

# 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 Trattig (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.

The motivation for generating this document was the enactment of the EU-directive on physical agents (electromagnetic fields, Directive 2013/35/EU), which defines exposure limits to electric and magnetic fields in the work place. This must be transposed into national law within the EU by 1<sup>st</sup> July 2016. After a lengthy consultation process this directive also contains a derogation for MRI. The EU expects that the MR community display a high degree of self-regulation, and develop effective training programs for workers in the field. As a first step it is then necessary to define the roles and responsibilities of workers, so that appropriate training programs can be developed, which may ultimately be offered by multiple providers.

A consistent challenge was to find a general form that could be translated into the working practice of different safety cultures and legislative environments. The proposed solution envisages that one person is operationally responsible for the facility and this is the MR medical or research director (MRMD/MRRD) and further that there is one person who is closely involved with scanning who takes on the role of MR safety officer (MRSO). This represents the minimum configuration for any site. Additionally, the role for a higher level of technical expertise was defined in the form of the MR safety expert (MRSE), but at the same time it was accepted that for small sites this level of expertise would not necessarily be available “in house,” and hence such

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

This document is aimed at facilitating the implementation of a suitable organizational structure for ensuring MR safety in and around MR imaging systems, suites, and their environment. These recommendations are applicable to both clinical and research MR settings. They represent the consensus of: the European Federation of Organisations in Medical Physics (EFOMP), the European Federation of Radiographer Societies (EFRS), the European Society for Magnetic Resonance in Medicine and Biology (ESMRMB), the European Society of Radiology (ESR), the International Society for Magnetic Resonance in Medicine (ISMRM), the Section for Magnetic Resonance Technologists (SMRT), the American Board of Magnetic Resonance Safety (ABMRS), and the Society for Cardiovascular Magnetic Resonance (SCMR).

The legal responsibility for MR safety may reside with an individual or with an institution. Operational responsibility may be delegated; however, legal responsibility cannot. Within this document it will be assumed that ultimate operational responsibility lies with a single individual, herein referred to as the *MR Medical Director* (MRMD) or *MR Research Director* (MRRD), who may also be legally responsible. Their credentials, background, and training/education may in some cases be defined by local or national laws, guidance, or institutional regulations. It is expected that a physician/radiologist acts as the MRMD/MRRD for the

situation in which the entire MR examination is being directed by patient care concerns in a clinical setting.

Operational responsibility may also be delegated to other individuals to ensure that, in practice, the requirements for MR safety are in force and carried out. In particular, this concerns the roles of an *MR Safety Officer* (MRSO), and an *MR Safety Expert* (MRSE). In the following it is assumed that the MRMD/MRRD and MRSO are of the organization conducting the scanning, whereas the MRSE may be external. If the MRSE is external, then their role is advisory. If they are of the organization, then the MRMD/MRRD may delegate technical (but not clinical) responsibility to them, in which case the MRSO may then report to the MRSE in the first instance, although ultimate responsibility will still reside with the MRMD/MRRD. In some countries the MRSE may have a legally defined operational role, in which case there will generally be a transfer of some (legal) responsibilities from the MRSO and/or the MRMD/MRRD to the MRSE.

The information in the next three sections lists the recommended responsibilities for management of MR safety for each of these three positions, whereby it should be noted that legal and statutory requirements may vary between nations and settings.

#### **MR Medical Director (MRMD)/MR Research Director (MRRD)**

The MRMD/MRRD shall ensure the following:

- That the MRMD/MRRD oversees, either in person or via delegation to another appropriately licensed and/or qualified individual, the safe execution of the MR examination on each and every patient/human subject examined in the MR system(s) or MR site(s) under his/her jurisdiction at all times and without exception. One MRMD/MRRD may preside over more than one MR system.
- That the MRMD/MRRD and/or the responsible radiologist/physician (in the case of clinical patients) shall be available/accessible to the operators of the MR system at all times during which the MR facility is accessible.
- That at least one MRSE is identified who can advise, on an as-needed basis, regarding all matters and issues relating to MR safety.
- That at least one MRSO is designated and available/responsible for each MR system. One MRSO may be designated to be responsible for the proper execution of MR safety practices at one or more MR systems.
- That MR-specific policies and procedures pertaining to the safe operation of MR services are up-to-date, and are appropriate to the patient/research subject population(s), clinical/research applications, and MR equipment in use.
- That appropriate MR safety and quality assurance programs are implemented.

- That an appropriate system for record keeping and analysis of adverse events is implemented with the involvement of the MRSO and, if/as needed, the MRSE.
- That appropriate ongoing risk assessment is conducted for the MR facility.
- That an appropriate investigation (for example, a root cause analysis) is performed for each reported MR safety adverse event for each site for whose safety the MRMD/MRRD is responsible and that records are kept of these analyses.

#### **MR Safety Officer (MRSO)**

The role of MRSO is often carried out by the senior Radiographer (in the USA this will generally be an MR technologist), but other suitably trained individuals could also fill this role. Multiple MRSOs could be appointed, provided only one is in charge at a given time. His/her responsibilities include the following:

- To be readily accessible and available (eg, to the operators of the MR system) at all times that the MR facility is accessible.
- Ensuring that proper policies and procedures for day-to-day MR safety are enforced.
- Developing, documenting, and introducing, in conjunction with and under the authority of the MRMD/MRRD, safe working procedures for the MR environment.
- Ensuring that adequate written safety procedures, work instructions, emergency procedures, and operating instructions are issued to all concerned after full consultation with the MRMD/MRRD (and, if/as needed, the MRSE).
- Ensuring that appropriate measures for minimizing risks to health that arise from the use of or exposure to the MR equipment, as per the direction of the MRMD/MRRD, are implemented and monitored.
- Managing hazards posed by the MR equipment, and monitoring the measures taken to protect against such hazards.
- Ensuring that all Heads of Departments and senior medical staff members who are responsible for personnel who will be involved with the MR system are informed of the formal procedures for training and authorization.
- Ensuring that medical, technical, nursing, and all other relevant staff groups (including ancillary workers) who may be exposed to the MR environment are educated appropriately on a regular basis as to the safety requirements and updated as necessary.
- Maintaining records of the personnel who have been educated appropriately as to the safety requirements.
- Consulting the MRMD/MRRD (and/or the MRSE) when further advice is required regarding MR safety.

- Reporting back to the MRMD/MRRD in a timely fashion any and all MR safety-related issues.
- Ensuring that there is a clear policy for the purchasing, testing, and marking of all equipment that will be taken into the MR-related critical areas.
- Providing and/or ensuring the provision of MR safety education and training in cooperation with, and as per the policies of the MRMD/MRRD.
- Providing safety advice regarding the selection, procurement, and installation of MR-related equipment (in consultation with the MRSE, if/as needed).
- Providing safety advice on the modification of MR protocols (in consultation with the MRSE, if/as needed).
- Maintaining regular contact with other relevant groups or committees responsible for the safety and welfare of personnel on site, such as, but not limited to, the local ethics committee and the local safety committee.

### **MR Safety Expert (MRSE)**

This position is expected to serve as a resource for the MRMD/MRRD and/or MRSE. The MRSE is often an MR physicist, but others with suitable technical MR expertise could also fill this role. The MRSE would not normally have a medical education and training and, hence, would neither be expected nor required to have any expertise regarding the safety of prescription medications or other non-MR medical procedures, such as the use of anesthetics, contrast agents, sedatives/anxiolytics, etc. It is understood that there may not be a sufficient number of individuals with the necessary qualifications to provide for the physical presence of an MRSE at each MR facility, and it may also not be necessary to have an MRSE at each site. Thus, the requirement herein is for ready access to the services and advisory assistance of an MRSE on an as-needed basis.

The MRSE roles include, but are not limited to, the following:

- Provide high-level advice on the engineering, scientific, and administrative aspects of the safe use of MR equipment.
- Provide advice on the development and continuing evaluation of a safety framework for the MR environment.
- Provide advice for the development of local rules and procedures to ensure the safe use of MR equipment.
- Provide safety (including diagnostic effectiveness linked to safety) advice on the modification of MR protocols.
- Provide safety (including diagnostic effectiveness linked to safety) advice regarding nonroutine MR procedures for individual subjects and specific subjects groups. This includes advice regarding safety related to implanted devices, metallic foreign bodies, tattoos, and other similar issues.
- Provide advice on the choice of MR Safety programs and MR Quality Assurance programs, and evaluations and audits thereof.

- Provide safety advice regarding the selection, procurement, and installation of the MR system and related equipment, as well as on the quality control programs regarding their performance.
- Provide safety advice regarding acceptance testing and, prior to the first clinical or human research use of the MR equipment, provide advice regarding performance testing procedures and testing following any major maintenance procedure.
- Establish and maintain links with any appropriate district, regional, and/or professional bodies.
- Report back to the MRMD/MRRD any MR safety-related issue(s).

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### **Abbreviations**

EFOMP	European Federation of Organisations in Medical Physics
EFRS	European Federation of Radiographer Societies
ESMRMB	European Society for Magnetic Resonance in Medicine and Biology
ESR	European Society of Radiology
ISMRM	International Society for Magnetic Resonance in Medicine
SMRT	Section for Magnetic Resonance Technologists

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