

SAFETY IN MAGNETIC RESONANCE IMAGING

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Abstract – MRI is regarded as a safe imaging modality because it does not involve exposure to ionising radiation. However, it has unique hazards of its own, some of which can result in death or serious injury if they are not appropriately managed. This paper discusses the hazards of MRI and their biophysical basis, describes relevant legislation and guidelines, and gives practical advice on managing safety in MRI facilities. Particular attention is drawn to the important roles that medical physicists have in ensuring patient and staff safety.

Keywords – MRI, magnetic resonance imaging, safety, MR safety

I. INTRODUCTION

One of the key advantages of MRI as a medical imaging modality is that it is free of the well-known hazards associated with ionising radiation. On this basis it is often stated, for example in research proposals that come across my desk, that it is a completely 'safe' modality. In fact, MRI involves unique hazards that, if not managed appropriately, can result in death or serious injury to patients or staff: in a sense it actually presents a more serious risk than the long-term stochastic effects arising from ionising radiation exposure. In practice MRI has an excellent safety record, because professionals working in the field, and particularly medical physicists, have developed robust safe working practices to mitigate the risks that exist. In this paper, we will describe the nature and biophysical mechanisms of the hazards encountered in MRI, then consider approaches to risk management and the legislation and guidelines that exist to protect patients, staff and the general public.

II. HAZARDS IN MRI

The hazards encountered in MRI arise primarily from the three types of electromagnetic field (EMF) used in the imaging process: the static magnetic field, gradient magnetic fields that are switched on and off rapidly, and the radiofrequency (RF) field. Each will be considered in turn in this paper. When discussing EMF hazards in this context, it is often helpful to distinguish between *direct* effects arising from interaction between the EMF and the human body and *indirect* effects, in which EMF interacts with some other object in such a way that the object presents a hazard. It is also important of course to distinguish between acute effects of EMF and those that may manifest in the longer term or as a result of prolonged or repeated exposure. MRI hazards that are not related to EMF include those

arising from the use of liquefied gases as cryogenics in superconducting magnets and those associated with the use of paramagnetic contrast agents, as well as more general health and safety issues (e.g. electrical and mechanical) which will not be discussed in this paper.

III. STATIC MAGNETIC FIELD HAZARDS

The most obvious hazard in MRI is due to the very strong magnetic field generated by the imaging system. Systems in clinical use are usually based around 1.5 T or 3 T magnets (tesla is the SI unit of magnetic flux density, informally referred to as magnetic field strength in MRI). There are an increasing number of 7 T systems in research centres, and isolated examples of whole body magnets of 9.4 T and 10.5 T. These are superconducting magnets and hence are *always switched on* (unless they are intentionally taken off field for maintenance reasons or in an emergency): unlike ionising radiation modalities, the hazard is always present, even when the MRI facility is closed. These magnetic fields are much stronger than those encountered in other walks of life, and tens of thousands of times stronger than the earth's magnetic field (which has a typical value of 50 μ T). A search on the Internet for 'MRI accidents' will yield numerous accounts and images of ferromagnetic objects that have been brought too close to MRI systems and have been pulled towards the scanner by the powerful magnetic field, the so-called projectile effect. Whilst these are often superficially amusing, there is a serious point behind them in that patients and members of staff have been killed or injured in accidents involving ferromagnetic projectiles. The 'index case' of this sort was the death of Michael Colombini, a six year old cancer patient who was killed whilst undergoing MRI in New York State in 2001 when an oxygen cylinder flew into the magnet and struck him in the head [1]. Such tragic accidents are extremely rare, but as recently as 2014 two members of staff were trapped against an MRI magnet for several hours and sustained serious injuries as a result of another oxygen cylinder projectile incident in Mumbai [2].

These indirect effects of the static magnetic field (B_0) arise from translational force (F) and torque (T) exerted on ferromagnetic objects as described by the following equations.

$$\mathbf{T} = \mathbf{m} \times \mathbf{B}_0 = mB_0 \sin \varphi \hat{\mathbf{n}} \quad (1)$$

$$\mathbf{F} = \mathbf{m} \cdot \frac{d\mathbf{B}_0}{dz} = \frac{\chi V}{\mu_0} B_0 \frac{dB_0}{dz} \hat{\mathbf{k}} \quad (2)$$

Where ϕ is the angle between the object and the magnetic field, μ_0 is the permeability of free space, and the magnetisation \mathbf{m} of an object of volume V and magnetic susceptibility χ is given by the following equation.

$$\mathbf{m} = \frac{\chi V \mathbf{B}_0}{\mu_0} \quad (3)$$

Some interesting points arise from this.

- The torque on an object depends on B_0^2 and so is greatest at the centre of the magnet bore.
- The force on an object depends on the product of B_0 and the spatial gradient of the field, so it is actually *zero* at the centre of the bore (where the field is uniform, i.e. $dB_0/dz=0$) and greatest close to the bore opening (see Figure 1).
- On a modern actively-shielded magnet the spatial gradient is very steep, and so the translational force on an object increases sharply as it is brought closer to the magnet, which increases the hazard as compared to older magnet designs.

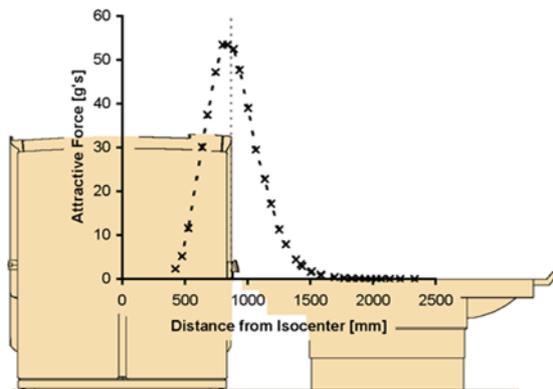


Figure 1. Translational force as a function of distance close to a typical 1.5 T magnet [3].

Many of the precautions in place in MRI facilities, particularly those intended to restrict access to the magnet room, are designed primarily to prevent projectile incidents. However, the static field may also interact with medical devices implanted in patients and staff members, and we will consider this aspect in more detail in Section VI below.

Whilst these indirect effects are of most practical concern, direct effects of human exposure to strong static magnetic fields cannot be excluded, particularly in view of the sparse scientific and epidemiological data on the subject [4, 5]. Since the body contains few ferromagnetic components, acute effects of this type are likely to be due to electric currents induced by motion of conductive tissues in the field rather than to torque or force. Such currents are the only potential direct effect mechanism of concern to the WHO [4].

There are numerous reports of sensory effects such as vertigo, nausea and a metallic taste in the mouth, usually

attributed to rapid movement close to MRI magnets. These effects which are transient and believed to be harmless [6, 7]. There is a growing understanding of the underlying biophysical mechanisms [8]. Investigation of reported memory problems among MRI workers ('mag-lag') has found no significant effects [9], but recent work has suggested neurobehavioural effects [10], which may result from interaction of the field with the vestibular system [11].

Passage of ions in flowing blood through the magnetic field generates a force on the ions which leads to build-up of an electrical potential across the blood vessel [12]. This effect is greatest in the aorta, and is manifested as an enhanced T-wave in the electrocardiogram (ECG) signal collected from a patient in an MRI scanner (see Figure 2). It has been estimated that at 10 T the current density induced at the sinoatrial node would be approximately 20% of that due to normal cardiac electrical activity [12]. A related cardiovascular effect is the magnetohydrodynamic force opposing the flow of blood through the field. A reduction in flow of 5% has been predicted at 10 T [12], consistent with a compensatory increase in blood pressure which has been measured in human subjects at 8 T [13].

Whilst they are transient and currently of little concern, these sensory, neurobehavioural and cardiovascular effects may well eventually limit the static magnetic field strength that can safely be used for human MRI.



Figure 2. ECG signal collected from patient outside (top) and inside (bottom) an MRI scanner.

Epidemiological studies are currently underway, and others have been proposed, to explore long-term effects of static field exposure. One issue in such studies is how to assess and classify exposure in the absence of routinely-available dosimeters [14, 15].

IV. SWITCHED GRADIENT FIELD HAZARDS

The During MR image acquisition, additional spatially-varying magnetic fields are switched on and off rapidly so facilitate spatial encoding. The resulting time-varying magnetic field (in the hundreds of hertz to kilohertz frequency range) induces an electric field in exposed conductive tissue. This in turn can generate a nerve action potential, leading to *peripheral nerve stimulation* (PNS). At onset, PNS results in a tactile sensation on the skin, but at higher gradient amplitudes and switching rates this escalates to loss of muscle control and eventually severe pain. The

performance of MRI gradients is limited to minimise the occurrence of PNS in patients. Concern is sometimes expressed about the possibility of cardiac ventricular fibrillation, but this could only occur at much higher levels of gradient exposure by which point PNS would have become intolerable to the patient. In some situations, such as interventional MRI, members of staff may be located close to the magnet bore opening during imaging. However, the limits imposed on gradient performance and the rapid fall-off in gradient field amplitude outside the imaging volume means that it is extremely unlikely that these workers would experience PNS.

The passage of electric currents through gradient windings to generate the magnetic fields causes a large force between the windings, and as the gradients are switched on and off the windings vibrate, leading to a loud noise (described as tapping, knocking, chirping, or squeaking, depending on the imaging technique being used). Acoustic noise is a major source of anxiety for patients undergoing MRI (the other being claustrophobia). Sound levels can reach 100 dB or more, requiring patients and any staff or carers remaining in the room during imaging to wear hearing protection in the form of ear plugs and/or ear defenders.

V. RADIOFREQUENCY FIELD HAZARDS

The radiofrequency field in MRI is used to excite protons in body tissues so that they subsequently emit a signal which is used to form MR images. The frequency required depends on the magnet field strength, for example 64 MHz at 1.5 T and 128 MHz at 3 T. At these frequencies, the biophysical effect of concern is induction of electric currents, leading to resistive heating of tissues. RF heating is usually expressed in terms of power deposition per unit mass of tissue (specific absorption rate, or SAR). SAR is proportional to B_0^2 ; this places constraints on the performance, and particularly the imaging speed, of ultra-high field MRI scanners, since the intervals between RF pulses must be longer to keep SAR within acceptable limits. The temperature rise resulting from a given SAR level depends on the thermal properties of the exposed tissues. Some tissues, such as the eyes and the testes, and also the foetus, have relatively poor thermoregulation, and some patients have impaired thermoregulation due to their clinical condition. In order to limit heating, it is important that the MR scanner room is not excessively warm or humid.

Excessive heating of the body can lead to heat stress and heat exhaustion and in certain cases, if heating is sufficiently intense and localised, to RF burns. One possible cause of burns is the formation of current loops within the body due to skin-to-skin contact (e.g. hands touching the sides of the body, see Figure 3). The small surface area at the point of contact leads to a high current density and hence intense local heating. Careful patient set-up and the use of insulating pads can help protect against this.

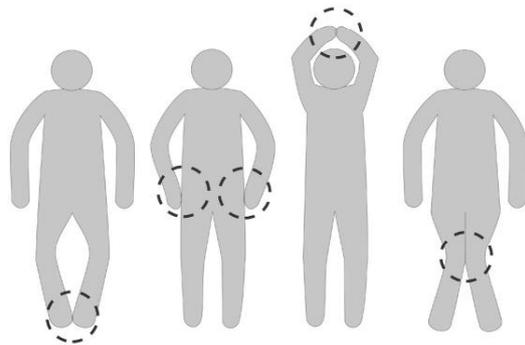


Figure 3. Poor patient set up may lead to formation of current loops and hence to burns.

As well as these direct effects, more serious burns can arise if electrically conductive objects are in contact with the patient during MRI. These can heat significantly, particularly if they are of such a length that they resonate with the RF field, which can lead to temperature rises in excess of 60 °C. In one incident, a pulse oximeter sensor left attached to a baby's forearm resulted in such severe burns that the limb had to be amputated [16]. In another, a patient with a deep brain stimulator (DBS) in place to treat Parkinson's disease underwent MRI for unrelated reasons and heating of the DBS electrode resulted in permanent right-sided hemiparesis [17] (it is possible to image patients with DBS implants safely in some circumstances if appropriate precautions are taken).

Whilst projectile incidents are the most dramatic form of MRI accident, data from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) shows that RF burns are more commonly reported to the agency by a factor of approximately 2.5 [18].

VI. IMPLANTS AND ANCILLARY EQUIPMENT

The safety of implanted medical devices in MRI is a complicated topic because of the plethora of devices available and the need to consider interactions with all three types of EMF. The force and torque exerted by the static magnetic field on devices with ferromagnetic components will depend on the composition and orientation of the implant, and their significance will depend on how strong they are relative to other forces acting on the implant. Fixation of a device to bone usually involves much greater forces than those generated by the magnet, and many devices are safe approximately six weeks after implantation due to ingrowth of tissue. In some clinical situations ingrowth does not occur, for example great caution is exercised over scanning patients with aneurism clips in the brain which, if ferromagnetic, could move and cause a life-threatening bleed. Most aneurism clips now in use are not ferromagnetic, but many MRI centres will not scan patients with these clips in place at all because of the serious consequences of a mistake. Concern is also sometimes expressed about 'magnetic braking': restricted movement of electrically conductive components of artificial heart valves due to induced eddy currents, although the force exerted on

the valve by flowing blood is far greater. RF and gradient field issues with implants usually relate to heating due to induced currents, although these currents can also interfere with the function of electronic implanted devices.

Since the advent of MRI, there has been particular concern about imaging patients with cardiac pacemakers, and a number of deaths have occurred due to inadvertent imaging of such patients [19]. Conversely, it has been argued for some years ago that, with carefully designed protocols, MRI of pacemaker patients can be performed safely [20]. However, as pacemakers were generally regarded as a contraindication for MRI, institutions carrying out this imaging were doing so at their own risk. The first 'MR Conditional' (see Section IX for definition) pacemaker received a CE mark in 2009 and FDA approval in 2010. There are now several models of MR Conditional pacemakers and implantable cardioverter defibrillators (ICDs) on the market. It is safe to image patients with these devices *as long as the manufacturer's conditions are strictly adhered to*. These conditions are contained within the Instructions for Use of the device, and include imaging at 1.5 T only, restrictions on RF and gradient usage, and usually restrictions as to the location of the pacemaker within the patient's body and of the patient within the MRI scanner. More recently, guidelines have been issued for safe use of MRI in patients with non-MR Conditional cardiac devices where clinical need outweighs potential risk [21]. These guidelines explicitly recommend the involvement of the MR Safety Adviser (an older term for MR Safety Expert, i.e. an expert medical physicist, see Section X) in the decision to scan.

As more and more people receive biomedical implants, and the number of people referred for MRI also continues to increase because of the growing range of clinical applications, it is important to strike the right balance and ensure that patients with implants are not unnecessarily denied clinically beneficial MRI examinations. This often requires partnership between a medical practitioner with understanding of the patient's clinical condition and the importance of the MR scan, a senior radiographer or technologist, and a medical physicist who can apply MR physics expertise on a patient-specific basis.

Further information about safe management and screening of patients who may have implants is given in Section X below.

For items of equipment not implanted in the body that might be brought in to the scanner room, concern focuses primarily on the static magnetic field and potential projectile effects. Standards for the testing and labelling of such equipment are discussed below. Many commonly-used items are available in an MR Conditional version (e.g. patient monitoring and anaesthetic equipment, wheelchairs and trolleys). When non-MR Conditional equipment needs to be used in the scanner room, robust precautions are needed. These might include securing the equipment to a wall or putting in place procedures to ensure that it cannot inadvertently be taken too close to the magnet.

VII. CRYOGEN HAZARDS

Most MRI scanners are based around superconducting magnets. Behind the fibre glass covers of the scanner there is a toroidal vacuum flask containing 1,500-2,000 litres of liquid helium at a temperature of $-268.93\text{ }^{\circ}\text{C}$ (4.2 K). The windings of the magnet itself are immersed in this bath of liquid helium, and so retain their superconductivity. Thanks to efficient refrigeration, the liquid helium boils off extremely slowly. However, some emergency situations (for example a member of staff trapped against the magnet following a projectile incident) may necessitate rapid deactivation of the magnet, which can be achieved by boiling off the liquid helium using a heater located in the cryostat. This is known as a 'quench', and results in elimination of the magnetic field within about 30 s. A quench can also occur spontaneously in some circumstances. A 'quench pipe' connected to the scanner vents the resulting helium gas into a safe area outside the building. It is important that regular checks are carried out on the quench pipe: it has been known for pipes to be blocked by frozen water or nesting animals. If the quench pipe fails, helium may fill the scanner room causing cold burns and asphyxiation. Furthermore, as helium warms from boiling point to room temperature it expands by a factor of 757, so there can be a huge build-up of pressure in the scanner room, which in some cases has caused rooms to explode! MRI scanner rooms are fitted with oxygen level sensors to warn of helium leakage, often linked to extraction fans. It is important to have a means of relieving build-up of pressure in the room, such as an outward-opening door, a pressure relief flap, or a safe way of breaking the glass of the observation window. An exclusion zone (typically 3 m) around the quench pipe outlet is also required.

A quench can be initiated in an emergency by pressing a 'quench button'. There are usually buttons in both the scanner room and the control room. In the Mumbai incident described in Section III [2], it appears that the quench button had for some reason been disconnected, so there was no easy way to deactivate the magnet. In another incident in the UK, the quench button wiring was destroyed by a fire in the MRI suite [22]. It took several weeks to deactivate the magnet, residing in the burn-out shell of the MRI suite, which fortunately was located remotely from the main hospital building.

VIII. CONTRAST AGENT HAZARDS

Contrast agents are used in MRI to enhance signal from structures of interest and in some types of functional imaging. Most MRI contrast agents are based on gadolinium, a rare-earth metal with a large paramagnetic moment which has a marked effect on the magnetic properties of body tissues. Gadolinium in its raw state is highly toxic, and consequently the gadolinium ion is attached to a chelate molecule for use as a contrast agent. Gadolinium-based contrast agents (GBCA) have been in clinical use since 1988, and historically have an excellent

safety record with a serious adverse reaction rate of only 0.03% [23]. However, in the late 1990s a new disease entity emerged known as Nephrogenic Systemic Fibrosis (NSF). This results in chronic, progressive and irreversible fibrosis of all body tissues, apart from the brain, and is associated with significant morbidity and mortality. It only occurs in patients with seriously impaired renal function. In 2006, a link was found between NSF and previous exposure to GBCA [24, 25]. It appears that renal failure slows excretion of GBCA from the body, hence increasing the likelihood of transmetallation with zinc or copper resulting in release of toxic gadolinium ions from the chelate. Different GBCA products present different levels of risk, depending on the structure of the chelate molecule. Current advice is not to use high risk agents in patients with serious renal impairment, and to avoid high and repeat doses [26]. With these precautions, few if any new cases of NSF are now occurring [27].

A new GBCA-related problem has come to light very recently. Progressive signal changes seen in certain regions of the brain in patients having repeated MR scans over a period of several years had previously been attributed to disease progression or treatment effects. However, in 2014 it was realised that this effect is actually due to retention of gadolinium in brain tissue, with the magnitude of the signal change strongly correlated with the number of contrast-enhanced scans that a patient has undergone [28]. It is now recognised that administration of certain types of GBCA can lead to accumulation of gadolinium in the brain and bones of patients, including those with normal renal function, persisting for at least 8 years and possibly permanently. It is not known whether this has any clinical significance, but it is clearly a worrying development [29]. To compound matters, it has been found that excreted gadolinium is not eliminated by waste water treatment and that consequently the concentration of anthropogenic gadolinium in bodies of water close to large cities is increasing [30, 31]. In this way, gadolinium is making its way into the drinking water supply.

IX. LEGISLATION, GUIDELINES AND STANDARDS

Legislation relating to EMF in general and to MRI in particular varies from country to country: a partial list of national regulations is maintained by the WHO [32]. Most countries do not have specific legislation relating to MRI, but MRI activities are subject to generic health and safety law. In the European Union (EU), this means the health and safety framework directive (89/391/EEC) [33], which has been transposed into national law by all EU member states. The provisions of the directive, which for example require employers to perform risk assessments, put safe working practices in place, and provide appropriate training to workers, apply to MRI just as much as to any other occupational setting. There is also now a directive relating specifically to occupational EMF exposure, which must be transposed into member state law by 1st July 2016 [34].

Following a lengthy campaign, with significant input from medical physicists, relating to exposure limits contained in the directive [35], medical MRI activities are excluded from these limits, which would have impacted significantly on clinical and research work (it is important to note that other provisions of the directive continue to apply). However, this exclusion is subject to certain conditions and it remains to be seen how these will be interpreted during legislative transposition and enforcement in different EU member states [36].

The International Commission on Non-ionising Radiation Protection (ICNIRP) has issued guidance on exposure to static magnetic fields [37] and to time varying fields in different frequency ranges [38, 39] and on movement through static fields [40]. There is also ICNIRP guidance on MRI safety specifically [41, 42]. The EMF exposure limits recommended by ICNIRP, which form the basis of those in directive 2013/35/EU [34], incorporate significant safety factors below the thresholds for adverse effects, which is unhelpful and unnecessary in the context of MRI, although the underpinning literature reviews are very useful.

EU legislation relating to medical devices also creates health and safety responsibilities for both manufacturers and users of MRI. MR scanners are medical devices, and so must carry a CE mark indicating conformity with the requirements of the Medical Devices Directive (MDD) [43]. These requirements include that ‘the device must be designed and manufactured in such a way that... they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons...’. Conformity is usually demonstrated by satisfying the relevant ‘harmonised standard’, which in the case of MRI is International Electrotechnical Commission (IEC) standard 60601-2-33 [44]. Unusually for a standard of this type, 60601-2-33 includes EMF exposure limits for both patients and workers, the latter being more appropriate in the MRI context than the ICNIRP guidelines discussed earlier. The standard adopts a tiered approach to EMF exposure limitation, with three operating modes defined by exposure thresholds.

- In the ‘Normal Operating Mode’, there is considered to be no risk of ‘physiological stress’ to patients.
- In the ‘First Level Controlled Operating Mode’, the threshold for physiological effects may be approached, and medical supervision is recommended.
- In the Second Level Controlled Operating Mode, there may be significant risk and local regulatory approval is required (e.g., from a research ethics committee), which should explicitly state the permitted levels of exposure.

The limits are summarised in Table 1. The PNS threshold referred to in the gradient exposure limits is the mean threshold for onset of PNS, which may be determined in a group of healthy volunteers.

The MDD is currently undergoing revision. The replacement legislation will take the form of an EU regulation, giving less leeway for variation in member state implementation.

EMF type	Exposure Limits
Static magnetic field	Normal: 3 T 1 st level: 8 T 2 nd level: > 8 T
Switched gradients	Normal: 80% of PNS threshold 1 st level: 100% of PNS threshold
Radiofrequency field (limits on core temperature and whole body SAR averaged over 6 minutes)	Normal: 39 °C, 2 W kg ⁻¹ 1 st level: 40 °C, 4 W kg ⁻¹ 2 nd level: > 40 °C, > 4 W kg ⁻¹

Table 1. EMF exposure limits in IEC standard 60601-2-33 ed3.2

Similar medical device legislation exists in many other jurisdictions, for example in the United States MRI is regulated by the Food and Drug Administration (FDA) as a Class II medical device [45].

Another IEC standard, IEC 62570 [46], defines symbols which may be used to label items that might be brought into the MR scanner room to indicate their safety status. The following three safety categories are defined.

- **MR Safe** - an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.
- **MR Conditional** - an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
- **MR Unsafe** - an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

One limitation of these definitions is that the ‘MR Conditional’ category is extremely broad, covering everything from biomedical implants that can only be exposed to MRI under very carefully controlled conditions (e.g. pacemakers) to non-ferromagnetic wheelchairs and

patient trolleys that are technically ‘MR Conditional’ as they contain electrically conductive components, but clearly by their nature cannot be used in such a way that this presents a hazard.

IEC 62570 is linked to other standards issued by ASTM International that set out procedures for testing devices to establish the conditions under which they may safely be used.

Some individual countries have adopted national guidance on MRI safety. In the UK, the MHRA produces guidance covering issues such as safety infrastructure, safe working practices, worker training, and control of access to MRI facilities [47]. In the Netherlands, safe working guidance was issued in 2008 with the support of the relevant professional bodies and government agencies [48]. The Austrian Standards Institute has developed standards on the role and training of MRI safety officers [49, 50].

X. SAFETY MANAGEMENT AND INFRASTRUCTURE:

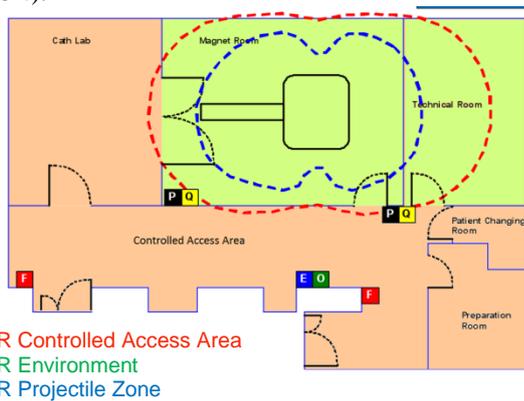
THE ROLE OF THE MEDICAL PHYSICIST

Several organisations have published recommendations regarding practical aspects of safety management and allocation of safety responsibilities in MRI facilities [47, 51, 52, 53, 54, 55]. Many of these documents refer specifically to the key role of medical physicists with expertise in MRI.

A distinction is generally drawn between the individual with day-to-day operational responsibility for safety in the MRI facility (the Responsible Person [47] or MR Safety Officer (MRSO) [51, 52, 54, 55]), often a senior radiographer or technologist, and an adviser with specialist expertise in magnetic resonance physics (often designated the MR Safety Expert (MRSE) [47, 51, 52, 54, 55]). The EFOMP guidelines [51] indicate that the MRSE should be a medical physicist with appropriate levels of qualification and experience, and ideally with professional accreditation. The IPPEM guidelines [52] set out specific knowledge and competences that this individual should have. In guidelines that are intended to extend to the United States, ultimate responsibility for safety is allocated to an MR Medical Director (MRMD) who is a medical doctor [53, 54, 55], reflecting the US legal situation. In other jurisdictions it is generally acknowledged that a medical practitioner has overall responsibility for the care of patients undergoing MRI [47]. Thus responsibility for MR safety should be a partnership, with those with day-to-day clinical and/or management responsibility having a close working relationship with a medical physicist possessing specialist training and expertise. Of course, it is not always practical for MRI facilities to employ a full-time MRSE: it is often more appropriate to contract with a larger centre for these services.

The single most important issue in MR safety is controlling access to the MRI facility, and specifically the scanner room itself. It is important to be able to regulate who has unrestricted access, to ensure that they have appropriate training, and to have procedures in place for

screening of patients, visitor and members of staff who have not had this training. The American College of Radiology (ACR) guidelines [53] recommend establishment of four zones, with proximity to the MR scanner and the concomitant degree of access control increasing from Zone I to Zone IV. In the UK, the MHRA guidelines [47] define the ‘MR Environment’ (MRE) as the area around the scanner containing the 0.50 mT field contour (this value was adopted historically to guard against interactions with pacemakers) and the ‘MR Controlled Access Area’ (MRCAA) as a region containing the MR Environment with suitable access control and signage. The MRE is known as the ‘Special Environment’ in IEC standard 60601-2-33 [44], and usually corresponds to ACR Zone IV (i.e. the scanner room itself); the MRCAA (the same term is used in the IEC standard) corresponds approximately to ACR Zone III (see Figure 4).



Figure

4. Typical layout of an MRI facility with MRCAA, MRE and MR Projectile Zone defined according to UK MHRA guidelines.

Staff with unrestricted access to the MRCAA/Zone III require appropriate training in MR safety. How this is delivered will vary, but ideally the MRSE/medical physicist should be involved in designing training, if not in its delivery. Such staff may be designated as ‘MR Personnel’ [53] or ‘MR Authorised Personnel’ [47], with subcategorization (and hence different training requirements) depending on specific duties and levels of responsibility.

Individuals who do not fall within these categories must be screened for safety before entering the MRCAA/Zone III. It is good practice to screen each patient three times: in writing at the time the patient booking is made, by means of a questionnaire when the patient arrives at the MRI facility, and verbally before the patient is taken into the scanner room. The screening questionnaire is critical, as it provides a lasting record of the screening process that has been undertaken. Details of the questionnaire used will vary between facilities depending on the nature of the work performed, and at our facility for example different forms are in use for different patient groups. An example is shown in Figure 5. In general, the questionnaire will screen for previous surgery (in which devices may have been

implanted), for foreign bodies (again focusing on implants, but also metal fragments the removal of which may have to be confirmed by x-ray imaging), and for some perhaps surprising things such as tattoos and contact lenses: these may contain pigments which can heat up during MRI.

Local Rules for GSTT and KCL MRI units at Guy's & St Thomas' Hospitals, London Version 4 Page 64 of 81

MRI Safety Questionnaire

non-cardiac version

This must be completed by **ALL** persons entering the MRI scan room

NAME	Date of birth	Weight	Height
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MRI scanning uses strong magnetic fields. For your own safety and the safety of others it is **very important** that you do not go into the MRI scan room with any metal in or on your body or clothing.

Please answer the following questions carefully, and ask if anything is not clear. All information is held in the strictest confidence.

please circle YES or NO

- Do you have a heart pacemaker? (These may stop working near the MRI scanner) YES/NO
- Have you had any surgery on your head? YES/NO
- Have you had any surgery on your head, brain or eyes? YES/NO
- Have you had any surgery in the past 2 months? YES/NO
- Do you have any foreign bodies inside you? (e.g. implants, devices, shrapnel) YES/NO
If yes, please list _____
- Have you ever had any metal particles in your eyes? (e.g. from welding or metal work) YES/NO
- Could you be pregnant? YES/NO
- Do you wear dentures, a dental plate or a brace? YES/NO
- Have you had blackouts, epilepsy or fits in the past 2 months? YES/NO
- Do you have any tattoos or transdermal patches (skin patches)? YES/NO
- Are you wearing coloured contact lenses? YES/NO
- An MRI contrast agent (dye) is often required to give us the best information from your MRI scan. Do you consent to an injection of contrast agent (dye) if required? YES/NO
If yes, please complete the MRI Contrast section overleaf
- Before entering the MRI scan room you must remove all metal objects, including coins, jewellery, body-piercings, hearing aids, dentures containing metal, clothing containing any metal, dental braces, artificial limbs or callipers.
Do you agree to remove all of the above before entering the MRI scan room? YES/NO
- Is there anything else you think we should know about in relation to your MRI scan? YES/NO
If yes, please give details _____

Anonymous data from your MRI scan may be used for teaching/research purposes.
If you are having an MRI scan of your abdomen/pelvis we may need to administer drugs that have a short term effect as part of your scan. Please complete the relevant questions related to your MRI scan overleaf.

Figure 5. Typical MRI safety screening questionnaire.

It is also important to manage the flow of people and equipment within the MRCAA/Zone III to ensure that MR Unsafe equipment is not inadvertently brought into the scanner room. However, there are instances in which this is necessary, a good example being a combined x-ray and MRI (‘XMR’) interventional suite in which clinical procedures using MR Unsafe equipment are intentionally carried out within the scanner room but at a distance from the scanner itself. In this situation it is useful to designate an additional ‘MR Projectile Zone’, perhaps at the 3 mT contour [47] (see Figure 4), and essential to adopt rigorous procedures to manage the movement of personnel and devices within the room so as to ensure patient and staff safety [56].

If at the point of referral or during screening it comes to light that a patient has an implant, it is necessary to establish the MR safety status of the device before imaging can go ahead. Ideally, the exact make and model of the implant should be established so that the manufacturer’s literature can be consulted. Alternatively an extensive list of devices and implants that have been tested for MRI safety, where appropriate indicating the conditions under which a device is safe in the MRI environment, is available at <http://www.mrisafety.com/Default.asp>. This is a US resource, but very widely used by the MRI community internationally. In practice, the number of patients with

implants now being referred for MRI is such that 'blanket' policies for particular types of implants are sometimes adopted so that the workload is manageable and efforts can focus on implants presenting a higher level of risk. This needs to be done with considerable caution, and with input from a medical physicist with appropriate expertise and experience.

Each MRI facility should interpret relevant legislation and available safety guidelines in the context of its own practice, installed base of MR equipment and physical layout and encapsulate this in a set of 'local rules'. Where a hospital has multiple MR scanners, it may be appropriate to have a core set of local rules that contain general advice and describe management arrangements applying to all of the facilities and a supplement for each scanner that included local information such as the boundaries of the MRCA/Zone III and MRE/Zone IV, the location of quench buttons and fire-fighting equipment, and how to obtain assistance in an emergency.

As new applications of MRI continue to develop, and with growing numbers of scanners installed and patients referred every year, it is important that safety standards are maintained at their current high level. The knowledge and expertise of medical physicists is indispensable in this endeavour.

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