Care (EC)


Standard EC.02.01.01

The organization manages safety and security risks.



Elements of Performance for EC.02.01.01

A 14. The organization manages magnetic resonance imaging (MRI) safety risks 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 metallic foreign objects (such as shrapnel)
- Ferromagnetic objects entering the MRI environment
- Acoustic noise

A 16. The organization manages magnetic resonance imaging (MRI) safety risks by doing the following: 

- Restricting access of everyone not trained in MRI safety or screened by staff trained in MRI safety 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 staff trained in MRI safety.
- 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 system, by its design, can have its magnetic field routinely turned on and off by the operator.

C 25.  The [critical access] hospital verifies and documents that technologists who perform magnetic resonance imaging (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, electrically conductive items, medical implants and devices, and risk for Nephrogenic Systemic Fibrosis (NSF)
- 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 procedures 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

* Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (<http://www.astm.org>).

MRI Safety In Accreditation

CBAHI

 **CBAHI**

المركز السعودي لاعتماد المؤسسات الصحية
Saudi Central Board for Accreditation of Healthcare Institutions

STANDARDS

RD 1 Qualified radiologist is responsible for managing the radiology department.

RD 2 The radiology department has adequate qualified staff.

RD.2.1 The radiology department has adequate staff, including:

RD.2.1.3 Radiation safety officer and supervisor (for radiotherapy nuclear medicine and diagnostics).

RD 3 The radiology department has policies and procedures that guide all radiological activities.

RD.3.1 The radiology department has policies and procedures to address all important radiological investigations and procedures, including:

RD.3.1.4 Magnetic Resonance Imaging.

RD 4 Requests for radiological investigations utilize a standardized method throughout the hospital.

RD 5 The radiology department implements a policy and procedure that defines the process and time limits of results reporting for all radiological studies.



RD 6 The radiology department implements a policy and procedure for reporting of critical results.

RD 7 Previous radiological studies can always be accessed.

RD.7.1 There is a master X-ray jacket or an access to all archived previous radiological studies (Picture Archiving and Communication System-PACS) for every patient.

RD 8 The radiology department has a documented and implemented safety plan.

RD.8.1 There is a safety plan that indicates the periodic inspection, maintenance, and calibration of all equipment.

RD.8.2 The safety plan involves the management of radioactive materials used for therapeutic and diagnostic purposes, particularly with regard to handling, storing, and transportation.

RD.8.3 The safety plan involves posting of safety warnings on the doors.

RD 9 The radiology department has a documented and implemented protocol for interventional radiological procedures.

RD 10 The radiology department ensures the safety of diagnostic imaging equipment.

MRI Safety In Accreditation

REDUCING MRI ACCIDENTS

9 BEST PRACTICES THAT COULD HAVE PREVENTED 74% OF REPORTED INJURIES*

Metrasens analyzed all of the MRI injury accidents reported to the FDA via their MedWatch program in 2015 and 2016 and tested which preventions would be most effective in keeping patients and staff safe.

In total we reviewed 112 MRI related injuries. 106 of these were categorized as being burns, hearing damage or injuries caused by projectiles. We looked closer at each of these incidents and evaluated whether best practice recommendations – taken from the ACR Guidance Document on MR Safe Practices (2013)* – could have helped prevent them. We've summarized our analysis below.

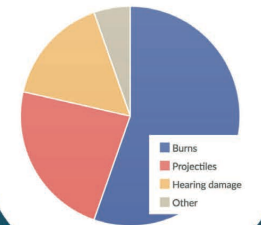


HOW MANY INCIDENTS ARE REPORTED EACH YEAR?

The graph on the left shows the numbers of injury accidents in the USA reported to the FDA each year (MR community consensus indicates that not all incidents are reported).

For our analysis we focused on those injuries reported in 2015 and 2016 only. We excluded events where there was: insufficient/no narrative; where the report was of a non-injury event; and where the injury was not from MR-specific causes.

95%
OF REPORTED INJURIES WE ANALYSED WERE RELATED TO BURNS, PROJECTILES OR HEARING DAMAGE



74% OF THESE INCIDENTS COULD HAVE BEEN PREVENTED BY FOLLOWING THE 9 BEST PRACTICES DETAILED BELOW*



THREE STEPS THAT COULD HAVE PREVENTED 69% OF MRI PROJECTILE INJURIES**

(The 69% is actually 100%, if we look at only clinical care scenarios, excluding service-related accidents).

<https://www.metrasens.com/mri-safety/mri-safety-infographic/>

MRI Safety In Accreditation

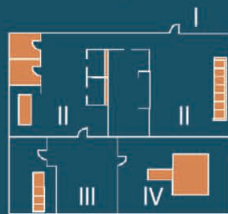
THREE STEPS THAT COULD HAVE PREVENTED 69%** OF MRI PROJECTILE INJURIES

(The 69% is actually 100%, if we look at only clinical care scenarios, excluding service-related accidents).



IMPLEMENT A 4-ZONE MODEL
LINKING ACCESS TO SCREENING
/ SUPERVISION

1



UTILIZE FERROMAGNETIC DETECTION
SYSTEMS FOR ADDITIONAL
SCREENING AND PROTECTION

2



LABEL OBJECTS WITHIN THE MRI
SUITE FOR MR CONDITIONS / SAFETY

3



<https://www.metrasens.com/mri-safety/mri-safety-infographic/>

MRI Safety In Accreditation

THREE STEPS THAT COULD HAVE PREVENTED 94%
OF MRI BURN INJURIES*

PROVIDE 1cm+ AIR / PADDING
BETWEEN THE PATIENT AND
THE ACTIVE COIL ELEMENT

1



2



3



REMOVE UNNEEDED ELECTRICAL
CONDUCTORS
(INSULATE REMAINING)

PREVENT SKIN-TO-SKIN
CONTACT E.G.
MEDIAL THIGHS, THUMB-THIGH ETC

<https://www.metrasens.com/mri-safety/mri-safety-infographic/>

MRI Safety In Accreditation

ONE ACR GUIDANCE DOCUMENT STEP THAT
COULD HAVE PREVENTED 11% OF MRI HEARING DAMAGE INJURIES*

... plus two steps that we believe would dramatically improve patient protection

REQUIRE USE OF HEARING
PROTECTION OR EVERYONE IN THE
MAGNET ROOM DURING THE EXAM

1



<https://www.metrasens.com/mri-safety/mri-safety-infographic/>

MRI Safety In Accreditation

80% OF THESE INCIDENTS COULD
HAVE BEEN PREVENTED BY FOLLOWING THE
9 BEST PRACTICES DETAILED



<https://www.metrasens.com/mri-safety/mri-safety-infographic/>

MRI Safety In Accreditation

Projectile Safety

	Require 4-Zones	Require FMD	Req. Device Labeling
Joint Commission (H)			
DNV Healthcare (H)			
ACR (OP)			
IAC (OP)			

MRI Safety In Accreditation

Projectile Safety

	Require 4-Zones	Require FMD	Req. Device Labeling
Joint Commission (H)	[kinda]	×	×
DNV Healthcare (H)	×	×	×
ACR (OP)	[kinda]	×	×
IAC (OP)	×	×	×

MRI Safety In Accreditation

RF Burn Protections

	Require Padding	Remove Conductors	Prevent Skin-to-Skin
Joint Commission (H)			
DNV Healthcare (H)			
ACR (OP)			
IAC (OP)			

MRI Safety In Accreditation

RF Burn Protections

	Require Padding	Remove Conductors	Prevent Skin-to-Skin
Joint Commission (H)	[kinda]	×	[kinda]
DNV Healthcare (H)	×	×	×
ACR (OP)	×	×	×
IAC (OP)	×	×	×

MRI Safety In Accreditation

Hearing Protection

	Require Protection	Verify Fit & Function	Provide Alt. Means
Joint Commission (H)			
DNV Healthcare (H)			
ACR (OP)			
IAC (OP)			

MRI Safety In Accreditation

Hearing Protection

	Require Protection	Verify Fit & Function	Provide Alt. Means
Joint Commission (H)	[kinda]	×	×
DNV Healthcare (H)	×	×	×
ACR (OP)	×	×	×
IAC (OP)	×	×	×

MRI Safety In Accreditation

- The prior 'scorecards' don't even touch on requirements managing complex device patients

MRI Safety In Accreditation

Change Is Coming

MRI Safety Program Assessment Checklist	
Site: _____	
The site's written MRI safety policy addresses the following:	Yes/No/NA
1. Designated MR medical director	<input type="checkbox"/>
2. Site access restrictions (MR zones)	<input type="checkbox"/>
3. Documented MR Safety education/training for all personnel	<input type="checkbox"/>
4. Patient and non-MR personnel screening	<input type="checkbox"/>
5. Pediatric patients	<input type="checkbox"/>
6. Magnet quench	<input type="checkbox"/>
7. Cryogen safety	<input type="checkbox"/>
8. Acoustic noise	<input type="checkbox"/>
9. Pregnant patients and staff	<input type="checkbox"/>
10. Contrast agent safety	<input type="checkbox"/>
11. Sedations	<input type="checkbox"/>
12. Thermal burns	<input type="checkbox"/>
13. Emergency code procedures	<input type="checkbox"/>
14. Device and object screening	<input type="checkbox"/>
15. Designation of MR safe/MR conditional status	<input type="checkbox"/>
16. Reporting of MR safety incidents or adverse incidents	<input type="checkbox"/>
17. Patient communication	<input type="checkbox"/>
18. Infection control and medical waste	<input type="checkbox"/>
ACR criteria for compliance:	Yes/No/NA
1. Written policies are present and readily available to facility staff.	<input type="checkbox"/>
2. Written policies are reviewed and updated on a regular basis.	<input type="checkbox"/>
3. Facility has appropriate MR safety warning signage and methods of controlled access.	<input type="checkbox"/>
Overall Pass/Fail	<input type="checkbox"/>

MRI Safety In Accreditation

Change Is Coming



Appendix One

Magnetic Resonance (MR) Safety Checklist

Hospital Name:

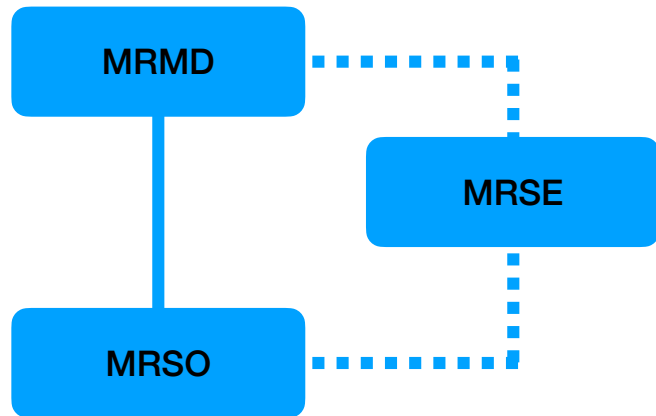
Region/Governance Name:

Date: .../.../.....

Code	D+	Criteria	Best Practices		Means of Verification	Is It Applicable		Score +	Remarks
						No	Yes		
MRS-1	S	Supervision of MR unit	MRS-1-1	There is a policy and procedure (PP) to assign the MR supervisor	Review PP				
			MRS-1-2	The responsibilities involve implementing MR policies and procedures					
			MRS-1-3	The responsibilities updating MR policies and procedures					
			MRS-1-4	The responsibilities involve provision of MR safety training					
			MRS-1-5	The responsibilities involve quality monitoring and improvement					
MRS-2	P	Implement the PP for MR supervisor	MRS-2-1	The PP for supervisor of MR unit is implemented.	Review documents/ interview				
MRS-3	S	Staff training on MR safety	MRS-3-1	There is a PP to ensure staff training on MR safety.	Review PP				
			MRS-3-2	This PP defines training required for staff in					

Organizational Structure For MRI Safety

Organizational Structure For MRI Safety



Recommended responsibilities for management of MR safety

FOREWORD

The following article was approved by consensus of the scientific and medical societies with major representation in Europe. The mode of operation was that an initial draft was provided by the safety committee of ISMRM (Fernando Calamante (chair), Bernd Ittermann, Emanuel Kanal). An intersociety working group on MR safety was established with representation from each society as follows: Alberto Torresin (EFOMP); Renato Padovani (EFOMP); Sija Geers-van-Gemeren (EFRS); Csaba Vandulek (EFRS); Linda Knutsson (ESMRMB); David Norris (ESMRMB, ISMRM, chair); Stephen Keevil (ESR); Gabriel Krestin (ESR); Siegfried Trattning (ISMRM); Titti Owman (ISMRM, SMRT).

Comments on the draft were circulated by email, and the Committee met several times by teleconference until the final version was agreed. Several non-European societies later approved the document, which is an important step towards international acceptance.

expertise could be accessed externally as necessary. In the typical configuration the qualifications for the three roles will be: MRMD/MRRD, MD/PhD; MRSO, radiographer (Europe), technologist (USA and elsewhere); MRSE, physicist. However, these are certainly not prescribed and may be readily fulfilled by workers with different backgrounds, also subject to national requirements. At present there are a number of certifications that could be appropriate, particularly at the level of the safety officer (for example, training courses offered by ESMRMB and ISMRM), and it is hoped that the generation of this document and its widespread acceptance will elicit more internationally recognized training courses that are matched to the three areas of responsibility defined here, as is already done in the USA by the newly formed American Board of Magnetic Resonance Safety.

RECOMMENDED RESPONSIBILITIES FOR MANAGEMENT OF MR SAFETY

<https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.25282>

Pediatric Population MRI Safety Benefits

- TEXT
- TEXT

Q&A

Thank You

Tobias Gilk, MRSO, MRSE



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[@tobiasgilk](https://twitter.com/tobiasgilk)



www.facebook.com/groups/MRIsafety