MRSO Exam Prep Course

Module 15

Other Standards

Section 15.1 American Society of Testing and Materials (ASTM)

The ASTM standard is used for marking products, materials, and objects in the MR environment. They also defined what constitutes the MR environment. The magnetic field in the MR environment is 5 Gauss or higher, exposing the patient and workers.

This organization also specifies how goods are tested and satisfy their requirements. This organization has several documents that assist in describing how things should be tested.

- **F2052**: Measurement of Magnetically Induced Displacement Force on Medical Devices in a Magnetic Resonance Environment. This specification specifies how things are tested in a static magnetic field.
- **F2119**: Standard Test Method for Evaluating MR Image Artifacts Caused by Passive Implants. This specifies how photos are checked for artifacts.
- **F2182**: Standard Test Method for Assessing Radiofrequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging. This explains why implants are heated by RF.
- **F2213**: Measurement of Magnetically Induced Torque on Medical Devices in a Magnetic Resonance Environment. This explains the static magnetic field on ferrous components-containing things.

The ASTM F2503 will be discussed. This article specifies items that are or are not a danger in the MR environment. They established the terminology: MR safe, MR conditional, and MR unsafe.

15.1.1 MR Safe

To be deemed MR safe, an object must be nonmetallic, nonmagnetic, and nonconductive. These items are identified by a label, which can be a green square with a green MR inside it or a solid green square with a white MR inscribed inside it. It is also critical to realize that a black and white version of each of these labels is developed. The MR safe sign in black and white can be portrayed as a solid black square with a black MR written inside of it, or a solid black square with a white MR written inside of it.

Image 15.1

15.1.2 MR Conditional

MR conditional items are defined as things that can be placed in an MR environment as long as certain safety requirements are met. Static magnetic fields and time-varying magnetic fields are examples of this. The MR conditional objects must handle each of these dangers and indicate how this object may be securely scanned. A black triangle with a black MR inscribed inside it filled with yellow is used to describe MR conditional implants. A solid black triangle with a black MR inscribed within is the black-and-white symbol for this.

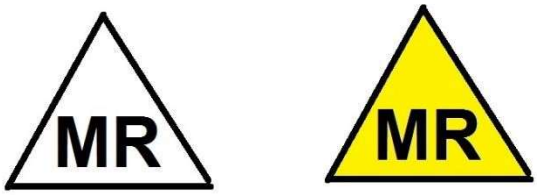

Image 15.2

15.1.3 MR Unsafe

When put in the MR environment, and unsafe object is regarded as an object that can cause injury to a patient. An MR inside a red circle with a red line through it, or a black circle with a black line through the MR inside, denotes an MR dangerous sign. It's also vital to know that if an item isn't tagged, it's assumed to be MR dangerous.

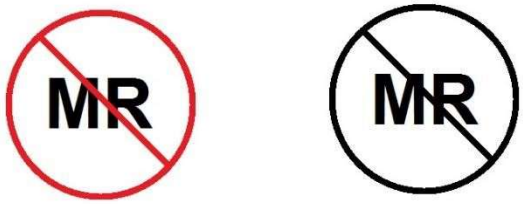

Image 15.3

Section 15.2 International Electrotechnical Commission (IEC)

15.2.1 Introduction

The International Electrotechnical Commission (IEC) developed a standard focused on the technical facets of medical diagnostic MR EQUIPMENT and MR SYSTEMS to ensure patients' well-being. Additionally, it addresses concerns regarding electromagnetic field (EMF) exposure for MR WORKERS operating, developing, manufacturing, installing, and servicing such equipment and systems. Annex AA contains justifications for limit values and requirements and citations to peer-reviewed publications utilized in developing this document's content.

The goal of this group is to set boundaries based on research undertaken by this organization or others, so that danger is reduced while performing an MR on a patient. The IEC defines the limitations that a patient can be subjected to when exposed to a static magnetic field and a time-varying magnetic field. It also addresses any auditory and artifact issues. This organization manages these constraints by developing distinct regulated modes of functioning.

Normal mode is the most used imaging mode in MRI and includes the least amount of non-ionizing radiation for patients. It refers to the environment that causes the least amount of bodily stress. The constraints associated with normal mode are depicted in the table below.

	Normal mode
	Body Transmit Coil over 6 minutes
Body Part	**Whole Body Partial Body**
Head/Torso	2 W/kg 10W/kg-(8W/kg * exposed patient mass/patient mass)
Limb/Extremity	2 W/kg 10W/kg-(8W/kg * exposed patient mass/patient mass)
Head	3.2W/kg

	Local Coil	
Head/Torso	10W/kg	
Torso	20W/kg	

	Gradient Stimulation Limit
	80% of maximum dB/dt exposure **0.8*rb(1+0.36/teff)**

Table 15.1

The first level mode raises the constraints associated with the time-varying magnetic field to the highest allowable level. In terms of SAR and peripheral nerve stimulation, it is intended to cause physiological stress in the patient. The graphic below depicts the constraints associated with the first level.

	First Level Controlled Mode
	Body Transmit Coil over 6 minutes
Body Part	**Whole Body Partial Body**
Head/Torso	4 W/kg 10W/kg-(6W/kg * exposed patient mass/patient mass)
Limb/Extremity	4 W/kg 10W/kg-(6W/kg * exposed patient mass/patient mass)
Head	3.2W/kg

	Local Coil	
Head/Torso	20W/kg	
Torso	40W/kg	
	Gradient Stimulation Limit	
	100% of maximum dB/dt exposure **1.0*rb(1+0.36/teff)**	

Table 15.2

The second level-controlled operation mode is intended for MRI studies. This enables limitations above the first-level mode.

The selection of exposure limits for MR WORKERS and PATIENTS is intended to safeguard them against transient adverse health effects and untenable risks. Furthermore, the current scientific

consensus holds that repeated EMF exposures do not provide any experimental or theoretical foundation for anticipating long-term adverse health effects in humans.

The responsibility for organizational aspects of the safety of functioning MR equipment lies with the RESPONSIBLE ORGANIZATION. This responsibility encompasses the following but is not limited to the following:

- Staff qualification for safety-related decisions;
- Sufficient staff training;
- Definition of medical responsibility, which includes

    - Protocols for screening patients for contraindications or conditions that may impact acceptable exposure;
    - Protocols for routine monitoring and medical supervision of patients during medical examinations;
    - Protocols for accessing and supervising the medical examination environment;

- Guidelines for medical responsibility.
- Protocols for expeditious evacuation of patients in a B_o HAZARD AREA;
- Emergency protocols about potential quenching of superconductive magnets, when relevant;
- Guidelines to restrict and mitigate electromagnetic field (EMF) exposure for MR personnel;
- Establishment and oversight of sufficient preventive maintenance measures;
- Assessment and enforcement of local regulations.

Section 15.3 Outside Marking Requirements of ME Equipment of Parts

Medical Electrical (ME)-related equipment and parts must correctly display information regarding their function and limitations. MR safety personnel should ensure the following to be displayed:

- MR EQUIPMENT model name
- VALUE NOMINAL B_o
- Software Version

Additionally, this identification must exhibit or grant direct access to the designated location for the following additional information:

- The static magnetic field's maximum strength (T/m) outside the fixed magnet covers
- Maximum spatial encoding gradient amplitude (mT/m)
- Maximum slew rate (T/m/s)
- Normal frequency range per nuclei
- Maximum gradient output

15.3.1 Physiological Effects

The following signs should be displayed around the MR Environment to warn individuals against possible physiological effects.

This sign should be placed at the entrance to the MR Environment.

Image 15.4

ISO 7010-W005
Warning: Non-Ionizing Radiation

For MR EQUIPMENT that generates a stray field exceeding 0.9 mT outside its FIXED magnet cover, this SAFETY SIGN shall be placed at the entrance of the MR ENVIRONMENT.

Image 15.5

ISO 7010-W006
Warning: Magnetic Field

For MR EQUIPMENT that requires hearing protection for PATIENTS or MR WORKERS, SAFETY SIGN ISO 7010-M003 shall be placed at the entrance of the MR EXAMINATION ROOM.

	ISO 7010-M003	Wear ear protection

Image 15.6

For MR EQUIPMENT that requires a cryogen refill, SAFETY SIGNs ISO 7010-M004 and ISO 7010-M009 should be placed near the location where the cryogen refill is performed.

	ISO 7010-M004	Wear eye protection
	ISO 7010-M009	Wear protective gloves

Image 15.7

The SAFETY SIGNs may be accompanied by text explaining that the static magnetic field is always on but that EMF and acoustic noise emission is restricted to the situation when the MR EQUIPMENT is scanning.

For MR EQUIPMENT that does not require the implementation of a designated MR ENVIRONMENT, the need for and location of the SAFETY SIGNs shall be described in the RISK MANAGEMENT FILE by the MANUFACTURER.

Information shall be provided in the instructions concerning specific physiological effects related to MR EQUIPMENT.

Additional Safety Signs

	ISO 7010-W010	Warning: Low temperature/Freezing conditions
	ISO 7010-P007	No access for people with active implanted cardiac devices
	ISO 7010-P014	No access for people with metallic implants

Image 15.8

15.3.2 Accompanying Documents

Additional documentation should provide the RESPONSIBLE ORGANIZATION with adequate information to perform its work according to local regulations and set requirements for exposure limits to PATIENTS and MR WORKERS.

These additional documents shall recommend that the training encompass the following specialized skills and knowledge pertinent to the intended operator, as appropriate:

- The RESPONSIBLE ORGANIZATION-established emergency procedures (discussed in the next section)
- Understand the dangers associated with the operation of MR equipment and evaluate them as necessary. Considerations should be made on the following:

- Attractive forces and torque
- Cryogens
- Heating and burns
- Peripheral nerve stimulation (PNS)
- Acoustic noise
- Interactions with other objects utilized within the MR EXAMINATION ROOM.

Emergency Procedures

Safety risks regarding the emergency procedures required for specific patient conditions should be considered. While the RESPONSIBLE ORGANIZATION is ultimately accountable for this subject, it is recommended that the MANUFACTURER provide feedback on potential safety risks with their product. Below are some processes used to mitigate some of the safety risks:

- A suggestion mandating the establishment of a protocol to promptly evacuate patients from the magnetic field's impact, utilizing the emergency field shutdown unit if required.
- A suitable strategy should be devised to attend to a PATIENT needing urgent medical attention, away from the magnet's field of effect due to the impossibility of safely and effectively operating metallic or electronic emergency equipment near the magnet.
- A protocol is suggested to be developed to isolate the patient from the magnetic field if an unforeseen implant is discovered within the cranial region. It is advisable to stabilize the patient's position, gradually withdraw them from the magnet, and give precedence to ensuring that the implant remains away from areas with high SFG. The PATIENT should not be seated near the magnet.
- Throughout the MR EXAMINATION, communication with the patient or monitoring of an anesthetized patient must be maintained.
- Addressing claustrophobic reactions in specific patients is imperative before conducting an MR EXAMINATION.

The system bore through the gradient field of the static magnetic field, which should be limited. The maximum dB/dt value the patient is exposed to should not exceed 3 T/s. This limit is independent of the patient's condition and, therefore, unrelated to a specific operating mode on the MR equipment unrelated to a particular operating mode on the MR equipment.

15.3.3 Dose

IEC has also established general public and MR-related personnel exposure limits concerning the static magnetic field. These restrictions are in place to safeguard both patients and employees. The general population is only allowed 400mT. This is the same as 4000 G. Technologists are also given varying dosages. Their head and torso have a 2 T restriction, whereas their limbs have an 8 T limit.

Patients younger than one month are limited to 4 T, whereas those older than one month are limited to 8 T.

It is critical to examine a magnetic spatial gradient map of the MR room (zone IV) to determine the location of the 5 G line.

RF Standards

The World Health Organization (WHO), ICNIRP, and the International Committee on Electromagnetic Safety (ICES, a division of IEEE) actively engage in the ongoing surveillance of potential health impacts associated with RF electromagnetic fields. The prevailing viewpoint among scientific expert groups suggests that safeguarding against excessive exposure to radiofrequency energy is primarily concerned with mitigating acute thermal effects, which occur either during or within a few hours following exposure. There is currently a lack of evidence supporting the association between oncological risks and RF exposures linked with MRI and exposure related explicitly to MRI. The utilization of globally uniform RF transmit fields, such as the Circulatory Polarized RF in a birdcage Volume RF Transmit Coil, results in a significant non-uniform distribution of RF deposition and SAR within the human body on a global scale. The presence of localized SAR "hot spots" has the potential to induce increases in local temperatures. However, it is essential to note that thermal diffusion and blood flow processes can mitigate these temperature rises. Numerical simulations can provide SAR values in localized regions. This SAR data can be used with established equations such as the Pennes Bioheat Equation to deduce temperature distributions.

The prevailing agreement derived from scientific studies that have undergone peer review suggests that issues pertaining to systemic overheating are of minimal significance when the core temperature of a patient does not surpass the values outlined in the provided table.

Operating mode ↓	Maximum CORE TEMPERATURE	Rise of CORE TEMPERATURE °C
NORMAL	38	0,7
FIRST LEVEL CONTROLLED OPERATING MODE	38,5	1,3
SECOND LEVEL CONTROLLED OPERATING MODE	> 38,5	> 1,3
NOTE Values relate to tympanic measurements.		

Table 15.3

A conversion of this table to Fahrenheit is:

Operating Mode	Maximum Core Temperature (F)	Rise of Core Temperature (F)
Normal	100.4	33.26
First Level Controlled	101.3	34.34
Second Level Controlled	>101.3	>34.34
NOTE: Values relate to tympanic measurements.		

Table 15.4

IEC regulates the limits for core temperature by imposing restrictions on the Whole Body SAR. Varied levels of exposure should be implemented for individuals with intact thermo-regulatory and cardiovascular capabilities (on stress levels within the first level controlled operating mode), as well as for more vulnerable patient populations (inside the normal operating mode). The presence of limited heat dissipation from the fetus and amniotic fluid indicates the necessity for decreased levels of RF exposure.

The primary basis for imposing temperature restrictions is the examination of functional alterations and structural harm in the brain, including the eye. Additionally, there is a concern regarding the potential strain on cardiovascular function due to an excessive demand for thermo-regulation ability. Induced stress encompasses the quick augmentation of sweat rate, simultaneous with the regulation of cutaneous blood flow and heightened cardiac output, perhaps leading to a reduction in arterial blood pressure. The specific thresholds at which biophysical control mechanisms are triggered or may become compromised are not adequately defined and may differ depending on factors such as age, pregnancy, obesity, hypertension, and additional stressors (e.g., diuretics, tranquilizers and sedatives, vasodilators and certain medications, chemotherapy or radiation therapy, and various other medical conditions). The International Commission on Non-Ionizing Radiation Protection (ICNIRP) has officially adopted and reaffirmed the utilization of a conservative limit of 1 °C for the increase in core body temperature. This value is the threshold for operational adverse health effects in occupational environments. In a controlled environment, permitting higher values when evaluating the benefit-to-risk ratio is possible. The primary objective of regulating core or blood temperature is safeguarding internal organs, particularly the brain. The ICNIRP has established conservative limits for the temperature increase in the brain, including the eye, which should not exceed 2°C. The permissible increase in core temperature outlined in this document was determined after examining the analysis described in ICNIRP standards, considering the medical setting in which an MR examination is conducted.

In the IEC standard, the concept of First Level Controlled Operating Mode to RF exposure is defined without considering the potential alterations in biochemical signaling pathways as a manifestation of physiological stress. The occurrence of intense perspiration and the resulting strain on the cardiovascular system due to the body's thermoregulatory response may need to be prevented in specific groups of patients [27]. Therefore, the threshold for the acceptable

operational mode is determined accordingly. There have been no documented instances of systemic health issues associated with hundreds of millions of MR scans conducted at comparable levels of exposure over the course of several decades. Hence, this study examines the acceptability of a 1.3 °C increase in core temperature for the first level controlled operating mode. When the temperature is increased by a at least 0.7 °C, technicians should consider a heightened level of protection in patients, especially for patients that are more sensitive or prone to fever. It is recommended that individuals of this nature undergo scanning exclusively in the standard operating mode.

Section 15.4 Food and Drug Administration (FDA)

The regulatory oversight of MRI equipment sales and usage in the United States is vested in the Food and Drug Administration (FDA) by statutory authorization. This organization is a regulatory body. It does not conduct research or testing, but it does examine and approve the restrictions connected with research and testing conducted by other organizations.

One of the FDA's guidelines is that the MR environment should be kept at a temperature no higher than 25°C.

In addition, the field limitations for patients exposed to a static magnetic field who are less than one month old are set at 4 Tesla. Any patient above the age of one month is restricted to a flux density of 8 Tesla. The FDA-approved thermal factors are similar to those of the International Electrotechnical Commission.

Auditory considerations are also approved by the FDA. They set a limit of 140 dB for the unweighted sound peak. They also established the A-weight with ear protection at 99 decibels.

MRI scanners are classified as Class II devices. As a device that can potentially cause harm to the public, Class II devices must be properly documented and their distribution regulated. The FDA has released guidance documents that outline non-binding criteria, which are highly recommended for obtaining premarket approval. These criteria encompass several aspects, such as hardware, software, performance, site design, and safety. After receiving approval, the FDA lacks the jurisdiction to conduct inspections on MRI facilities. These operations fall within the purview of several state government departments. Additional organizations, such as the American College of Radiology (ACR) and The Joint Commission (TJC), offer quality and safety standards for the certification of MRI centers, enabling them to operate and perhaps receive reimbursement for their services.

Section 15.5 International Commission on Non-Ionizing Radiation Protection (ICNIRP)

ICNIRP is dedicated to addressing the potential risks associated with human exposure to electromagnetic radiation across various forms and frequencies. This organization has released official statements and guidelines pertaining to the effects of static and radiofrequency fields on individuals, including patients and workers, within the MRI setting. The proposed limitations on workers put forth by the group exhibit a relatively more cautious approach compared to the regulations set by the IEC and hold greater sway within the European context.

The occupational dosage used in MRI is defined by the ICNIRP. It states that any field strength larger than 2 Tesla has been linked to sensory difficulties in patients, including dizziness, nausea, and migraines. It also specifies the torso, limbs, and dosages that are suitable to fore general population. Because an occupational employee should not be subjected to a time-varying magnetic field during an MR test, it does not define it. This organization's torso limit is based on a flux density of 2 Tesla. The dosage to the limbs is restricted to a flux density of 8 Tesla. The general public is restricted to 400 milli-Tesla.