

# Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use

November 2014

## Acknowledgements

The following are acknowledged for their contribution to this document:

BAMRR

BIR MR committee

British Chapter ISMRM

HSE

IPEM MR SIG

Metrasens Ltd

SCoR

Siemens

Philips Medical

GE Medical

S. Keevil

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Mr D Grainger, Medicines and Healthcare Products Regulatory Agency, London

## Revision history

This version	Date published	Changes
v4.0	November 2014	Text changed since 3 <sup>rd</sup> edition is in dark blue.

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# 1 Introduction

## 1.1 Background

This is the 4<sup>th</sup> edition of the safety guidelines and aims to provide relevant safety information for users of magnetic resonance imaging (MRI) equipment in clinical use but will have some relevance in academic settings and to users of laboratory MR equipment.

This guidance is intended to:

- bring to the attention of those involved with the clinical use of such equipment important matters requiring careful consideration before purchase and after installation of equipment
- be an introduction for those who are not familiar with this type of equipment and act as a reminder for those who are
- act as a reminder of the legislation and published guidance relating to this equipment
- draw the attention of the users to the guidance published by relevant organisations.
- Reflect current risks and hazards.
- draw on the experience of MHRA and contributing organisations on safe use of MRI equipment.



**This document provides general guidance on good practice. Following the guidance is not compulsory and other actions may be equally valid.**

## 1.2 Formatting



Warnings and caution



Recommendations

Text changed since 3<sup>rd</sup> edition is in dark blue.

Defined terms are in SMALL CAPITALS.

Links are formatted in blue.



Recommended reading / reference

Text reproduced from other MHRA documents

## 1.3 Defined terms

The following terms are used in this document:

MR ENVIRONMENT

MR CONTROLLED ACCESS AREA

MR PROJECTILE ZONE

**MR SAFE**

**MR CONDITIONAL**

**MR UNSAFE**

MR AUTHORISED PERSON

AUTHORISED PERSON (NON-MR ENVIRONMENT)

AUTHORISED PERSON (MR ENVIRONMENT)

AUTHORISED PERSON (SUPERVISOR)

MR OPERATOR

MR RESPONSIBLE PERSON

MR SAFETY EXPERT

## 2 The hazards in MRI

### 2.1 Introduction

During MRI diagnostic imaging and spectroscopy, individuals being scanned and those in the immediate vicinity of the equipment can be exposed to three variants of magnetic fields simultaneously:

- the static magnetic field ( $B_0$ )
- time-varying magnetic field gradients (dB/dt)
- radiofrequency (RF) magnetic fields ( $B_1$ ).

The hazards of each of these are discussed separately in the following sections [2.2](#), [2.3](#) and [2.4](#).

Users of superconducting magnets will also be at risk from cryogen hazard. This is discussed in [Appendix 1](#).

#### 2.1.1 Published guidance on safety limits of exposure

In the UK, The Centre for Radiation, Chemical and Environmental Hazards, part of Public Health England, (formerly part of the Health Protection Agency (HPA) (formerly the National Radiological Protection Board (NRPB))) publishes guidance on exposure to magnetic fields. Publications to date are:



Protection of Patients and Volunteers Undergoing MRI Procedures [1] was published in 2008 and reviews the guidance published by ICNIRP in 2004 [12].

- occupational and general public exposure to static and time-varying electromagnetic fields (EMF) guidance in 2004 [2]
- the risk of cancer from extremely low frequency EMF exposure guidance 1992 [3] and 2002 [4].

As experience is gained, recommendations regarding acceptable levels of exposure may change. If in doubt, seek advice on the current recommendations from the [Centre for Radiation Chemical and Environmental Hazards at Public Health England](#).

The **International Electrotechnical Commission** (IEC) provides a standard (IEC 60601-2-33) for manufacturers of MRI equipment to follow. This standard focuses on the safety requirements of MRI equipment used for medical diagnosis. It is a comprehensive source of information on the limits incorporated by manufacturers into their systems design. The third edition to this standard was published in 2010 [5] replacing the second edition from 2002 [6]

The **International Commission on Non-Ionizing Radiation Protection** (ICNIRP) published guidance on time-varying electromagnetic fields in 1998 [7,8], exposure to static fields in 2009 [9], on low frequency fields on 2010 [10] and electric fields induced by movement in 2014 [11]. This guidance is for occupational and general public exposure.



For MRI clinical exposure to patients, ICNIRP published a statement in 2004 [12] and an update in 2009 [13].

#### 2.1.2 MR safety marking

ASTM International's standard F2503 [14] for the marking of devices brought into the MR environment should be used. This has also been published by IEC as standard IEC 62570:2014 [15]



Users should update all safety markings in line with the latest version of ASTM International standard F2503 and ensure that all relevant staff are made aware of them.

The definitions and example colour labels are given in [Table 1](#) (black and white versions are acceptable).

**Table 1 Definitions from ASTM international standard F2503-13**

<p><b>MR SAFE</b></p> <p>‘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’ *</p>	
<p><b>MR CONDITIONAL</b></p> <p>‘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.’</p>	
<p><b>MR UNSAFE</b></p> <p>‘an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.’</p>	
<p><b>MR ENVIRONMENT</b></p> <p>‘the three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.’</p>	
<p>* <b>the updated definition now specifically prohibits items containing conductive, metallic and magnetic materials.</b></p>	

✓ The MHRA recommends that all equipment that may be taken into the MR ENVIRONMENT is clearly labelled using these markings and **where possible, the appropriate descriptive text should be used** (see examples in [Appendix 5](#) ).

✓ Users should always consult the conditions for safe use that accompany **MR CONDITIONAL** devices before allowing them into the MR ENVIRONMENT.

✓ Devices which are not labelled are considered to be **MR UNSAFE**

**2.1.2.1 Artefacts**

It should be noted that ASTM F2503 does not address image artefact. Image artefact is addressed in their standard F2119 [16]. The presence of an artefact may indicate a malfunction that needs to be urgently addressed for safety reasons (eg coil coupling) or could potentially obscure important clinical detail.

## 2.2 Static magnetic fields ( $B_0$ )

### 2.2.1 Safety issues concerning strong static magnetic fields

Safety issues to consider with a strong static field,  $B_0$  are: biological effects, projectile hazards, compatibility of implantable medical devices and compatibility of peripheral equipment.

Currently, commercially available clinical systems in the UK range from 0.2 tesla (T) to 3 T with a few research units operating above 3 T. The majority of scanners installed in the NHS for general diagnostic purposes are 1.5 T in strength.

A review [17] discusses the safety of static magnetic fields experienced by patients in MRI systems.

#### 2.2.1.1 Fringe fields

There are fringe fields with every magnet. However, the extent and steepness of the fringe field gradient depends on the main magnet field strength, the design of magnet (open versus tunnel bore) and the shielding employed (active, passive cladding, or whole room shielding). Each installation will differ due to the surrounding structures ie large metal objects including lifts and support beams.

It is essential that staff at every MR site should have a thorough understanding of the fringe fields relating to each scanner that is on their site. Manufacturers will supply calculated fringe field plots prior to installation but an independent measurement of the 0.5 mT isocontour may be considered to confirm that it does not extend outside the designated controlled area. All **MR AUTHORISED PERSONNEL** should be made aware that the fringe fields depend not only on the field strength but also on the design of the magnet and the type of shielding.



Fringe field plots showing at least the 0.5 and 3 mT contours should be on display in MRI departments. These should be shown to staff and explained clearly.



Staff moving from one type of scanner to another should be aware of the differences between scanner fringe fields and should not be complacent.

#### 2.2.1.2 Spatial field gradient, $dB/dz$

The spatial field gradient,  $dB/dz$ , is the rate that the magnetic field changes with distance. MR safety conditions will often quote a maximum spatial field gradient value.

### 2.2.2 Biological effects

The principal interactions of a static magnetic field,  $B_0$ , with the body and its functions are the creation of electrical potentials and resulting currents generated by body movements (a 'dynamo effect') and the possible displacement of naturally generated currents within the body by  $B_0$  (a 'motor effect').

The 2008 HPA document's [1] summary stated that:

'The biological effects most likely to occur in patients and volunteers undergoing MRI procedures are the production of vertigo-like sensations and these acute effects are associated with movement in the field. The probability of clinically relevant physiological effects or of significant changes in cognitive functions occurring in fields of up to 4 T seems low. In addition, the accumulated experience of MRI procedures in clinical situations, where exposures using fields of 3 T are becoming increasingly common, does not suggest that any obvious detrimental field-related effects occur, especially in the short term.

Much less is known about the effects of fields above 8 T. Similarly, very little is known about the effects of static magnetic fields in excess of a few tesla on growth and behavioural development of fetuses and infants, suggesting some caution is warranted regarding their imaging.

Moving patients slowly into the magnet bore can avoid movement-induced sensory effects. It is clear that sensitivity to these effects varies considerably between individuals, and thresholds for motion induced vertigo in sensitive people have been estimated to be around  $1 \text{ T s}^{-1}$  for greater than 1 s.'

The World Health Organisation published a comprehensive review of the possible health effects of exposure to static electric fields and exposure to static magnetic fields in 2006 [18] and they noted that:

‘Physical movement within a static field gradient is reported to induce sensations of vertigo and nausea, and sometimes phosphenes and a metallic taste in the mouth, for static fields in excess of about 2 – 4 T. Although only transient, such effects may adversely affect people. Together with possible effects on eye-hand coordination, the optimal performance of workers executing delicate procedures (eg surgeons) could be reduced, along with a concomitant reduction in safety. Effects on other physiological responses have been reported, but it is difficult to reach any firm conclusion without independent replication.’

The 2009 ICNIRP amendment conclusions [13] regarding the static field are:

‘current information does not indicate any serious health effects resulting from acute exposure to static magnetic fields up to 8 T. It should be noted, however, that such exposures can lead to potentially unpleasant sensory effects such as vertigo during head or body movement.’

### 2.2.3 Attractive force

The potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field is a **serious** concern in MR units. A patient fatality occurred where the patient was struck in the head with an oxygen cylinder [19]. This risk is only minimised by the strict and careful management of the MR unit. Ferromagnetic materials will experience an attractive force when placed in a magnetic field gradient; the force will be proportional to the field strength,  $B_0$ , and the **spatial** field gradient,  $dB/dz$  [20]. Once ferromagnetic materials become magnetically saturated, above say 0.5 T, there will no B dependence for either displacement force or maximum torque.

The force experienced in MRI scanners is at a maximum just inside the **opening** of the magnet. This is where the field gradient is near its maximum and the magnetic field is rising. It then falls off towards the imaging volume where the gradient falls to zero [21].

Normally all equipment brought into the scan room, from wheelchairs, stretchers and emergency trolleys to cleaning equipment, should not contain significant amounts of ferromagnetic material in order to avoid the projectile effect from the static magnetic field. See section 4 of these guidelines, for the management of peripheral equipment in MR units.



No equipment should be taken into the **MR ENVIRONMENT**, in particular the magnet room, unless it has been identified as being either **MR SAFE** or **MR CONDITIONAL** and the conditions are met.

### 2.2.4 Torque

As well as the attractive force, ferromagnetic objects will also experience a torque that will try to align that object along magnetic field lines. Torque is largely shape dependent and is proportional to the field strength,  $B_0$ , and to the angle the object is away from alignment with the field [20]. ASTM has published a standard for measuring torque [22].



For some implants, torque may be the limiting effect when assessing safety.

### 2.2.5 Lenz effect

When a conductor moves through the flux of a magnetic field, a potential difference is induced that is proportional to the rate of change of the flux. Lenz's law states that the induced potential difference is in a direction to oppose the change inducing it. The result is to induce a magnetic field in the moving conductor, which will resist that movement. The Lenz effect is not large up to 1.5 T but can be significant at 3 T depending on the geometry of the conductor. One area of concern however is that of mitral and aortic valve replacements. Robertson et al. [23] have investigated the significance of this effect on valve opening times at various field strengths. They found that at the most common field strength, 1.5 T, the effect is less than 1% of the pressure effect for mitral and aortic valves. However, this was shown to increase significantly when field strength is increased – at 4.7 T the effect is 10% but at 7 T the effect is approximately 30%.

## 2.2.6 Interaction with implantable medical devices

The strong static magnetic field can affect implantable medical devices in exposed people (staff, patient or volunteer). Any ferromagnetic component within an implantable medical device may experience both an attractive force (ie the device will try to move to the iso-centre) and/or a torque force (ie the device will try to turn to line up with field lines). Both of these effects can cause tissue damage and/or damage to the implantable medical device.

Examples of implantable medical devices are stents, clips, prostheses, pacemakers and neuro-stimulators. The range is extensive, therefore it is essential to read about the management of implantable medical devices in section 4.11 of these guidelines. Issues of implantable medical device compatibility are discussed by Shellock [24, 25].



There have been a number of deaths following the scanning of patients with implanted pacemakers. However, in most cases the presence of the pacemaker was undetected before scanning. Permanent damage to some components (such as the reed switches) may occur when exposed to certain magnetic fields.

Product static field immunity levels are given in Table 2.

In addition, the pacemaker may experience a torque when in the static magnetic field, which is sufficient to cause displacement in the chest wall. Further discussion on this and the management of pacemaker wearers is explained in section 4.11.

**Table 2 Immunity levels**

Product	Standard	Unaffected up to:	Affected in field but full function returns.
Implantable cardiac pacemakers	EN 45502-2-1:2003 [26]	1 mT	10 mT
Implantable defibrillators	EN 45502-2-2:2008 [27]	1 mT	50 mT

## 2.2.7 Interaction with other equipment

The static field can affect monitoring equipment that has ferromagnetic components. Issues concerning monitoring equipment compatibility are discussed in reference [24]. Firstly, the function of the equipment could be affected. Secondly, all equipment with significant ferromagnetic components has the potential to be a projectile hazard. Devices may also be affected by currents induced by movement through a static magnetic field.



It is recommended that appropriate **MR CONDITIONAL** monitoring and support equipment (eg ventilators, anaesthesia machines, pumps, etc.) is used. If the equipment is modified in any way, its compatibility may need to be re-examined. Staff should know any conditions (eg distance to magnet bore) which may affect the equipment's safety (see also sections 4.9 and 4.12.13) and these should be clearly marked on the equipment. Accessories to monitoring equipment should also be checked for compatibility eg ECG leads and electrodes.

## 2.3 Time-varying magnetic field gradients (dB/dt)

These are the switched fields generated during scanning to determine position of a signal.

### 2.3.1 Safety issues concerning time-varying magnetic field gradients

The safety concerns with the time-varying magnetic field gradients are biological effects: peripheral nerve stimulation, muscle stimulation and acoustic noise.

In MR, three orthogonal magnetic field gradients are switched on and off to select the region of diagnostic interest and to spatially encode the MR signals. As a general guide, the faster the imaging or spectroscopy sequence, the greater the rate of change of the gradient fields used and the resultant current density induced in the tissue.

### 2.3.2 Biological effects

Subjecting the human body to time-varying electromagnetic fields can lead to induced electric fields and circulating currents in conductive tissues. At any particular location, the currents induced will be determined by the rate of change of the magnetic field and the local distribution of the body impedance, which is primarily resistive at frequencies below about 1 MHz. The time-varying field gradients employed in MR scanners are of relatively low frequency when compared, for example, to radiofrequency fields and microwaves.

Time-varying magnetic fields induce electric currents that potentially interfere with the normal function of nerve cells and muscle fibres. An example of this is peripheral nerve stimulation (PNS). A more serious response to electric currents flowing through the body is that of ventricular fibrillation, which is prevented in clinical scanners operating within IEC limits [6].

An overview into the biological effects of time-varying magnetic field gradients is given in references [28] and [24].

### 2.3.3 Peripheral nerve and muscle stimulation

At low frequencies, induced currents are able to produce the effect of stimulation of nerve and muscle cells [29]. The extent will depend on the pulse shape and its repetition rate. This stimulation can be sufficient to cause discomfort and in extreme cases might result in limb movement or ventricular fibrillation. The body is most sensitive to fibrillation at frequencies of between about 10 Hz and 100 Hz and to peripheral nerve stimulation at up to about 5 kHz. Above these frequencies, nerve and muscle cells become progressively less responsive to electrical stimulation.

The 2008 HPA document's [1] summary stated that:

'Exposure to switched gradient fields induces time-varying electric fields and currents in biological tissues. These can cause stimulation of excitable tissues, if of sufficient intensity and appropriate frequency. The rapidly changing fields induced by the high rates of gradient field switching used in MRI systems will preferentially stimulate peripheral nerves. These thresholds are well below those for ventricular fibrillation for induced current pulse widths of less than 3 ms. Hence, limiting exposure of patients and volunteers to switched gradient fields can be based on minimising any uncomfortable or painful sensations caused by the field.'

For information on the restriction levels see appendix A2.1.3

### 2.3.4 Implant interaction

The time-varying magnetic field gradients can interact with implants. This may result in device heating and vibration. These effects are covered by the ISO standard – ISO/TS 10974 [30].

## 2.4 Radiofrequency magnetic fields ( $B_1$ )

### 2.4.1 Safety issues concerning radiofrequency fields

The main safety issues for radiofrequency (RF) fields used in MR are thermal heating leading to heat stress induced current burns and contact burns.

At all frequencies, induced currents will lead to power dissipation within the body's tissues, which in turn will lead to accumulation of energy with time and a rise in body temperature. At frequencies above 0.1 MHz heating effects predominate and this has a major consequence for magnetic resonance imaging. The RF field distribution is not uniform – in-homogeneity increases with increasing field strength, and depends on coil design.

Absorption of energy from radiofrequency fields used in MR results in the increased oscillation of molecules and the generation of heat. If this occurs in human tissue, a compensatory dilation of blood vessels results in an increase in blood flow and the removal of the excess heat, which is dissipated mainly through the skin.

The electromagnetic and thermal characteristics of different organs and parts of organs will differ. The eyes are an example of organs that have very little blood flow. In fact, the lens of the eye has none, and therefore takes time to disperse thermal energy. The testes are organs separated from the main volume

of the body and are regarded as heat sensitive. Normally their temperature is a few degrees below body temperature.

A rise of 1°C is generally acceptable to a normal healthy person. The actual temperature rise at any time will depend on the balance between the energy absorbed and the energy transferred from the region of the body concerned. The ambient temperature, air flow, clothing and humidity all play a major role in the rate of dissipation. The lower the ambient temperature and the lower the humidity, the greater the transfer. For more information on RF induced temperature rise in the human body see reference [31].

## 2.4.2 Heat stress

Heat stress is of particular concern for some patients, such as those suffering from hypertension, or pregnant women, or those on drugs such as diuretics or vasodilators that may compromise these responses. One fundamental issue is excessive cardiovascular strain resulting from thermoregulatory responses to body temperatures raised over a short period of time by more than 0.5°C in vulnerable people. MR scanners limit temperature rise by limiting SAR. A review of RF heating is given in reference [31].

The 2008 HPA document's [1] summary stated that:

'Exposure to RF fields of sufficient intensity can induce heating in biological tissue, while effects in the absence of heating remain controversial. Hence restrictions on exposure to RF fields used in MRI procedures are based on limiting both body core temperature rises and temperature rises in parts of the body.'

There are uncertainties concerning the effects of increased heat loads on infants and pregnant women, and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications. These people should be imaged with caution.'

The 2004 ICNIRP report conclusions [4] regarding radiofrequency field exposure are:

'For whole-body exposures, no adverse health effects are expected if the increase in body core temperature does not exceed 1°C. In the case of infants and persons with cardiocirculatory impairment, the temperature increase should not exceed 0.5°C. With regard to localized heating, it seems reasonable to assume that adverse effects will be avoided with a reasonable certainty if temperatures in localized regions of the head are less than 38°C, of the trunk less than 39°C, and in the limbs less than 40°C.'

## 2.4.3 Burns



Burns are the most often reported MRI adverse incident in England [32].

### 2.4.3.1 Contact burns

A review of burns in MR is given in reference [33]. The radiofrequency field will induce currents in conductors and can raise their temperature significantly. Burns to volunteers and patients from contact with such metallic objects can be avoided by careful positioning and set up within the bore of the magnet. Examples of causes are: contact with metal in clothing, coils, coil leads, ECG connectors and oxygen monitor probes. Section 4.12 of these guidelines discusses how to screen and set up patients to avoid this hazard.

### 2.4.3.2 Induced current burns



There have been many reports to the MHRA of burns that have occurred when the arms or the legs have been positioned in such a way as to create a conductive loop pathway [34, 35].



Induced current burns are frequently not immediately sensed by the patients. As such, patients typically cannot warn the radiographer of discomfort or pain prior to thermal damage.



Foam pads, 1–2 cm thick, should be used to insulate the patient from cables, the bore and between limbs.

Section 4.12.8 of these guidelines discusses how to position patients to avoid this hazard.

## 2.5 Acoustic noise

A characteristic of the switching gradient fields is the production of acoustic noise. When the alternating low-frequency currents flow through the gradient coils, which are immersed in the high static magnetic field  $B_0$ , forces are exerted on the gradient coils that move like a loudspeaker coil and generate sound waves. The level of this acoustic noise at the location of the patient or volunteer can reach an unacceptable and even dangerous level [36]. Exposure to a loud noise can result in a reduction of the sensitivity of the hair cells in the organ of corti and a shift in the threshold of hearing. This may be temporary if the cells can recover or permanent if the exposure is very loud ( $>140$  dB(A)), prolonged or frequently repeated.

The 2008 HPA document's [1] summary stated that:

'Although there is little risk of a permanent threshold shift in hearing in those exposed to noise associated with MRI procedures on a one-off or occasional basis, certain scans may exceed the discomfort threshold, particularly for sensitive individuals. Temporary threshold shifts can be induced if patients and volunteers are not adequately protected, which may cause discomfort and be accompanied by other effects such as tinnitus. There is some limited subjective evidence from leisure-related noise exposures and MRI adverse incident reports that permanent effects may be induced in unprotected subjects.

Clinically significant temporary threshold shifts in patients and volunteers undergoing MRI procedures are unlikely in most subjects for noise levels below 85 dB(A), given the relatively low frequencies encountered in MRI, and the typical examination times of less than an hour. However, there are variations in sensitivity between individuals, both in terms of the threshold of discomfort and in terms of the production of temporary threshold shifts. In its 2004 guidance, ICNIRP recommended that patients or volunteers should be given the choice of whether to wear protection if noise levels fall between 80 and 85 dB(A). If followed, this recommendation may inadvertently result in some sensitive patients feeling discomfort or receiving a clinically significant temporary threshold shift, particularly if the examination time is relatively long.'

IEC recommend that hearing protection should be used if equipment is capable of producing more than 99 dB(A).



The MHRA has received reports of staff, carers and patients suffering a temporary threshold shift, extended periods (including persistent, chronic) of ringing of the ears and tinnitus after exposure to MR noise without ear protection.



Groups of particular concern are paediatric and neonate patients, the fetus, unconscious patients and those with pre-existing aural conditions such as tinnitus, recruitment or hypersensitivity.



The use of earplugs, ear defenders, or other means of hearing protection is highly recommended [37]. Staff training in the use and selection of ear protection is also necessary. See the section on acoustic noise levels in reference [37] and sections 2.6.2, 3.2.5, 3.3.2.4 and 4.12.9 in this document.



Staff should carefully instruct any person remaining in the MR scanner room during the MR exam on the proper use of hearing protection, and verify fit and function of hearing protection in place prior to the initiation of the MR exam.

## 2.6 Pregnancy and MR exposure

### 2.6.1 Overview of guidance

Below are extracts from relevant guidance on each hazard.

#### 2.6.1.1 Static fields

The 2009 ICNIRP update [13] regarding pregnancy and static fields stated:

‘It remains the case that, as noted by ICNIRP (2004), very little is known about the effects of static magnetic fields in excess of 4 T on the growth and development of fetuses and infants, and therefore some caution may be warranted regarding their imaging above 4 T.’

#### 2.6.1.2 Time-varying magnetic field gradients

Details on research into the effects of low frequency EMF on embryo and fetal development are given in reference [38].

The 2004 ICNIRP report conclusions [12] regarding pregnancy and the time varying field are:

‘There is no clear evidence that exposure to static or low frequency magnetic fields can adversely affect pregnancy outcome.’

#### 2.6.1.3 RF fields

The 2008 HPA document's [1] stated that:

‘There are uncertainties concerning the effects of increased heat loads on infants and pregnant women and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications.

These people should be imaged with caution.’

The 2004 ICNIRP report recommendation [4] regarding radiofrequency field exposure of pregnant patients is:

‘Excessive heating is a potential teratogen; because of uncertainties in the RF dosimetry during pregnancy, it is recommended that exposure duration should be reduced to the minimum and that only the **normal operation level is used.**’

#### 2.6.1.4 The 2004 ICNIRP report recommendation regarding exposure to pregnant patients is:

‘There is at present insufficient knowledge to establish **unequivocal** guidance for the use of MRI procedures on pregnant patients. In these circumstances, it is advised that MR procedures may be used for pregnant patients only after critical risk/benefit analysis, in particular in the first trimester, to investigate important clinical problems or to manage potential complications for the patient or fetus.’

#### 2.6.1.5 IEC

‘The instructions for use shall describe that scanning of pregnant PATIENTS with the WHOLE BODY RF TRANSMIT COIL should be limited to the NORMAL OPERATING MODE with respect to the SAR level.’

### 2.6.2 The fetus and noise exposure

Since the early 1990s concerns have been expressed regarding the possible effects of excessive noise on fetal health. Reviews of the evidence HSE 1994 [39]; HSE 1999 [40] and American Academy of Paediatrics 1997 [41] remain inconclusive regarding effects on prematurity or fetal hearing following exposure to noise.

Reeves et al looked at this issue in 2010 [42] found ‘no significant excess risk of neonatal hearing impairment after exposure of the fetus to 1.5 T MR imaging during the second and third trimesters of pregnancy’.

### 2.6.3 Pregnant patients conclusion



The MHRA recommends that pregnant patients be scanned in **NORMAL MODE** whenever possible.



If there is a need to scan in **CONTROLLED MODE** the decision to do so should be based on the information above about risks weighed against the clinical benefit to the patient and made at the time by the referring clinician, an MR radiologist and the patient.



See 'Team working within Clinical Imaging Dept RCR/SCoR joint guidance' [43] and the General Medical Council 'Good Medical Practice Guidance for Doctors' [44] for further guidance when a consultant radiologist may not be responsible or available at remote centres.

This decision should be recorded in the patient's notes. Whenever the decision to proceed with the examination is taken, the scan should be carried out using a sequence that finds an optimal solution of minimising the RF and noise exposure.

### 2.6.4 Pregnant staff conclusion



The MHRA recommends that throughout their pregnancy it is advisable that staff do not remain in the scan room whilst scanning is underway due to the concerns of acoustic noise exposure and risks to the fetus.



The Management of Health and Safety at Work Regulations [47] have specific requirements for expectant mothers. There is a requirement to undertake a risk assessment relating to the hazards caused by physical agents.

In general, it is expected that the level of the time-varying electromagnetic fields, **switched gradients** and the radio frequency **radiation** will be relatively low except in the immediate vicinity of the scanning aperture. This may be of concern in the interventional situation [24]. The level of the static magnetic field exposure is dependent on the field strength and shielding incorporated into the design of the magnet.

## 2.7 Cryogenics

### 2.7.1 Overview

There should be no hazards from cryogenics provided adequate attention has been paid to the provision of venting directly to the outside of the building of all potential sources of helium and nitrogen following normal boil-off or in the event of a pressure release valve bursting. However, for completeness and as a warning, reference is made to some of the potential hazards and **the need for the training** of those involved in handling cryogenics.

The hazards in the use of low temperature liquefied gases for MR systems are:

- asphyxiation in oxygen-deficient atmospheres
- cold burns, frostbite and hypothermia from the intense cold
- explosion following over-pressurisation from the large volume expansion of the liquid following evaporation.

### 2.7.2 Working with cryogenics

See appendix **A1.1** for more information on working with cryogenics.

### 2.7.3 Quench pipe safety

A warning sign must be sighted at the vent outlet, see appendix A1.1.6 for an example.



The MHRA is aware of issues with the design and maintenance of quench pipes which may lead to failure of the pipes during system quench and the possibility of causing serious injuries [45].

MRI scanner manufacturers are not usually responsible for the maintenance of quench pipes and do not routinely check them during planned preventive maintenance.



Before installation of new MRI equipment, the **MR RESPONSIBLE PERSON** should check with suppliers and their local estates department departments or project management team to ensure that:

- the external quench pipe terminal has been designed and fitted in such a way as to prevent the ingress of rain and foreign bodies and positioned such that in the event of a quench, no risk will be posed to any personnel. Care must be taken to ensure that the vent outlet is positioned a safe distance to any openable window, walkway or escape routes. A warning sign must be sighted at the vent outlet.
- the quench pipe is manufactured and installed in accordance with the material and installation specifications and guidance of the manufacturer. It is the Trust's Project Managers responsibility to approve the installation of the quench pipe before the magnet is connected.
- the quench pipe is sized correctly to ensure that the pressure created by a quench within the pipe is within the limits of the quench pipes pressure capability and the maximum pressure recommended by the manufacturer of the MRI scanner. The quench pipe must be sized based on the MRI manufacturers' recommendations and design calculations.



In accordance with the recommendations of superconducting MR manufacturers, the MHRA recommends annual inspections of all vent piping. This should include, at least, a visual inspection of the external piping. A basic guide to the installation and specification is detailed in appendix A1.3.

## 2.8 Other hazards

### 2.8.1 Phantom fluids

Whilst handling sealed/closed phantoms is not hazardous, contact with the liquid after a leak or smashed phantom should be controlled due to the toxicological nature of some phantom fluid components, such as nickel.

Sites should prepare procedures for dealing with phantom fluid spills, clean-up and disposal as per COSHH [94].

## 3 Exposure limits and guidance

### 3.1 Introduction

#### 3.1.1 Exposed groups

A number of organisations have proposed limits to protect exposed persons from effects of EMF and noise. Details of those limits are reproduced in [Appendix 2](#), and the MHRA's recommendations are presented here.

Exposed persons can be grouped into three categories:

1. Patients for diagnosis, volunteers engaged in clinical trials and carers.
2. Staff (employed / self-employed workers).
3. General public (visitors/educational visitors).

#### 3.1.2 Sources of advice

The primary sources of information for exposure limits for patients and volunteers in the UK are the 2008 HPA report [1], IEC standard 60601-2-33:2010 [5] and the ICNIRP statement of 2004 and 2009 [12, 9]. All three organisations recommend an approach based on restriction levels. Care must be taken not to confuse the terminology for levels between these documents.

Exposure information will be provided in the MRI system instructions for use.

### 3.2 Patients, volunteers and carers exposure



The MHRA recommends using the three-mode approach to the clinical operation of MRI equipment in line with IEC, HPA & ICNIRP.

#### 3.2.1 Modes of operation

- **NORMAL MODE** of operation when risk of ill effect to the patient is minimised.
- **CONTROLLED MODE** of operation when the exposure is higher than the normal mode and although the risks are minimised, some people may experience some effects at this level, such as sensory disturbance or transient **discomfort** due to PNS. The patient will benefit by the enhanced imaging performance. Scanning requires patient monitoring [4.12.13](#)
- **RESEARCH / EXPERIMENTAL MODE** when exposure is only restricted to prevent harmful effects. Scanning in this mode will require approval of a **research** ethics committee and patient monitoring [4.12.13](#).

For a summary of HPA, IEC and ICNIRP guidance on modes of operation see appendix [A2.1.1](#).

All the following exposure recommendations are subject to the conditions for entry of individuals to the **MR CONTROLLED ACCESS AREA** (see section [4](#)).

#### 3.2.2 Static magnetic fields ( $B_0$ )

Modes of operation are chosen to prevent effects caused by motion-induced currents.

- **NORMAL MODE** – the patient should not experience effects such as vertigo, dizziness or nausea.
- **CONTROLLED MODE** – some patients may experience effects such as vertigo, dizziness or nausea.
- **RESEARCH / EXPERIMENTAL MODE** – exposure is unrestricted.

For a summary of HPA, IEC and ICNIRP guidance on static field see appendix [A2.1.2](#).

#### 3.2.3 Time-varying magnetic field gradients (dB/dt)

Modes of operation are chosen to restrict PNS and prevent cardiac muscle stimulation.

- **NORMAL MODE** – some patients may experience PNS but uncomfortable PNS is prevented.
- **CONTROLLED MODE** – some patients may experience uncomfortable PNS.
- **RESEARCH / EXPERIMENTAL MODE** – exposure is restricted to prevent cardiac stimulation.

For a summary of HPA, IEC and ICNIRP guidance on limitation of the time-varying magnetic field see appendix [A2.1.3](#).

### 3.2.4 Radiofrequency magnetic fields ( $B_1$ )

Modes of operation are chosen to restrict SAR such that temperature rise is restricted. The basic restriction is to limit whole body temperature rise under moderate environmental conditions.

- **NORMAL MODE** – a whole body temperature rise of  $>0.5^\circ\text{C}$  will be prevented.
- **CONTROLLED MODE** – a whole body temperature rise of  $>1^\circ\text{C}$  will be prevented.
- **RESEARCH / EXPERIMENTAL MODE** – exposure is restricted in order to avoid tissue damage ( $2^\circ\text{C}$  for HPA).

For a summary of HPA, IEC and ICNIRP guidance on limitation of SAR and temperature rise see appendix [A2.1.4](#) and [A2.1.5](#).

### 3.2.5 Acoustic noise



Hearing protection shall always be provided for patients and volunteers unless it can be demonstrated that noise levels will not exceed 80 dB(A). This to minimise temporary hearing loss and prevent permanent hearing loss.

The hearing protection should be chosen to match the noise frequency spectrum of the MR system in use and to reduce noise at the eardrum to **below 85 dB(A)**, the instructions for use should be consulted for the manufacturer's recommendations. For high noise sequences ear plugs and muffs can be used in combination, however the protection provided is less than the sum of the two [46].

For a summary of HPA, IEC and ICNIRP guidance on limitation of acoustic noise see appendix [A2.1.6](#).

## 3.3 Occupational exposure limits in MR

### 3.3.1 Management of Health and Safety at work

Exposure to EMF shall be managed within the framework of the Management of Health and Safety at Work Regulations [47]. This includes the requirement to:

- complete risk assessments
- implement preventive and protective measures where necessary.

There are particular requirements for new or expectant mothers and young persons (under 18).



The **MR SAFETY EXPERT** should be familiar with the Management of Health and Safety at Work Regulations 1999 and its Approved Code of Practice and Guidance [48].

Application of ICNIRP guidance [49] on occupational exposure will aid in this process. However, as the limits set incorporate safety factors, exceeding a limit will not necessarily result in harm [50]. The manufacturer of a CE marked scanner will have included in the instructions for use details on safety and hazards (this will probably be in line with IEC [6]).

### 3.3.2 Risk assessment

The risk assessment and protective measures should specifically consider the following issues:

#### 3.3.2.1 Static magnetic fields

Prevention of interactions between ferromagnetic material and the static field. Prevention of motion-induced effects such as vertigo, dizziness or nausea that may lead to danger.

#### 3.3.2.2 Time-varying magnetic field gradients

Prevention of PNS. PNS is unlikely to occur in staff outside the imaging volume.

#### 3.3.2.3 Specific absorption rate

Prevention of heat related disorders. Heating is unlikely to occur in staff outside the imaging volume.

#### 3.3.2.4 Acoustic noise

Occupational exposure to noise is now specifically regulated by the Control of Noise at Work Regulations 2005 [51]. For a summary of the Control of Noise Regulations see appendix A2.2.2.

#### 3.3.2.5 Staff with implants

Interactions between the exposed worker's implant and the magnetic fields of the MRI equipment.

### 3.3.3 The Physical Agents (EMF) Directive

On June 29, 2013, the European Commission published Directive 2013/35/EU [52] on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). The directive has a conditional derogation for MRI equipment:

'exposure may exceed the ELVs [exposure limit values] if the exposure is related to the installation, testing, use, development, maintenance of or research related to magnetic resonance imaging (MRI) equipment for patients in the health sector, provided that all the following conditions are met:

- (i) the risk assessment carried out in accordance with Article 4 has demonstrated that the ELVs are exceeded;
- (ii) given the state of the art, all technical and/or organisational measures have been applied;
- (iii) the circumstances duly justify exceeding the ELVs;
- (iv) the characteristics of the workplace, work equipment, or work practices have been taken into account; and
- (v) the employer demonstrates that workers are still protected against adverse health effects and against safety risks, including by ensuring that the instructions for safe use provided by the manufacturer in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>13</sup> are followed'

Member States have been given 3 years, up to 1 July 2016, to transpose the directive into national law. The commission shall make available nonbinding practical guides at the latest six months before 1 July 2016 that will include the establishment of documented working procedures, as well as specific information and training measures for workers exposed to electromagnetic fields during MRI related activities falling under Article 10(1)(a).

For details of its implementation see the HSE website [53].

## 3.4 Exposure limits for general public

The Management of Health and Safety at Work Regulations [47] covers risks to the general public. This will include volunteer workers and educational visitors.

The general public should not have access to the MR ENVIRONMENT and it is unlikely that they will be exposed above the recommended limits for correctly installed units.

For a summary of the exposure limits applicable to the general public, see appendix A2.3.

## 4 Management of MR units

### 4.1 Responsibility and organisation

#### 4.1.1 Need for caution

Experience has shown that there are certain key areas where caution needs to be exercised when using MRI equipment in clinical applications:

- the control of all people having access to the equipment and its immediate environment
- the use of pre-MRI screening for implants and other clinical contraindications
- the potential projectile effect when ferromagnetic materials are present in the strong static magnetic field associated with the equipment
- the control of the exposure to which individual patients and volunteers are subjected, in particular radio-frequency heating, contact burns and acoustic noise levels
- the control of exposure to staff especially when working with higher field units or during interventional procedures
- use of equipment out of normal hours eg research work, quality assurance testing, maintenance work, MRI autopsy, veterinary work.

#### 4.1.2 Organisational responsibility

For optimum safety to be achieved in any organisation there must be a joint understanding of the responsibilities of management and the responsibilities of individuals. Management and individuals must be fully aware, at all times, of the need for safety and the consequences that may arise if vigilance is relaxed.

The employing authority is ultimately responsible for the implementation and maintenance of procedures to ensure the health and safety of all persons. The employing authority must be satisfied that organisational arrangements exist for the safe installation and use of MRI equipment within its authority.

In any establishment in which MRI equipment is being used, the chief executive or general manager or equivalent of the hospital or institution has responsibility at all times for all aspects of safety with respect to the equipment, its location, its use, the subjects scanned, and all personnel who have access to the equipment location.



The American College of Radiology (ACR) guidance document on MR safe practices: 2013 is a useful reference document which was updated in 2013 [54]. It uses a 4 zone system as indicated in Figure 1.



The second edition of Safety in Magnetic Resonance Imaging [55] was issued by SCoR and BAMRR in 2013 and updates the 2007 document.

#### 4.1.3 MR RESPONSIBLE PERSON

It is recommended that the chief executive or the general manager delegate the day-to-day responsibility for MR safety to a specified **MR RESPONSIBLE PERSON** who might most effectively be the clinical director, head of the department, clinical scientist, medical physicist or MR superintendent radiographer of the institution where the equipment is located.

If more than one diagnostic MR system is available for clinical use, then the appointment of more than one **MR RESPONSIBLE PERSON** may be appropriate especially if these are in different divisions (eg radiology and cardiology). Clear, written instructions detailing the extent of the delegation and the ensuing managerial responsibilities of each **MR RESPONSIBLE PERSON** and the relationship between these responsibilities should be brought to the attention of all staff involved at any time with such equipment and its location. This includes all categories of staff, including emergency staff, both employed by the employing authority or institution or under contract. It must be ensured that:

- a suitable delegation, safety and good working practice policy is in place

- medical, technical, nursing and all other relevant staff groups, (including ancillary workers), are educated appropriately as to the requirements of the policy and updated as necessary.

The **MR RESPONSIBLE PERSON** should not take on the role of **MR SAFETY EXPERT**. Each **MR RESPONSIBLE PERSON** should retain close contact with other relevant groups or committees responsible for safety and welfare of personnel on site, such as a research ethics committee, local safety committee and local radiation safety committee. Links should be established with any appropriate district, regional and/or professional bodies. The **MR RESPONSIBLE PERSON** should be able to demonstrate compliance with the competencies listed in the former National Occupational Standard HCS MR1, now reproduced in A3.1 [56].

#### 4.1.4 Local rules

It is recommended that the **MR RESPONSIBLE PERSON** ensures that adequate written safety procedures, work instructions, emergency procedures and operating instructions, are issued to all concerned after full consultation with the **MR SAFETY EXPERT** and representatives of all **MR AUTHORISED PERSONNEL** who have access to the equipment (see section 4.7). Local rules should be reviewed and updated at regular intervals and after any significant changes to equipment.

#### 4.1.5 MR SAFETY EXPERT – previously MR safety advisor

It is recommended that, in order to cover all the necessary aspects of safety, each **MR RESPONSIBLE PERSON** should be in full consultation with an **MR SAFETY EXPERT**. The expert should be a designated professional with adequate training, knowledge and experience of MRI equipment, its uses and associated requirements.

The **MR RESPONSIBLE PERSON** should not take on the role of **MR SAFETY EXPERT**. The **MR SAFETY EXPERT** provides scientific advice to the **MR RESPONSIBLE PERSON**.

The **MR SAFETY EXPERT** will have an advanced knowledge of MRI techniques and an appropriate understanding of the clinical applications of MRI. Ideally they will be a physicist with expertise in MRI. Clinical units should appoint an **MR SAFETY EXPERT** who acts according to recognised standards ie they should normally have Health and Care Professional Council (HCPC) registration or General Medical Council (GMC) specialist registration.

The **MR SAFETY EXPERT** should be in a position to adequately advise on the necessary engineering, scientific and administrative aspects of the safe clinical use of the MR devices including site planning, development of a safety framework, advising on monitoring the effectiveness of local safety procedures, procurement, adverse incident investigation and advising on specific patient examinations. Their knowledge of MR physics should enable them to advise on the risks associated with individual procedures and on methods to mitigate these risks.



IPEM's policy statement [57] - 'Scientific Safety Advice to Magnetic Resonance Imaging Units that Undertake Human Imaging' has recommendations on the role of the MR Safety Expert.

#### 4.1.6 Referring clinicians

Referring clinicians should be made aware of the safety aspects and contraindications associated with MRI equipment that are specifically relevant to their patients, prior to submitting them for scanning. See section 4.10.2. Locally prepared referral guidance may be helpful.

#### 4.1.7 Staff training

It must be recognised that there will be a wide range of staff with differing disciplines and responsibilities that will need access to the equipment and its environment (see sections 4.5.6 and 4.17).

The training of all appropriate categories of staff in terms of their normal duties and their duties in the event of an emergency is essential before installation, and for all new staff subsequent to installation. Annual reviews of the training status as well as updates and refresher courses for all staff will be required during the operating life of the MR unit (see section 4.17).

### 4.1.8 Health and safety committee

An appropriate way to ensure that the necessary responsibilities are established and carried out may be to set up a health and safety committee incorporating MR safety with attendance by the [MR RESPONSIBLE PERSON](#)(s), [MR SAFETY EXPERT](#)(s) and representatives of all [MR AUTHORISED PERSONNEL](#) who have access to the equipment.

### 4.1.9 Third party MR units

These are special cases in terms of responsibility and location, with a wide range of possible variations. Careful consideration must be given to all aspects of responsibility to ensure full conformity with these guidelines and how these responsibilities will be shared (see sections [4.18](#) and section [4.22](#)).

## 4.2 Control of access

It is absolutely vital to control access of personnel and equipment to the [MR CONTROLLED ACCESS AREA](#) and to control those individuals who are scanned.

### 4.2.1 Supervision of exposed persons

All unauthorised persons should be supervised by an [MR AUTHORISED PERSON](#) trained to perform safety screening whilst in the [MR CONTROLLED ACCESS AREA](#).

Section [4.3](#) describes all categories of exposed people. Particular attention should be paid to pregnant women (see section [2.5](#)) and to individuals with implanted [devices](#), both active and passive and those that may have metal embedded in them by accident or intention (see sections [4.10](#) and [4.12](#)). The maximum level of exposure will take place within the magnet during scanning and fields will fall off progressively to the point where outside the [MR ENVIRONMENT](#) they should have a negligible effect.

## 4.3 Categories of exposed persons

### 4.3.1 Patients for diagnosis

Patients should be screened [before entering the MR ENVIRONMENT](#) by a suitably trained and experienced member of MRI unit staff who is fully conversant with the clinical safety aspects of exposure to MRI equipment. Any questions or doubts about the suitability of the patient for MRI should be referred to the supervising [clinical MR OPERATOR](#) or [MR RESPONSIBLE PERSON](#). This process and the outcome should be documented. The supervising [MR OPERATOR](#) will remain responsible for the health and safety of the patient throughout the exposure and for any subsequent deleterious effects that are shown to be due to the scans (see sections [4.10](#), [4.12](#) and [4.13](#)).

Only personnel that have been appropriately trained and are experienced in the use of the MRI equipment should scan patients. As appropriate, patients should be fully informed and fully consenting. It is recommended that this include:

- screening questionnaires that are completed, verified and approved, according to local policy, before MR imaging
- written MR information that should be made available to all patients and others well before their scan.

### 4.3.2 Volunteers as part of a research studies and sequence development

The scanning of all volunteers as part of a research study requires prior approval from a research ethics committee. All volunteers, including staff participating in experimental trials of MR imaging and spectroscopy techniques, should be screened before exposure. The volunteer should have given informed consent before the procedure is undertaken (see section [4.10](#)).

#### 4.3.2.1 Testing sequences

Volunteers engaged for in house testing of sequences etc. should be managed through clinical governance procedures [[1](#)]

### 4.3.3 Staff

Only **MR AUTHORISED PERSONNEL** should have free access to the **MR CONTROLLED ACCESS AREA**. Unauthorised staff must be screened for a wide range of factors (see section 4.12.5) and seek authority to enter the **MR CONTROLLED ACCESS AREA**.

### 4.3.4 General public

The general public will not have access to the **MR ENVIRONMENT** and it is therefore unlikely that any member of the public will be exposed above the recommended limits for correctly installed units.

### 4.3.5 Carers

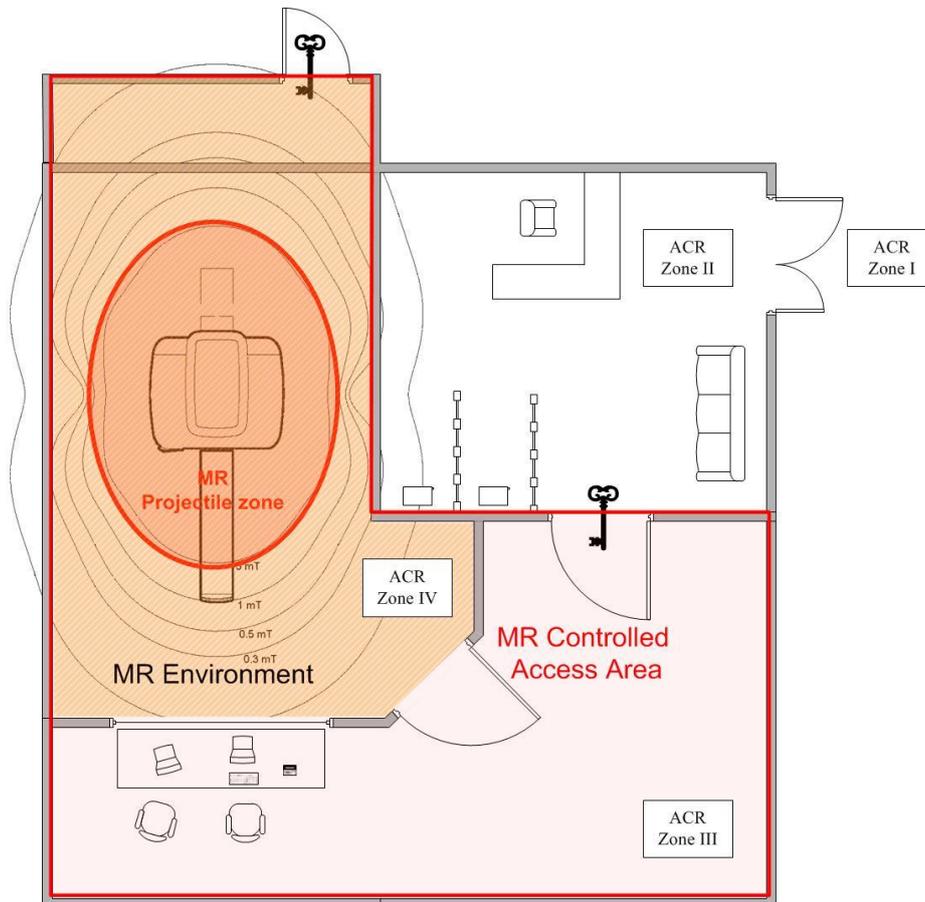
In cases where a carer or other individual accompanying a patient is needed to enter the **MR ENVIRONMENT** (for example to provide reassurance to the patient during the scan), they should be screened in a similar way to patients.

## 4.4 MR CONTROLLED ACCESS AREA

### 4.4.1 Definition of MR CONTROLLED ACCESS AREA

A locally defined area of such a size to contain the **MR ENVIRONMENT**. Access shall be restricted and suitable warning signs should be displayed at all entrances.

An example of the layout is given in [Figure 1](#).



**Figure 1 Example layout of an MRI unit**

### 4.4.2 Access to MR CONTROLLED ACCESS AREA

Access to the **MR CONTROLLED ACCESS AREA** shall be controlled by suitable control methods.

This may include the provision of self-locking doors. Devices for operating the locks such as keys or plastic cards, should all be non-magnetic and should only be made available to **MR AUTHORISED**

**PERSONNEL.** Where key codes are used and non-authorised staff are regularly gaining access, the code should be changed.

Free access to the **MR CONTROLLED ACCESS AREA** should be given only to **MR AUTHORISED PERSONNEL**. All other personnel, including unauthorised staff and visitors must be appropriately screened and seek authority to enter the **MR CONTROLLED ACCESS AREA**.

## 4.5 MR ENVIRONMENT

### 4.5.1 Definition of MR ENVIRONMENT

As defined by ASTM, ‘the three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.’

### 4.5.2 Screening for entry to the MR ENVIRONMENT and MR CONTROLLED ACCESS AREA



Screening is to be performed by an **MR AUTHORISED PERSON** trained to perform safety screening.



It is recommended that screening for entry into the **MR CONTROLLED ACCESS AREA** includes at least verbal questioning. A written questionnaire and provision of information about potential hazards is additionally required before authorisation to enter the **MR ENVIRONMENT** is given.

The questionnaire, which each person fills in, should be signed by the individual, verified, and then countersigned by an **MR AUTHORISED PERSON**, before entry is permitted (see section 4.12.5). This process should be subject to regular audit.

Information that is recorded and held as part of a patient's treatment and that is relevant to the patient's diagnosis and treatment should be treated as part of the patient's medical record whether or not it is physically held with the rest of the patient notes. The Department of Health has guidance on the management of patient records [58].

If the information relates to staff, and is relevant to their professional duties, then it should be regarded as part of their HR record and should be kept in line with local policy on HR records

Where personal information (whether for staff or patients) is held at the unit it should of course be held securely and treated in accordance with the provisions of the Data Protection Act [59].

The access of patients and volunteers to the **MR CONTROLLED ACCESS AREA** is covered by the sections on patient and volunteer management (4.10 and 4.12).

### 4.5.3 Warnings for those entering the MR ENVIRONMENT

All those seeking to enter the **MR ENVIRONMENT** must be warned of:

- the possible hazards of the magnetic field, in particular to the operation of active implantable devices, including pacemakers (see section 4.11.1.1 and section 5.4.7 on warning signs).
- the potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field.
- the possible malfunction of certain implantable medical devices if subjected to magnetic fields (see section 4.11). There is a considerable amount of literature available on the subject of which devices are affected see references [60, 61, 62, 63].



A person fitted with a heart pacemaker, and/or other implantable medical devices that could be affected, must not enter the **MR ENVIRONMENT** unless the device is an **MR CONDITIONAL** device and the **MR AUTHORISED PERSON** trained to perform safety screening has confirmed that **all** of the implant manufacturer's stated conditions for safe operation are met.

#### 4.5.4 Precautions for the MR ENVIRONMENT

Before entering, everyone must take the following precautions:

- they must remove mechanical watches, credit cards, other magnetic recording media and ferromagnetic objects. These may be placed in a suitable locker
- they must remove from their clothing all ferromagnetic objects such as coins, pins, scissors, keys, tools, hair grips, certain spectacles that have ferromagnetic parts, etc
- ferromagnetic objects such as tools, gas cylinders, trolleys, life support systems etc must not be allowed into the **MR ENVIRONMENT** except under a strict system of work.

It is not always obvious that an object is ferromagnetic. A ferromagnetic material detector may be used to check items in order to determine an object's ferromagnetic status.

#### 4.5.5 Supervision

During their presence in the **MR ENVIRONMENT**, unauthorised staff and visitors must be under supervision by an **MR AUTHORISED PERSON** trained to perform safety screening who is either in the **MR ENVIRONMENT** or can see the visitor at all times by some means.

#### 4.5.6 Access to MR ENVIRONMENT

The access of patients and volunteers is covered by the sections on patient and volunteer management (4.10 and 4.12). It is the ultimate responsibility of the chief executive of the institution to ensure that:

- all staff, having or likely to need access are adequately informed of the safety requirements and abide by them
- all those entering have been adequately screened in person and in terms of what they will be carrying.

### 4.6 MR PROJECTILE ZONE

#### 4.6.1 Definition of MR PROJECTILE ZONE

A locally defined volume containing the full extent of the 3 mT magnetic field contour, **or other appropriate measure**, around the MRI scanner. (A field strength of 3 mT was historically chosen to avoid the projectile hazard and it is also the relevant static field action level given in the Physical Agents (EMF) Directive [52]).

**For the majority of MRI units, restrictions on the introduction of grossly ferromagnetic objects associated with the risk of projectiles are applied to the entire magnet room and consequently only 2 defined areas, MR CONTROLLED ACCESS AREA and MR ENVIRONMENT are sufficient.**

There may be some sites who may find it useful to define a region within the **MR ENVIRONMENT** associated with the risk arising from ferromagnetic portable objects within the **MR ENVIRONMENT**. In such cases this term provides a clearer description of the hazard associated with such a region.

Where there is only one defined area all references in these guidelines to **MR PROJECTILE ZONE** will apply to the whole of the **MR ENVIRONMENT**.

### 4.7 MR AUTHORISED PERSONNEL

#### 4.7.1 Definition

An **MR AUTHORISED PERSON** is a suitably trained member of staff authorised to have access to the **MR CONTROLLED ACCESS AREA**.

It is important that staff working within an MRI unit are suitably trained and aware of their responsibilities for the safety of themselves and others. Sites may choose to subdivide access and supervision rights of the **MR AUTHORISED PERSON** to better reflect working practice:

##### 4.7.1.1 AUTHORISED PERSON (NON-MR ENVIRONMENT)

An **MR AUTHORISED PERSON** authorised to have free access to the **MR CONTROLLED ACCESS AREA** but not the **MR ENVIRONMENT**. They may supervise other persons only in this area.

- People who need free access to the **MR CONTROLLED ACCESS AREA**, but do not have permission to enter the **MR ENVIRONMENT** without an **AUTHORISED PERSON (SUPERVISOR)** and are not permitted to let others into the **MR CONTROLLED ACCESS AREA**, eg management, clerical staff, radiologists without any formal safety training

#### 4.7.1.2 AUTHORISED PERSON (MR ENVIRONMENT)

An **MR AUTHORISED PERSON** authorised to have free access to the **MR ENVIRONMENT** but not to supervise others.

- People who additionally are given free access to the **MR ENVIRONMENT** and take responsibility for their own safety within the **MR ENVIRONMENT**, eg supporting clinical staff, basic researchers.

#### 4.7.1.3 AUTHORISED PERSON (SUPERVISOR)

An **MR AUTHORISED PERSON** who is authorised to have free access and to supervise others in the **MR ENVIRONMENT**.

- People who need to perform safety screening of other people and take responsibility for the safety of others within the **MR ENVIRONMENT**, eg radiographers, clinical scientists.

### 4.7.2 Authorisation of personnel

The delegated **MR RESPONSIBLE PERSON** should formally approve certification of a member of staff as an **MR AUTHORISED PERSON** when the member of staff has satisfactorily completed training in their responsibilities and the safety requirements of MRI equipment. The MR unit should maintain a list of all **MR AUTHORISED PERSONNEL** together with full details of their training and certification with ready access available to the **MR RESPONSIBLE PERSON(s)**, **MR SAFETY EXPERT(s)** and **MR OPERATOR(s)**.

### 4.7.3 Training and authorisation

It is the responsibility of the **MR RESPONSIBLE PERSON** (the chief executive in the case of no delegation) to inform, as appropriate, all heads of departments and senior medical staff, who may have personnel that will be involved with MRI equipment, of the formal procedures for training and authorisation. All heads of departments and senior medical staff should emphasise to their staff that responsibility rests with the individual, who must at all times be aware of the potential hazards within the **MR CONTROLLED ACCESS AREA** and personally behave in such a manner as not to endanger his or her own health or safety or that of others.

**Table 3 Access and supervision rights of MR AUTHORISED PERSONNEL**

	<b>MR ENVIRONMENT</b>	<b>MR CONTROLLED ACCESS AREA outside MR ENVIRONMENT.</b>
<b>AUTHORISED PERSON (NON-MR ENVIRONMENT)</b>	May not enter without supervision	May enter and supervise
<b>AUTHORISED PERSON (MR ENVIRONMENT)</b>	May enter	May enter and supervise
<b>AUTHORISED PERSON (SUPERVISOR)</b>	May enter and supervise	May enter and supervise

### 4.7.4 Screening of MR AUTHORISED PERSONNEL

All **MR AUTHORISED PERSONNEL** must have satisfactorily passed appropriate screening for the required level of access. Repeat screening should take place at least annually and appropriate records should be maintained. All **MR AUTHORISED PERSONNEL** must satisfy themselves that they conform at all times, to the requirements of the screening process.

### 4.7.5 Responsibilities of MR AUTHORISED PERSONNEL

- On entering the **MR CONTROLLED ACCESS AREA**, all **MR AUTHORISED PERSONNEL** must comply with the safety recommendations given in section 4.4.

- All other persons, which will include visitors, patients and unauthorised staff, should have access only if accompanied by an [MR AUTHORISED PERSON](#).
- The [MR AUTHORISED PERSON](#) will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the [MR CONTROLLED ACCESS AREA](#).
- All [MR AUTHORISED PERSONNEL](#) who act as volunteers for scanning must conform to the appropriate requirements referred to in section [4.10](#).

## 4.8 MR OPERATOR

An [MR OPERATOR](#) is an [MR AUTHORISED PERSON](#) who is also entitled (see [4.7.2, above](#)) to operate the MRI equipment. [MR OPERATORS](#) are normally radiographers or radiologists but may include assistant practitioners, physicists, maintenance and research staff.

Sites may designate two types of MR Operators – clinical and technical/non clinical.

## 4.9 Control of equipment taken into the MR ENVIRONMENT

### 4.9.1 Equipment policy

The [MR RESPONSIBLE PERSON](#) should ensure that there is a clear policy for the purchasing, servicing and return to use, testing and marking of all equipment that will be taken into the [MR ENVIRONMENT](#).

### 4.9.2 Responsibility for entry

Control of equipment entering the [MR ENVIRONMENT](#) on a day-to-day basis is the responsibility of the [MR OPERATOR](#) responsible for the examination at the time. Only equipment that is known to be suitable should be taken into the [MR ENVIRONMENT](#) except if this is done under a system of work.

### 4.9.3 Labelling of equipment



The MHRA recommends that all equipment that may be taken into the [MR ENVIRONMENT](#) is clearly labelled using these markings **and where possible, the appropriate descriptive text should be used** (see examples in [Appendix 5](#)).

When labelling equipment as **MR CONDITIONAL** the conditions under which the device was tested must (where possible) also be included on the label. Equipment that is **MR CONDITIONAL** under one set of conditions may not be safe under other conditions, for example at a higher field strength. Without additional information, a facility that uses a particular system might mistakenly believe that this device would be safe for use with other systems.

Descriptions of **MR CONDITIONAL** should specify information such as the maximum magnetic field in which the device was tested, the magnitude and location of the maximum spatial gradient, the maximum rate of change of the gradient field, and radio-frequency fields tolerated in terms of RF interference, RF heating and type of transmit mode.

Departments will need to re-examine each device's safety status whenever changes are made to the MR environment, such as when switching to a new MR system or upgrading an existing system.

Example labels are given in section [Appendix 5](#).

### 4.9.4 Ancillary equipment

Normally, all equipment brought into the [MR ENVIRONMENT](#) – from wheelchairs, stretchers and emergency trolleys to cleaning equipment – should not contain significant amounts of ferromagnetic material in order to avoid the projectile effect from the static magnetic field.



Exceptions exist. There are circumstances in which ferromagnetic equipment is brought into the [MR ENVIRONMENT](#) under carefully controlled conditions – eg during combined X-ray and MRI interventional procedures in XMR suites.



Do not make assumptions about equipment such as pillows and sandbags. Pillows may contain springs and sandbags may contain metal pellets, increasing the risk of injury due to the projectile effect [64]. Devices which are not labelled are considered to be **MR UNSAFE**.

#### 4.9.5 Consumables

Many items such as consumables cannot be reasonably labelled. Sites should have processes in place to ensure that these items are safe.

#### 4.9.6 System of work

Sites should have systems of work in place for those exceptions where ferromagnetic objects need to enter the **MR ENVIRONMENT** eg during combined X-ray and MRI interventional procedures in XMR suites or work by the MRI engineering staff.

#### 4.9.7 Testing magnet



It is recommended that users have access to a strong > 0.1T handheld magnet or ferromagnetic detector for testing items [54] to be taken into the **MR ENVIRONMENT**.

### 4.10 Patient/volunteer management – clinical considerations

#### 4.10.1 Volunteers

- All volunteers, including staff participating in experimental trials of MR diagnostic equipment, should be screened for a wide range of factors before exposure (see section 4.12).
- Volunteers should be consenting and fully informed.
- Volunteers engaged for in house testing of sequences etc. should be managed through clinical governance procedures [1]
- In the case of volunteers taking part in trials over a period of time they should be reassessed at regular intervals.
- Local policies should include those who should be excluded as volunteers, for example women who are or may be pregnant and people under 18 years of age. It may also be prudent to state other parameters eg maximum number of scans that may take place per annum.
- A favourable opinion should be obtained from an appropriate research ethics committee; this should normally be a committee recognised by the UK Health Departments under the Governance Arrangements for Research Ethics Committees (GAfREC) [65, 66], but may be an institutional (university or other) convened ethics committee.
- Following advice from the National Research Ethics Service (NRES), it should be noted that under the Research Governance Framework for Health and Social Care, experimental procedures require ethical review where they are to be carried out in the formal research setting and managed as research. If undertaken outside the research setting, ethical review and research and development approval would not be required, although many NHS organisations have clinical ethics committees that would be an appropriate source of advice. National Institute for Health and Clinical Excellence (NICE) guidance on the interventional procedures programme will apply in such cases [67].



The MHRA recommends that centres have policies in place for the reporting and onward referral of those volunteers who are found to have abnormal scans.



The ethical issues arising from incidental findings during imaging research were discussed at a meeting in 2010. This is a complex area and researchers should review the report 'Management of Incidental Findings Detected During Research Imaging' [68]

## 4.10.2 Patient referrals



It is recommended that referrals be made on a dedicated MR request form. (This may not be possible at present with some electronic patient booking systems.)

Referrals should only be accepted from a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the employer's procedures to refer individuals for MRI. It is the responsibility of the referrer to identify those patients with implants and/or contraindications to MR before referral. However, the person taking the patient/volunteer into the **MR ENVIRONMENT** should be certain that all departmental safety checklists have been carried out and is entirely confident that it is safe to do so.

Healthcare organisations should require referrers to supply sufficient medical data (such as previous diagnostic information or medical records) relevant to the MR examination requested by the referrer to enable the accepting clinician to decide on whether there is a hazard associated with the exam.

The accepting clinicians or supervising radiologists must be fully informed of the patient's state of health and medical history when accepting requests for scans.

Patients should be exposed only with the approval of a registered medical practitioner who should be satisfied either that the exposure is likely to contribute to the treatment of the patient or that it is part of a research project that has been approved by a **research** ethics committee.

### 4.10.3 Responsibility for patients/volunteers whilst in the unit

While the patient is within the **MR CONTROLLED ACCESS AREA**, their health and well-being should be delegated to a clinician or supervising radiologist who is fully conversant with the current clinical aspects of the use of the particular MRI equipment and its effects on the safety, health and well-being of the patient.

The clinician or supervising radiologist will remain responsible for the safety, health and well-being of the patient throughout the period that the patient is within the **MR CONTROLLED ACCESS AREA** and any subsequent deleterious effects that are shown to be due to the scans.

Only personnel that have been appropriately trained, and are experienced in the use of MRI equipment, should scan patients.

Responsibility needs to be defined in research volunteer settings where there may not be a clinician or supervising radiologist.

### 4.10.4 Pregnancy and MR imaging



The MHRA recommends that pregnant patients be scanned in **NORMAL MODE** whenever possible.



The MHRA recommends that the decision to scan during pregnancy should, where possible, be made at the time by the referring clinician, an MR radiologist and the patient. The decision should be based on the hazards mentioned earlier and the hazards of alternative procedures weighed against the clinical benefit to the patient.

The Society of Radiographers advise in Section 9.3 of their guidance [55]

'Although it is likely that an initial discussion as to whether MRI is the most appropriate modality would take place between a referring clinician and a radiologist, there are many MRI units operating as standalone/satellite units often without access to radiologists. It is within the scope of practice for a suitably trained and experienced MR radiographer to advise patients and referring clinicians on the risks and benefits associated with MRI and to offer advice on the most appropriate imaging exam'

This decision should be recorded in the patient's notes. Whenever the decision to proceed with the examination is taken, the scan should be carried out using a sequence that finds an optimal solution of minimising the RF and noise exposure. Special attention should be given as accepted sound pressure

levels may still be of concern to pregnant women and the fetus. Pregnant women should not normally be exposed above the advised lower levels of restriction.

#### 4.10.5 Thermoregulatory response

The tolerance levels of exposure for individual patients and volunteers depends to a considerable extent on their individual physiological responses and condition of health, especially their thermoregulatory condition which may be very different from those of a typical healthy individual. It is important to have an in-depth understanding of the effects of fluctuating fields on the nervous and muscular systems together with that of the specific energy absorption rate.

Patients with certain medical disorders or under medication may be at some risk when scanning above the advised lower levels of exposure. In particular, patients with compromised thermoregulatory function may be particularly susceptible to RF heating; such patients may well include those with cardiac and circulatory problems, a fever, those with impaired renal function, those taking certain drugs such as vasodilators and diuretics and those with certain cancers.

In addition, neonates, infants, pregnant women and the elderly are likely to be considered compromised in this respect. In these circumstances, the clinician in charge must weigh the benefit of diagnosis against any possible risk.

The prevailing ambient conditions surrounding the patient and volunteer such as temperature, humidity and airflow will affect the rate of cooling of the individual and should also be taken into account (see section A2.1.4).

### 4.11 Implanted medical devices and other contraindications to scanning

Implantable medical devices fall into two main categories:

- **Active implantable medical devices.** These include: pacemakers, defibrillators, neurostimulators, cochlear implants and drug pumps, where functionality is dependent upon an energy source such as electrical, mechanical or pneumatic power.  
Some active implants contain an integral power source whereas others derive their necessary power through close coupling between an implanted coil and an external coil which forms part of the completed system. Active implants contain metal components, which may suffer damage during exposure to MR and the implant as a whole may be attracted by the magnetic field. Sensing/stimulation lead electrodes may inappropriately sense electrical energy induced by either the magnetic or RF fields and modify therapy. A potential may exist for tissue damage from induced current especially RF, where high current density flows through very small surface electrodes. Larger metallic components may also suffer temperature increase.
- **Non-active implantable medical devices.** These are passive in that they require no power source for their function. For example: hip/knee joint replacements, heart valves, aneurysm clips, coronary stents and breast implants.

Both active and non-active implantable medical devices can contain metallic components, which may render the device incompatible with MR and therefore contraindicated by the implant manufacturer or may cause artefacts that can affect image quality. However, there are a large number of implantable medical devices that are either **MR SAFE** or **MR CONDITIONAL**.

Surgeons should be encouraged to provide patients with accurate documentation and information about medical devices implanted into them.



The MHRA recommends that the hospital or clinical institution should develop a policy for the identification, documentation, imaging and provision of any necessary aftercare for patients with implantable medical devices undergoing an MR examination.

Information pertaining to implantable medical devices should be available before the patient attends their examination in order to allow time to confirm compatibility of the device.

Users should refer to the implant manufacturers for advice on the compatibility of each implantable medical device.

There are a number of implantable medical devices that will need careful consideration before exposing the patient or volunteer. Some examples are given below but the list is not meant to be definitive.



Shellock produces a website [63] with details of tested devices and a 'Reference Manual for Magnetic Resonance Safety, Implants and Devices' on an annual basis [69]. Care should be taken when referring to this document as devices may be different in the USA to those in use in the UK.

Other online resources are available on a commercial basis such as MagResource [70].

#### 4.11.1 Examples of active implantable medical devices

##### 4.11.1.1 Cardiac pacemakers/cardioverter defibrillators and leads



Patients and prospective volunteers with implanted pacemakers must not be examined by MR diagnostic equipment and should be kept outside the 0.5 mT (5 Gauss) stray field contour unless the device is **MR CONDITIONAL** and the patient is to be scanned in line with the implant manufacturer's guidance.

The static magnetic field, the time-varying magnetic gradient fields and the radio-frequency fields required for MR all create a hostile environment thought to cause severe disruption of pacemaker function. Concerns include:

- pacemaker movement
- unexpected programming changes eg resetting to default parameters
- inhibition of pacemaker output
- inappropriate sensing of fast transients and elevated cardiac rates
- transient asynchronous pacing
- pacemaker reed switch malfunction
- rapid cardiac pacing
- the induction of ventricular fibrillation
- local thermogenic cardiac tissue destruction.
- RF heating risks may exist for patients who have retained epicardial or pericardial pacing wires, even if the pulse generator has been removed.

These have all been cited in support of the view that MR examinations for patients who have a pacemaker or cardioverter defibrillator must be avoided.

MRI safety for pacemaker and implantable cardioverter-defibrillator (ICD) patients continues to be a source of debate in the medical literature. This issue has gained importance in recent years, as MRI scans have become more extensively used in diagnostic imaging, with scan volume increasing.

Various limited studies have now been reported in literature which promotes the view that MRI can be safe but these are somewhat controversial. Observations are that sample sizes were low, pacing capture has been observed (in animals) for up to 12 hours, some pacemakers experienced an 'electrical reset', and some ICD models experienced post-scan interrogation problems. The greatest concern would be the observed change in pacing threshold and that there was no long-term follow-up of patients to detect latent or longer term changes.



A person fitted with a heart pacemaker must not enter the **MR ENVIRONMENT** unless the device is an **MR CONDITIONAL** device **and** the **MR OPERATOR** has confirmed that **all** of the implant manufacturer's stated conditions for safe operation are met.



There have been a number of deaths following the scanning of patients with implanted pacemakers where in most cases the presence of the pacemaker was undetected. This emphasises the responsibility of the referring clinician to identify those patients with implants and/or contraindications to MR, before referral for examination.

References [24], [60] and [71] provide further information.

#### 4.11.1.2 Neurostimulators

A wide variety of neurostimulators are now in use for the control of pain, functional electrical stimulation or limb movement through the stimulation of muscles and nerves, deep brain stimulation in the treatment of involuntary movement, such as in Parkinson's Disease, neurostimulation for bladder/bowel control as in continence devices, and vagus nerve stimulation for the control of epilepsy seizures.

Neurostimulators may either contain an integral power source or derive their power through coupling to an external part of the device.

Neurostimulators may be implanted in the abdomen, the upper chest region or (in the case of neurostimulators for functional movement) within or adjacent to limbs, with leads and electrodes running subcutaneously to the target site, such as the spinal cord or the appropriate nerve or muscle requiring stimulation.

Concerns about MR safety relate to the radiofrequency and gradient fields that may interfere with the operation of these devices. Malfunction of the device could potentially cause pain or discomfort to the patient or damage to the nerve fibres at the site of the implanted electrodes. Additional concerns include the potential for heating of the neurostimulator, its leads, lead electrodes and the subsequent thermal injury to surrounding tissue.



The MHRA recommends that patients implanted with neurostimulators should not undergo MR unless the device is a **MR CONDITIONAL** device and the **MR OPERATOR** has confirmed that **all** of the **implant** manufacturer's stated conditions for safe operation are met.

#### 4.11.1.3 Implantable drug infusion pumps

Programmable implantable infusion pumps usually contain ferromagnetic components and a magnetic switch and therefore are usually a contraindication for MR procedures.

Other implanted infusion pumps are not directly programmable but have a constant flow rate and also contain ferromagnetic components. Infusion pumps can be powered by an internal power source via an integral battery, through a type of mechanical clockwork mechanism or powered by gas pressure through an internal pressure reservoir system. The latter may be susceptible to temperature changes in surrounding tissues.

For all these devices please refer to the manufacturer for advice on MR safety [24, 60].

#### 4.11.1.4 Programmable hydrocephalus shunts

The pressure setting of programmable hydrocephalus shunts may be unintentionally changed by the magnetic field associated with MR procedures. This could lead to over- or under-drainage of cerebrospinal fluid and result in deterioration of patient health. If these patients are to undergo an MR examination then a programmer and a trained clinician should be available to verify the correct setting and to reprogram the device (if required), immediately following the MR procedure. Advice must be given to the patient on how to recognise over- and under-drainage and who to contact should these conditions develop. Further guidance was provided in Safety Notice SN 2001(27), now withdrawn, and is reproduced below.

In order to reduce the risk of over- or under-drainage associated with an incorrect pressure setting in programmable hydrocephalus shunts, hydrocephalus shunt implant centres and all MRI departments should develop a policy for identifying, documenting and imaging programmable hydrocephalus shunts. Suggested items for inclusion are given below.

1. Advising patients of the type of shunt provided and whether a potential may exist for reprogramming by MRI. Ideally, this information should be provided at implant, but consideration could be given to contacting patients retrospectively.
2. Providing patients with appropriate device documentation (eg a 'shunt passport') which can be shown to clinicians. This could include details of:
  - the manufacturer, model, batch, and serial number of the shunt;
  - the pressure setting - this should be updated each time it is adjusted;
  - information for the patient and MRI departments warning of the potential hazards.
3. Keeping information about hydrocephalus shunts, e.g.
  - manufacturers' literature, such as manuals and pressure setting charts;
  - information to aid in the interpretation of X-rays, such as X-rays detailing the appearance and features of various models of shunt.
4. Ensuring that the pre-MRI screening questionnaire specifically asks 'Do you have a hydrocephalus shunt?' and if affirmative, 'Is it a programmable shunt?'
  - If the hydrocephalus shunt is non-programmable, then MRI at 1.5 T may proceed, unless contra-indicated by the manufacturer's instructions.
  - If the patient does not know the type of shunt, or the current pressure setting is unknown, and this information cannot be obtained from the patient's notes, a plain skull film should be taken and interpreted before proceeding with MRI. Where doubt exists about shunt identity, the relevant clinician should be consulted.
5. Following MRI, advising patients of the symptoms of over and under-drainage and providing details of who to contact should they develop.

In all cases where a patient with a programmable shunt is to undergo MRI, a programmer and a trained clinician should be available to check the setting and to reprogram (if required) immediately following MRI.

MRI departments should be prepared to deal with shunts that have been implanted in other centres and about which little information is available.

#### 4.11.1.5 Cochlear implants

Cochlear implants usually have ferromagnetic components, and are activated by electronic and/or magnetic mechanisms. However, some devices are **MR CONDITIONAL** and the patient can be scanned in line with the implant manufacturer's guidance.

#### 4.11.2 Examples of non-active implantable medical products

##### 4.11.2.1 Hip/knee joint replacements

Patients and volunteers with large metallic implants eg hip implants, where heat generation may occur, are not excluded but should be monitored carefully, both in the approach to the magnetic field and during the examination. If discomfort is experienced, MR exposure should be discontinued.

The presence of large metallic implants may also severely degrade image quality if near to the imaging volume.



The presence of bilateral hip implants appears to increase the risk of discomfort and burns [32].

##### 4.11.2.2 Heart valves

Many patients and volunteers with prosthetic cardiac valves have been safely scanned without the danger of valve displacement. Under testing, the measured attraction to the static magnetic field is often minimal compared to the force exerted by the beating of the heart [24, 60]. The manufacturer should be asked to confirm MR safety of the device.

##### 4.11.2.3 Occlusive clips/staples

A wide variety of these devices have been evaluated for MR safety.

Some occlusive clips are ferromagnetic and can be displaced by the static magnetic field, particularly during the first six weeks after insertion. Occlusive clips applied to the fallopian tubes can similarly be displaced if local fibrosis has not yet occurred. If there are any doubts about the nature of the clip during the first six weeks after its insertion, [advice from the MR SAFETY EXPERT](#) should be sought.

**Aneurysm clips** [72] in the head are a **particular danger**, as fibrosis may not always occur.



Scanning must not proceed unless there is positive documented evidence that the aneurysm clip is non-ferromagnetic. For example, titanium, tantalum and vanadium are non-ferromagnetic, whereas stainless steel has varying degrees of para- and ferromagnetism.

This is still a very controversial area with MR units split on whether or not to scan patients with aneurysm clips under any circumstances. Where MR units do scan patients, the radiologist and the referring clinician/implanting surgeon should be responsible for obtaining and checking the documented evidence that the clip is safe to scan. It is recommended that a local policy is developed for staff to follow.



People accompanying patients, who themselves have aneurysm clips, should not under any circumstances enter the [MR ENVIRONMENT](#).

For further information please see references [24] and [60].

#### 4.11.2.4 Intravascular stents, filters and coils

A wide variety of these devices have been evaluated for MR safety. Although most of these implants are made from non-magnetic metals, some have exhibited magnetic properties. However, these devices typically become securely attached to the vessel wall after surgery in approximately 6–8 weeks due to tissue growth. An MR examination should not be performed if the device is not firmly in place or positioned properly within the vessel.

Devices that are non-ferromagnetic are considered safe for patients undergoing MR imaging up to 1.5 T immediately after implantation. However, if the device is made from material that is weakly ferromagnetic eg certain stainless steels, a period of 6–8 weeks is still recommended to allow for tissue growth [61].

Unfortunately not all manufacturers differentiate between non-ferromagnetic and weakly ferromagnetic, resulting in confusion for the MR safety aspects of these implants.

Heating of stents may be an issue depending on the stent's materiality, length, and the transmit frequency of the MR system, particularly in patients with multiple devices implanted. In these cases, [advice from the MR SAFETY EXPERT](#) should be sought.

Obtaining information that clearly identifies the device, (material, brand name, serial/model number etc), and the manufacturer is essential. Users should refer to the manufacturer for advice relating to MR safety.

#### 4.11.2.5 Ocular implants

The potential exists for the implant to be moved or dislodged causing tissue damage. In addition, problems may be caused by the possible demagnetisation of permanent magnets used to locate false eyes. For patients with retinal tacks made from ferromagnetic material, there is a high risk of injury to the eye and possible loss of vision [24, 60]. Users should refer to the manufacturers for advice relating to MR safety.

#### 4.11.2.6 Penile implants

There are many different penile implants on the market, some of which have demonstrated deflection forces during exposure to the static magnetic field of the MR system. Unless MR safety is assured it is recommended that patients with these implants do not undergo an MR procedure, as there is a potential for patient discomfort and/or injury.

#### 4.11.2.7 Tissue expanders and implants

Some breast tissue expanders and mammary implants contain injection sites that are used for saline placement to expand the prosthesis during surgery. The injection ports may contain stainless steel and may also be constructed with magnetic ports to aid site detection. Some of these devices will experience

attraction forces by the magnetic field. Hence, the device may produce significant torque and movement of the expander. RF induced heating may also occur. As such, these implants containing injection sites are contraindicated for MR [60].

For Trilucent™ (soya bean oil) breast implants, although the MHRA has recommended that women with these implants should consider having them removed, a small number of these will still be in situ. They incorporate a small passive transponder. There is a small possibility that RF induced heating may cause localised heating of the surrounding tissue or breast implant adjacent to the transponder [73]. The degree of temperature rise or degree of damage that might be caused is difficult to predict. However, MRI is the only effective non-surgical means of diagnosing rupture of Trilucent™ breast implants and has been used on several hundreds of patients for this purpose without report of any incident to the MHRA. As such, if MRI is carried out it should be done so with caution and awareness to the RF induced heating effect. Sequences should be chosen to minimise the possibility of this effect.

#### 4.11.2.8 Intrauterine devices

Intrauterine contraceptive devices (IUD) are usually made from plastic with an active copper element. Testing has indicated that these objects are safe for patients using MR systems operating at 1.5 T or less. [60]

#### 4.11.3 Conclusion on implantable medical devices

-  Users should refer to implanting clinicians and the manufacturers for advice on the MR safety of all implants.
-  MR units should develop and follow local policies with regard to MR for those patients with implanted medical devices.
-  Whenever MRI equipment is replaced or upgraded checks will need to be made to ensure that devices are still suitable for their particular MR environment.
-  When in doubt the user should assume the device is **MR UNSAFE**.
-  When in doubt as to whether or not to scan, assessment of the risk versus benefit may help to determine the way forward.
-  It may be helpful for the user to refer to MR safety websites, textbooks, any pertinent peer reviewed literature and the work done by Shellock and Kanal on implants [24, 60, 61].

#### 4.11.4 Transdermal patches

 Burns due to the presence of metallic components in medicinal patches have been reported to the MHRA.

 Heating of patches containing fentanyl may result in a serious overdose. A drug safety update was issued in 2008 [74].

 Transdermal medicinal patches containing metal **and those that may be affected by heat** should be removed and replaced after scanning if this can be done without affecting patient treatment.

#### 4.11.5 Tattoos

Tattoos may contain iron oxide or other ferromagnetic substances that are conductive. During scanning, patients should be asked to report any discomfort immediately. ACR recommends that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MRI process if these tattoos are within the volume in which the body coil is being used for RF transmission. [54]

#### 4.11.6 Makeup

All make-up, particularly eye make-up should be removed as it may also contain metallic fibres.

#### 4.11.7 Metallic foreign bodies

The presence of metallic objects such as bullets, pellets, shrapnel, concealed body piercing, rings, shot etc., or other types of metallic fragments, in particular ferromagnetic objects, is a particular hazard both external and internal to the body. This is of particular relevance to patients who are or have been involved in the manufacture of metal products. The embedded metal fragments will heat up and may move or become dislodged. Consideration must be given to the site of the metallic foreign body; the potential for injury is greater if the object is near soft tissue structures and/or significant vessels eg aorta or carotid artery.

##### 4.11.7.1 Penetrating foreign body in the eye

One of the most vulnerable parts of the body is the eye. The adequate screening of patients and others with **suspected** intra-ocular ferromagnetic metallic objects is most important before they are allowed to enter the [MR ENVIRONMENT](#).



Where the presence of metal fragments in the eye is **suspected but unproven** and no X-ray is available, it should be policy to obtain an ocular X-ray to confirm or negate presence of metal before MR scanning is performed [24, 60, 61].

##### 4.11.7.2 Body piercing

Most body piercing is made from non-ferromagnetic materials (this can be tested by use of a strong hand-held magnet). The main issue may be artefact induction and heating if the piercing is near the imaging volume, if there is any doubt about the safety of the piercing or potential to cause artefacts, it should be removed.

#### 4.11.8 Indwelling catheters

Indwelling catheters are unlikely to contain ferromagnetic material but connections, safety pins and support stands should be checked, removed and an appropriate substitution made.

#### 4.11.9 Assistive technology

Metallic orthoses, spectacles and hearing aids should be removed if there is a possibility of heat generation and/or damage relating to electric circuitry failure. Sensory problems for the patient resulting from their removal must be catered for.

### 4.12 Patient/volunteer management – scan preparation

#### 4.12.1 Availability of previous examinations

It is essential that there is a process in place whereby images and reports of any relevant previous imaging examinations are available before the MR examination. For some patients their medical records or notes will also be required.

#### 4.12.2 Patient identification

There should be a policy to ensure that the patient is correctly identified. The policy should include provision to ensure correct identification of the unconscious and/or sedated patient, children, those patients who are deaf, those patients with learning difficulties, patients with mental health problems and those for whom English is not their first language.

### 4.12.3 Reassurance and explanation

A suitably trained person should describe the examination to the patient or volunteer and any accompanying family or staff, explaining the sights, sounds and experiences to be anticipated and predicting the likely length of examination.

Pamphlets and other handout information on the MR procedures, including copies of screening questionnaires should be made available to all patients and others **well before** MR imaging takes place.

### 4.12.4 Patient measurement



The MHRA recommends that patients' **height** and weight are measured before scanning. It is important that a current measurements are used at the time of scanning in order for the MRI equipment to predict the SAR levels to which the patient will be exposed.

### 4.12.5 Screening prior to examination

Screening should take place on several occasions prior to actually starting the examination.

The first patient interview will cover major safety questions such as pacemakers, aneurysm clips, electronic implants and pregnancy. This should take place at the time that the request is generated in order to prevent an inappropriate examination being booked.

On arrival in the unit the patient should be asked to complete a screening form. An appropriately trained and experienced **MR AUTHORISED PERSON** should then review the screening form with the patient. The person performing this review should understand all the issues and potential hazards within the MR environment and should be familiar with the screening form. The patient and the member of staff should sign the form.

Immediately prior to entering the scan room it is recommended that the **MR OPERATOR** performing the examination should visually and verbally screen the patient. For further information related to the screening process users may wish to refer to reference [24].

Procedures should be in place for patients who are unable to complete a checklist or have an identified medical history, for example an unconscious and unidentified patient with head injury. It should set out how safety checks can be instituted in this case (eg check X-ray, physical examination for pacemaker by referring consultant).

While the use of conventional metal detectors is not recommended, ferromagnetic detection systems may additionally be used [54]. Their use for the screening of persons should be recorded onto the MRI Safety Questionnaire prior to countersigning by an appropriately trained MRI approved member of staff.

Examples of screening forms are available from the BAMRR [75] and MRI safety website [63].

Screening must take place every time the patient attends the MR unit, even if the patient has already had a previous MR examination (see also section 4.5.2).

Screening consent/checklist forms should conform to standards for patient information eg plain English, 14-point size font minimum and available in alternative languages appropriate to local population (Welsh, Urdu, etc.) and will include the following: (the list is not definitive)

- any relevant patient condition including recent surgery, pregnancy, breastfeeding, medication, conditions relating to thermoregulatory function, breathing disorders, allergies to drugs and/or contrast medium etc.
- the presence of implantable medical devices including: cardiac pacemakers, cardioverter defibrillators, heart valves, electronically activated implantable drug infusion pumps, cochlear implants, neurostimulators, programmable hydrocephalus shunts, aneurysm clips, ocular implants, penile implants, joint replacements, etc.
- the presence of metallic objects:
  - in the body such as bullets, pellets, shrapnel, or other types of metallic fragments
  - attached to the body such as body piercing
  - on the body such as hairpins, jewellery, brassieres, hearing aids, spectacles, dentures with metal components, make-up, tattoos, transdermal patches etc.

- clothing with metallic / conductive content

It is important to identify the presence of metallic items on the patient and remove these items for safekeeping, together with magnetised bank, credit and library cards. The appropriateness of metal and ferromagnetic material detectors is dealt with in section 5.4.10.

#### 4.12.6 Patient clothing



Scanning patients wearing fabrics containing conductive fibres has resulted in patient burns [76].



It is recommended that patients change into appropriate clothing provided by the MR unit to ensure safety and to prevent artefact production. The material and design of such clothing should not contain metallic fibres, labels, pockets, buttons or fasteners, nor should it inhibit heat loss.

#### 4.12.7 Claustrophobia

The space available in the magnet interior with or without the radiofrequency coils can be restrictive. Patients who are not normally claustrophobic may find it unpleasant. It is worth spending time and effort optimising patient comfort and ensuring confidence. Continual reassurance throughout the scan is essential and light sedation may occasionally be required (if appropriate).

Exceptionally, an accompanying relative or attendant appropriately screened, checked and authorised, may be allowed to remain in the scan room in verbal and, if necessary, physical contact with the patient.

#### 4.12.8 Positioning the patient

Two issues are important here: patient comfort and patient safety. Time taken to ensure that the patient is comfortable will lead to greater patient compliance with the scan. With regard to patient safety, the prevention of burns is the major concern.



Poor positioning of the patient and associated cables, leads and sensors, have been the cause of many burns reported to the MHRA.



Electrical burns may not be painful immediately as they can start to cause tissue damage at temperatures as low as 43°C [34].

To avoid burns caused by RF heating [62]:

- ensure that sufficient insulation is placed between the cable and the patient if contact cannot be avoided
- do not loop conductive cables or allow cables to cross one another
- do not pass cables diagonally across the patient
- ensure that cables run parallel to the bore of the magnet and as close to the centre of the bore as possible
- ensure that cables do not touch the bore of the magnet
- ensure that cables exit the bore of the magnet as close to the centre as possible
- ensure that the patient's skin does not touch the bore of the magnet, or come within 1 cm of touching, transmitting RF coil elements. Use insulation such as the foam pads provided by the MR manufacturer if necessary
- ensure that no conductive loops form with any parts of the patient's body ie avoid skin-to-skin contact. Foam pads can be placed between the thighs, between the arm or hand and the trunk and between the ankles to avoid the formation of any conductive loops
- ensure that sensors are placed outside the scanning area whenever possible, as well as away from RF coils

- ensure that regular checks for damage are made on all coils, cables and leads for damage and do not use if damage is seen
- Use only high impedance leads; fibre optic leads are preferred
- ensure that the patient is instructed to inform staff immediately if they feel any focal warming
- ensure that the sites of all sensors are regularly checked for any evidence of heating if the patient is unconscious or for any reason unresponsive
- ensure that you are familiar with and follow the manufacturer's instructions at all times. This includes using only the monitoring equipment, ECG wires, leads, electrodes and accessories recommended by the MR system manufacturer.



The use of clothing or blankets as a form of insulation is not recommended.



The MHRA recommends that users use foam pads, 1–2 cm thick, to insulate the patient from cables, [transmitting RF elements](#), the bore and between limbs.

#### 4.12.9 Acoustic noise

The time-varying magnetic field gradients produce audible noise within the magnet interior. This is particularly relevant to fast scan sequences and high field equipment. Patients should be clearly warned of this. Audible noise should be kept to a minimum. All patients and volunteers being scanned should wear hearing protection. When the noise level exceeds 80 dB(A) it is recommended that staff and others remaining in the scan room wear non-metallic earplugs and/or ear defenders (see appendix [A2.2.2](#)). In the case of the anaesthetised patient hearing protection should always be provided even at moderate levels. Staff should be trained in the selection and fitting of hearing protection.



The fit and function of hearing protection should always be verified before commencing scans.

Manufacturers should have specified the noise level for normal operation of the equipment but sites must carry out their own risk assessments related to acoustic noise exposure [\[51\]](#).

#### 4.12.10 Setting bore conditions for scan duration

Adequate lighting and ventilation in the magnet interior are important. Care should be taken if pillows, blankets or covers are used to ensure that they are suitable and that heat loss is not inhibited. At all times during scanning, the [MR OPERATOR](#) should be in a position see any signs of discomfort or concern exhibited by the patient.

#### 4.12.11 Communication

A two-way intercom between operator and patient is ideal. Patients should generally be encouraged to close their eyes and relax during the procedure. Recorded music or narrative of the patient's choice can be made available via a suitable system.

#### 4.12.12 Panic alarm

An alarm / panic button must be provided at all times. The device should be given to all patients with an explanation of its intended use.

#### 4.12.13 Patient monitoring

Patients should be monitored routinely if the potential exists for a change to their physiological status during the MR procedure. For patients who are unstable, anaesthetised, sedated or at risk, monitoring is required. Monitoring is recommended when scanning patients in the [RESEARCH / EXPERIMENTAL MODE](#). Local policies should be agreed and followed (see section [4.13](#)).

All monitoring should be undertaken using dedicated **MR CONDITIONAL** equipment [24, 60, 61, 62]. Use only high impedance leads (fibre optic leads wherever possible). Care must be taken to place all leads, electrodes and sensors correctly (see section 4.12.8).



There have been adverse incidents reported where inappropriate devices have become hot enough to cause severe burns, due to the heating effect of the radiofrequency field.

In ECG monitoring, artefacts relating to the T-wave amplitude have been recorded at 0.3 T and are attributed to rapid movements of blood which, acting as a conductor perpendicular to the static field, induces a voltage potential. The magnitude of this effect has been investigated up to 8T [77]. However, this change in the ECG trace does not appear to be clinically significant.

Patients who are being monitored must be advised to inform staff immediately if warming or discomfort is felt at the sensor site.



The MHRA recommends that regular inspections of sensor sites must be made if the patient is anaesthetised or unresponsive for whatever reason [24, 60, 61, 62, 78] (see section 2.2.7).

Responsibility for the correct placing of all leads, cables and sensors must be **clearly** defined and included in local procedures.

The **MR OPERATOR** must always maintain visual and audio contact with the patient. The **MR OPERATOR** must not leave the control room whilst the patient is on the table unless it is to enter the scan room.

## 4.13 Management of patients when scanning in the CONTROLLED MODE

### 4.13.1 Advice from the IEC

The IEC recommends medical supervision of patients undergoing scanning in the controlled mode. Medical supervision should include arrangements for the adequate medical management of patients who may be at risk from some parameters of exposure to MRI equipment due to their own medical condition, the levels of exposure or a combination of both. Medical supervision requires a positive assessment by a qualified medical practitioner of the risk versus benefit for a particular scan, or a decision by a qualified practitioner that the patient satisfies a set of objective criteria, formulated by a medical practitioner, for the parameters of the scan and the condition of the patient. Medical supervision may entail physiological monitoring.

### 4.13.2 Advice from ICNIRP

ICNIRP recommends that exposures above the normal mode are carried out under medical supervision.

'real-time temperature monitoring may be performed during MR procedures in the controlled operating mode for patients at risk and should be performed in all cases in the experimental operating mode.'

### 4.13.3 Conclusion from the MHRA



The MHRA recommends that MR units develop their own local protocols for the medical supervision and monitoring of patients to be scanned in the controlled mode. In most cases, visual supervision of a conscious patient by the **MR OPERATOR** will be sufficient to ensure the safety of the patient.

Protocols should include:

- Groups of patients for whom monitoring is appropriate.
- Parameters to be monitored.
- **Burn prevention.**
- Detail of what parameter changes are significant and what changes are artefacts caused by the static field.

- Who should be responsible for interpreting the results of any monitoring?
- How to obtain appropriate medical help when required.

The number of sequences should be limited to those that are necessary.

Pregnant women should not normally be exposed above the lower advised levels of restriction.

## 4.14 Anaesthesia

### 4.14.1 Introduction

The continuous presence of a strong magnetic field and restricted access to the patient means that the provision of anaesthesia within MR units presents unique problems.

A nominated consultant anaesthetist should be responsible for anaesthesia services in MR units.

Adequate space should be made available for the provision of anaesthesia services. Immediate access from the scan room to the anaesthetic preparation/recovery area is essential as, in the event of an emergency, resuscitation should not take place within the magnet room.



Exceptions exist. There are circumstances in which resuscitation can be undertaken in the MR ENVIRONMENT under carefully controlled conditions – eg during combined X-ray and MRI interventional procedures in XMR suites.

A remote monitoring facility should be available to allow the anaesthetic team to remain outside the scan room once the patient is stable, should they wish to do so.

The responsibility for the safe positioning of sensors and all cables/leads needs to be clearly defined.



The Association of Anaesthetists of Great Britain and Ireland has updated its guidelines specific to MR [78, 79]. It is recommended that they be read in conjunction with this document.

### 4.14.2 Preparation

Patients should be prepared in a side room outside the MR ENVIRONMENT and no ferromagnetic equipment should be brought into the MR PROJECTILE ZONE. Plastic intravenous cannulas should be carefully taped to the patient and plastic connectors used at all times. Drip set-up, patient intubation and induction of anaesthesia with or without ventilation should be carried out in the side room. Visual inspection and full monitoring (as above) are essential.

### 4.14.3 Equipment

All equipment entering the MR PROJECTILE ZONE must be suitable [62]. The hazards associated with using the wrong equipment include the projectile effect, burns and equipment malfunction. Funding for dedicated MR CONDITIONAL or MR SAFE equipment should be sought during the planning phase.

The need for acoustic protection during MR imaging might make audible alarms inappropriate (see appendix A2.2.2). Clear visible alarms should be provided on all monitors when the anaesthetist is in the scan room with the patient. Anaesthetists remaining in the control room should have an unobstructed view of the remote monitor, anaesthetic machine and patient.

### 4.14.4 The supply of gases

Piped gases and suction will be required in the anaesthetic room, the scan room and the recovery area. Gas scavenging systems will also be required. The emergency oxygen cylinder should be connected via an area valve service unit in the event of failure to the mains supply. This cylinder should be secured and marked to ensure that it is not inadvertently taken into the MR ENVIRONMENT [105]. Further information is available from NHS Estates or from the Association of Anaesthetists of Great Britain and Ireland.



Where users are unsure of the compatibility of gas cylinders, they should be checked with a strong hand-held magnet or ferromagnetic detector before being allowed into the controlled area. This should include valves, regulators and keys.

#### 4.14.5 Appropriate training

An appropriately trained and experienced anaesthetist, who is fully conversant with the clinical safety aspects of exposure to MR diagnostic equipment, **must** attend the patient at all times when anaesthetics are being administered.

### 4.15 Record of scans

#### 4.15.1 Records and archiving

The MHRA has previously recommended that detailed records are kept of the imaging parameters. These data now form part of the DICOM image header.

The Digital Imaging and Communications in Medicine (DICOM) standard was created by the National Electrical Manufacturers Association [80] (NEMA) to aid the distribution and viewing of medical images. Part 3 [81] of the standard contains details of the general and modality modules.

If sites do not transfer all images to PACS then a local backup should be kept.

Other information that should be kept is:

- details of contrast media administered to the subject (see section 4.16).

This information should be held with a copy of the patient/volunteer consent form.

This information will form part of the patient notes and should be held in safe keeping for a period that ensures compliance with the current guidance from the Department of Health [58].

The data should be recorded chronologically in a log of scans, the current volume of which should be available at all times at the operator's console. All volumes of the scan log, all the patients' and volunteers' records should be held in safe keeping for a period that ensures compliance with the current guidance from the Department of Health. It should be in a form from which full details can be retrieved within this period if required.

### 4.16 Contrast media and anti-spasmodics

#### 4.16.1 Supervision

The administration of contrast media to patients must be under the supervision of a registered medical practitioner. The medically qualified professional will take the ultimate responsibility for the health of the patient during the scan and any subsequent deleterious effects that arise from the administration of the contrast medium.

Current regulations on prescribing state that a nurse independent prescriber or pharmacist independent prescriber can prescribe any licensed medicine for any medical condition within his/her competence.

Note that podiatrists and physiotherapists are now permitted to train as independent prescribers. Some drugs and contrast agents may be administered by non-medical practitioners under a Patient group directive (PGD) or a patient specific directive (PSD). PGDs can only be used by certain registered and regulated health care professionals. Support staff can use PSDs but not PGDs

There are still some limitations for nurse independent prescribers on controlled drugs, and pharmacist independent prescribers who are as yet, unable to prescribe controlled drugs [82].

For units with a remote consultant radiologist, advice is given in RCR/SCoR [43] and RCR guidance [44].

The administration of contrast media to patients must be within the legal framework and PSDs and PGDs are legal requirements for a non-medical practitioner to be able to administer a Prescription Only Medicine (POM).

## 4.16.2 Contraindications to administration of contrast agents

Prior to administration, care should be taken to ensure that there are no contraindications relating to administration of the agent to the patient. Units are encouraged to develop local policies relating to those patients who have an allergic history, are pregnant or breastfeeding, as well as for children and neonates. The unit must have readily available drugs and equipment to deal with all possible reactions including anaphylactic shock [24].



It is thought that gadolinium containing contrast agents can cause a condition known as nephrogenic systemic fibrosis in patients with advanced kidney dysfunction. Details of this condition and guidance on the use of gadolinium containing contrast agents can be found on the MHRA website [83] and reproduced below:

### Advice for healthcare professionals:

The following risk-minimisation measures should be used for gadolinium-containing contrast agents:

#### Renal-function monitoring

- Renal function should be tested in all patients receiving high-risk agents, and is generally advisable for patients receiving medium-risk or low-risk agents. It is particularly important to screen patients aged 65 years or older

#### Renal impairment

- For patients with severe renal impairment (glomerular filtration rate [GFR]<30 mL/min/1.73m<sup>2</sup>), use of a high-risk agent is contraindicated. If use of a medium-risk agent cannot be avoided or if it is necessary to use a low-risk agent, a single lowest dose possible can be used and should not be repeated for at least 7 days
- For patients with moderate renal impairment (GFR 30–59 mL/min/1.73 m<sup>2</sup>), if it is necessary to use a high-risk agent a single lowest dose possible can be used and should not be repeated for at least 7 days

#### Perioperative liver-transplantation period

- Use of a high-risk agent is contraindicated. If use of a medium-risk agent cannot be avoided or if it is necessary to use a low-risk agent, a single lowest dose possible can be used and should not be repeated for at least 7 days

#### Neonates

- Use of a high-risk agent is contraindicated. For medium-risk or low-risk agents, use a single lowest possible dose and do not repeat for at least 7 days

#### Infants

- Use a single lowest dose of agent possible and do not repeat for at least 7 days

#### Breastfeeding

- Discontinue for at least 24 hours after use of a high-risk agent. The decision of whether to continue or suspend breastfeeding for 24 hours after use of a medium-risk or low-risk agent should be at your discretion in consultation with the mother

#### Pregnancy

- Use of any gadolinium-containing contrast agent is not recommended unless absolutely necessary

#### Haemodialysis

- There is no evidence to support the initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis

#### Recording of the agent used

- When they become available, peel-off tracking labels found on the vials, syringes, or bottles should be stuck onto the patient record to accurately record the name of the gadolinium contrast agent used. The dose used should also be recorded

#### Reporting of suspected adverse reactions

- Please report to us on a Yellow Card any suspected adverse reactions, including NSF, to gadolinium-containing contrast agents

### 4.16.3 Injection of contrast agents

If injection of contrast agents takes place in the **MR ENVIRONMENT** attention must be paid to the use of only dedicated **MR CONDITIONAL** or **MR SAFE** devices.



The MHRA recommends the use of remote control power injectors for dynamic scanning and contrast-enhanced magnetic resonance angiography wherever possible.

### 4.16.4 Records of administration

Full details of the contrast medium administered must be recorded including the:

- name of the administrator
- name of the contrast agent
- manufacturer
- batch number
- concentration
- quantity administered
- method of administration.

The above should be detailed with the subject's relevant scan details in the equipment scan log. This should be held together with the subject's personal records and in safe keeping for a period that ensures compliance with the current guidance from the Department of Health. It should be in a form from which full details can be retrieved within this period if required.

### 4.16.5 Adverse events

Suspected adverse drug reactions should be reported to the MHRA by use of a Yellow Card, which is available from: MHRA, CHM Freepost, London SW8 5BR or electronically via the MHRA website (<https://yellowcard.mhra.gov.uk>).

Defective medicines can be reported to the Defective Medicines Report Centre.

## 4.17 Training

### 4.17.1 Introduction

To avoid accidents, it is **essential** that all personnel associated with MRI equipment be adequately trained. It must be recognised that there will be a wide range of staff with differing disciplines and responsibilities that will need access to the equipment and its environment.



It is recommended that the **MR RESPONSIBLE PERSON** ensures that adequate written safety procedures, emergency procedures and operating instructions are issued to all concerned after full consultation with the designated professionals and representatives of all who have access to the equipment.

The training of all appropriate categories of staff in terms of their normal duties and those in the event of an emergency is essential before installation and for all new staff subsequent to installation. Regular reviews of the training status as well as updates and refresher courses for all staff will be required during the operating life of the MR diagnostic unit.

A particular area of concern is that of an emergency which can relate to the safety of the person scanned and the staff, or of an environmental emergency such as a fire. Careful consideration must be given to setting up the correct form of training for the specialist staff who may be involved in any form of emergency which needs their entry into the **MR CONTROLLED ACCESS AREA/MR ENVIRONMENT** and the necessary liaison with the appropriate groups both within and outside the establishment.

An appropriate way to ensure that the necessary responsibilities are established and carried out may be to set up a MR safety committee under the leadership of the [MR RESPONSIBLE PERSON](#).

An [example](#) of training requirements is given in Table 4.

**Table 4 Summary of training requirements**

	A	B	C	D
Full training and instructions from the supplier or manufacturer in the use of the equipment, its hazards and what action to take in the case of an emergency. Those with the necessary training and experience should form the basis of the team training subsequent members of this category.	✓	-	-	-
They must be fully aware of the relevant content of the MRI instructions for use.	✓	-	-	-
They must be aware of the location of the MR ENVIRONMENT and its hazards	✓	✓	✓	✓
They must understand the safety aspects relating to: <ul style="list-style-type: none"> <li>- The electrical safety of the equipment.</li> <li>- The main static magnetic field and associated equipment.</li> <li>- Radio-frequency (RF) fields and associated equipment.</li> <li>- Gradient magnetic fields and associated equipment.</li> </ul>	✓	✓	-	-
They must understand emergency procedures arising from causes other than equipment failure.	✓	✓	-	-
They must understand the local regulations and procedures in connection with the MR diagnostic equipment and its location.	✓	✓	-	-
They must understand the significance of the <a href="#">MR CONTROLLED ACCESS AREA</a> , <a href="#">MR ENVIRONMENT</a> and <a href="#">MR PROJECTILE ZONE</a> and be able to differentiate clearly between them. In particular they must be fully conversant with: <ul style="list-style-type: none"> <li>- The projectile effect.</li> <li>- The effect of magnetic field upon implants and prostheses.</li> <li>- The effect of magnetic fields upon personal effects such as credit cards and watches.</li> </ul>	✓	✓	✓	-
They must understand the consequences and effects of quenching of superconducting magnets (section 5.4).	✓	✓	-	-
They must be fully aware of the recommendations on exposure to MR.	✓	✓	-	-
They must have had full instruction in, and must understand the consequences of, the correct selection, fitting, and use of ear protection.	✓	✓	-	-

#### 4.17.2 Categories of personnel

The list below gives examples of typical categories of staff who will or may need to enter the [MR CONTROLLED ACCESS AREA/MR ENVIRONMENT](#) in the course of their duties. The choice of individuals, their number and their category needs careful consideration before authorisation is given.

**Category (A): MR OPERATOR** Those wishing to operate, maintain or modify the MRI equipment such as radiographers, radiographic assistant practitioners, radiologists, scientific staff, technical staff, MRI service engineers and in certain cases suitably qualified and trained research staff.

**Category (B):** Personnel who do not fall into category (A) but are present with a volunteer or patient **during scanning** such as radiologists, anaesthetists and nurses.

**Category (C):** All staff who are required to enter the [MR ENVIRONMENT](#) when scanning is not taking place, eg dedicated cleaning staff, estate maintenance staff.

**Category (D):** All other staff who are required to enter the [MR CONTROLLED ACCESS AREA](#) but will not enter the [MR ENVIRONMENT](#).

The following identifies specific topics for consideration in the training of various categories of staff that need to enter the [MR CONTROLLED ACCESS AREA](#) in the course of their duties.

#### 4.17.3 Training requirements for category (A) personnel ([MR OPERATORS](#))

Those wishing to operate, maintain or modify the MRI equipment such as radiographers, radiologists, and scientific and technical staff and in certain cases suitably qualified and trained research staff.

- They must be competent to undertake the technical duties required of them. Their supervisor or line manager must determine this. At least one person in this category should have received full training and instructions from the supplier or manufacturer in the use of the equipment, its hazards and what action to take in the case of an emergency. Those with the necessary training and experience should form the basis of the team training subsequent members of this category.
- They must have had full instruction in, and must understand, the safety aspects relating to:
  - the electrical safety of the equipment.
  - the main static magnetic field and associated equipment.
  - radio-frequency fields and associated equipment.
  - gradient magnetic fields and associated equipment.
- They must have had full instruction in, and must understand, emergency procedures arising from causes other than equipment failure.
- They must have had full instruction in, and must understand, the screening process required, for all patients, volunteers, Authorised and Unauthorised Persons and visitors, before granting permission to enter the restricted area.
- They must have had full instruction in, and must understand, the local regulations and procedures in connection with the MR diagnostic equipment and its location.
- They must fully understand the significance of the [MR CONTROLLED ACCESS AREA](#), [MR ENVIRONMENT](#) and [MR PROJECTILE ZONE](#) and be able to differentiate clearly between them. In particular they must be fully conversant with:
  - the projectile effect.
  - the effect of magnetic field upon implants and prostheses.
  - the effect of magnetic fields upon personal effects such as credit cards and watches.
- They must have had full instruction in, and must understand the consequences and effects of quenching of superconducting magnets (section 5.4).
- They must be fully aware of the recommendations on exposure to MR.
- They must have had full instruction in, and must understand the consequences of, the correct selection, fitting, and use of ear protection.

#### 4.17.4 Training requirements for category (B) personnel

Personnel who do not fall into category (A) but are [regularly](#) present with a volunteer or patient **during scanning** such as radiologists, anaesthetists and nurses.

Staff in this group should have an understanding of the hazards in the [MR ENVIRONMENT](#) and how to minimise them.

This category rates second only to category (A) as a potential source of [MR AUTHORISED PERSONNEL](#). All requirements of category (A) also apply to category (B), except for those that relate to the operation of the equipment.

#### 4.17.5 Training requirements for category (C) personnel

Staff who are required to enter the [MR ENVIRONMENT](#) when scanning is not taking place. They must be fully instructed on the potential hazard of ferromagnetic objects.

Certain members of this category may justify certification as a [MR AUTHORISED PERSON](#). If members of this category become authorised they should only be responsible for themselves and not be allowed to supervise others.

#### 4.17.6 Training requirements for category (D) personnel

Staff who may enter the [MR CONTROLLED ACCESS AREA](#) but will not enter the [MR ENVIRONMENT](#) should be aware of the location of the [MR ENVIRONMENT](#) and its hazards.

### 4.18 Special issues – management of mobile MRI equipment

#### 4.18.1 Introduction

The full contents of these guidelines apply to the operation of mobile MRI equipment in clinical use and must be taken fully into account.

#### 4.18.2 Responsibility and organisation

There will be two organisations responsible for the direction and management of the equipment:

- The organisation responsible for providing the mobile equipment and associated staff.
- The hospital or clinical institution responsible for the patients and volunteers who are being examined in the mobile equipment.

A wide range of variations in the division of responsibilities can be envisaged. Two extremes are:

- The hospital or clinical institution hires the equipment and is responsible for its location, operation and all staff. The hospital or clinical institution will take on the full responsibility for virtually all aspects referred to in these guidelines.
- The patients and volunteers are sent to the mobile unit for clinical examination and diagnosis and the equipment is located on a site that is not the responsibility of the hospital. The provider of the mobile MR facility will take on all the responsibilities referred to in these guidelines.

In any other situation, the hospital or clinical institution will take on the overriding responsibility. Both parties should consider all aspects of these guidelines and formally agree the extent of their separate and mutual responsibilities.

#### 4.18.3 Issues of particular concern

Attention must be paid to:

- [manufacturers recommendations](#) regarding minimum distances from ferromagnetic objects such as [building structure](#) and [parked/moving cars](#).
- which executive takes on the ultimate responsibility for all aspects of safety.
- the need to appoint one or more [MR RESPONSIBLE PERSON](#)(s).
- the need to appoint one or more [MR SAFETY EXPERT](#)(s).
- the need for access to advisors and close contact with other relevant groups.
- the need to give clear written instructions detailing the extent of the delegation and the ensuing responsibilities to all staff involved at any time with the equipment and its location.
- the need to appoint suitably trained [MR AUTHORISED PERSONNEL](#).
- the location of the mobile equipment during operation.
- the need to control access to the MRI equipment.
- the provision of a [MR CONTROLLED ACCESS AREA](#), [MR ENVIRONMENT](#) and an [MR PROJECTILE ZONE](#).
- the control of exposure to all personnel, patients, volunteers, staff and the general public.
- management of patients and volunteers for scanning.
- records of patients' and volunteers' exposures.
- control and record of the use of contrast agents.
- the training of all personnel associated with the MRI equipment.
- acceptance testing, maintenance of the equipment, regular quality assurance of the equipment and the handling of incident reports.
- the need to control the effect on the environment of the static magnetic field, radiofrequency field and time-varying electromagnetic field gradients.
- potential equipment failure.
- emergency procedures.

- the safety of the equipment during transit.
- meeting requirements of The Carriage of Dangerous Goods Regulations [84]
- noise concerns.

Special attention must be given to the [MR CONTROLLED ACCESS AREA](#) and [MR ENVIRONMENT](#) that must be adequately partitioned or fenced off in such a way that members of the public do not have free access beyond the 0.5 mT (5 Gauss) magnetic field contour. [MR AUTHORISED PERSONNEL](#) must carefully control access to such units.

If in normal operation the 0.5 mT magnetic contour extends beyond the confines of the mobile unit then on no account must the equipment be moved until the field has been reduced to the point where the 0.5 mT magnetic contour is contained within the confines of the mobile unit or is not accessible to members of the public.

Careful consideration should be given to the possibility of an emergency due to an accident during transit. Ideally, the magnet should be de-energised immediately following the accident.

## 4.19 Special issues – management of open systems

### 4.19.1 Fringe fields

Users of open systems should have a good understanding of the fringe field lines. All designs of open magnets differ; C-shaped open magnets can have quite extensive fringe fields compared to four-pole open systems.

Areas around the magnet where exposure is greatest shall be Identified, and clearly marked at the time of commissioning.

### 4.19.2 Distortion

Open magnet designs often have relatively high static magnetic field and/or gradient field distortion levels. Sites should measure and quantify distortion in their quality assurance procedures; particular attention is needed when comparing systems for purchase and during the acceptance test. The distortion is a feature of magnet design and is not likely to vary on a day-to-day basis.

## 4.20 Special issues – management of interventional units

### 4.20.1 Staff numbers

Greater numbers of personnel and a wider range of equipment will require access to the [MR ENVIRONMENT](#) making the control of access possibly more difficult. Procedures will need to reflect this. Responsibilities must be clearly identified before each procedure commences. For example who is responsible for the correct positioning of cables in the scanner bore.

### 4.20.2 Exposure assessment

The MR unit may need to [re-assess](#) the risk to staff in terms of static field, noise, RF, and gradient (dB/dt) exposure [for interventional work](#). Detailed field plots will identify areas around the magnet where exposure is greatest. It is the responsibility of the employer to assess staff exposure levels.

### 4.20.3 Geometric accuracy

Geometric accuracy is particularly important for those MR units wishing to undertake MR guided stereotactic procedures. Some magnet designs can often have relatively high static magnetic field and/or gradient field distortion levels. MR units should measure and quantify geometric distortion in their quality assurance procedures; particular attention should be paid when comparing systems for purchase and during the acceptance test. The distortion is a feature of magnet and gradient design and is not likely to vary so much on a day-to-day basis. Image scaling should be checked on a regular basis as the gradient calibration can drift with time.

#### 4.20.4 Compatibility of equipment

There is a wider range of instruments and monitoring equipment used during an MR interventional procedure compared with a typical routine diagnostic scan. The cost and availability of these will need to be taken into account during the planning process.

#### 4.20.5 Compatibility of accessories

Care should be taken to ensure that any stereotactic frames used during MR guided neurosurgical biopsy and/or functional neurosurgery are either **MR CONDITIONAL** or **MR SAFE**. The availability of these devices will need to be confirmed.

#### 4.20.6 Infection control

The need to prevent cross-infection may require the installation of specialised air handling systems, such as those found in the operating theatre environment.

Hand hygiene facilities shall be placed as near to the area as safely possible.

#### 4.20.7 Cleaning and decontamination

Users should follow the instructions provided by the scanner manufacturer when cleaning the system.

### 4.21 Special issues – management of radiotherapy planning units

#### 4.21.1 Accuracy of laser lights

Any MR system used for radiotherapy should be regularly assessed for laser light accuracy. The laser light specification should be clarified from the manufacturer's information and then tested independently for confirmation. MR units should be aware that loose gantry covers could affect the laser light's positioning accuracy. MR localisers are not always lasers and are not manufactured or installed to the standards required for radiotherapy planning. Therefore they should not be relied on as radiotherapy planning lasers. If these are required, specific and appropriate lasers should be installed such that they meet the necessary requirements.

#### 4.21.2 Geometric accuracy

Radiotherapy relies on geometric accuracy. Some magnet designs can often have relatively high static magnetic field and/or gradient field distortion levels. MR units should measure and quantify geometric distortion in their quality assurance procedures; particular attention should be paid when comparing systems for purchase and during the acceptance test. The distortion is a feature of magnet and gradient design and is not likely to vary so much on a day-to-day basis. Image scaling should be checked on a regular basis as the gradient calibration can drift with time.

Some distortions will depend on the bandwidth of the imaging sequence being used. (eg chemical shift or  $B_0$  distortion), and may differ in different orientations.

#### 4.21.3 Compatibility of accessories

There will be a need for immobilisation devices in order to replicate the positioning of the patient for radiotherapy treatment. The availability and compatibility of these devices will need to be confirmed.

### 4.22 Other Health and Safety requirements

#### 4.22.1 Overview of the Health and Safety at Work etc Act

The UK Health and Safety at Work etc Act 1974 and other relevant statutory provisions clearly defines mandatory responsibilities and statutory requirements. It includes the responsibilities of the employer, the self-employed, anyone who has control of premises, the supplier of articles for work, all who have access including visitors to the site of work, and the employee at work [85]. A number of aspects of the Act are particularly relevant to the safety of MRI equipment in clinical use. It is strongly recommended that all those with responsibilities for this type of equipment familiarise themselves fully with the relevant

requirements of the Act. The following is typical of relevant features covered by the Act but is by no means definitive. A guide to this act is available [37].

#### **4.22.2 Duty of employers under the Act**

Under the Act it is the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his/her employees. The duty extends to:

- The provision and maintenance of plant and systems of work.
- The provision, as is necessary, of information, instructions, training and supervision.
- The maintenance of any place of work under the employer's control in a condition that is safe and without risk and the maintenance of means of access to and of egress from it.
- The preparation and the revision, as often as may be appropriate, of a written statement of policy and to bring it to the notice of all of his/her employees.

There is a duty under the Act for every employer and self-employed person to conduct his/her undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his/her employment are not exposed to risks to their health or safety. It is important for the relationships between employers and their duties of care for their own staff and the way that their conduct of their business may have an impact on the safety of the staff of other employers. This cooperation between employers is vital for successful management of health and safety in the workplace.

#### **4.22.3 Duty of control of premises under the Act**

There is a duty under the Act for each person, who has to any extent control of premises or the means of access to or egress from any plant or substance in such premises. They must ensure, as far as is reasonably practicable, that persons using the premises and plant or substance in the premises are safe and without risks to health.

#### **4.22.4 Duty of every employee under the Act**

Under the Act, every employee has a duty, while at work:

- to take reasonable care for the health and safety of him/herself and of other persons who may be affected by his acts or omissions at work
- to co-operate with his employer or any other relevant person to meet the requirements imposed on the employer as is necessary to ensure safety and welfare.

#### **4.22.5 Other regulations and guidance**

There are other regulations and guidance which will be relevant to MR units. These include:

- the Management of Health and Safety at Work Regulations [86]
- the Provision and Use of Work Equipment Regulations [87]
- the Manual Handling Regulations [88]
- patient handling assessments
- the Workplace (Health, Safety and Welfare) Regulations [89]
- Display Screen Equipment Regulations [90]
- Personal Protective Equipment (PPE) Regulations [91]
- Electricity at Work Regulations [92]
- Control of Substances Hazardous to Health Regulations (COSHH) [93]
- Pressure Vessels Regulations [94]
- The Health and Safety (First Aid) Regulations [95]
- the need for a comprehensive risk assessment programme
- considerations of pregnant staff – both pre- and post-natal
- management of stress, violence and lone working in the workplace [96, 97, 98].

For the current version of each regulation please consult the HSE website. The list above is meant as a guide but is by no means definitive.

# 5 Equipment Management

## 5.1 Procurement

### 5.1.1 The project team

The purchasing of MRI equipment should be undertaken using a consultation group including a wide range of personnel. The group may typically include the following:

- radiologists
- radiographers
- engineering estate staff
- healthcare management
- financial management
- [MR SAFETY EXPERT](#)
- MR physicist (unless the [MR SAFETY EXPERT](#) is also an MR physicist).
- manufacturer representation as and when appropriate
- the trust PACS manager.

### 5.1.2 Advisors to the project team

The project team will require advice from:

- A consultant anaesthetist
- clinical specialities wishing to make use of the proposed service
- nursing staff
- structural engineers
- electrical engineers
- RF shielding experts
- magnetic shielding experts
- architects
- purchasing and supplies department.

Consultation of those mentioned above is essential to facilitate good purchasing decisions, a smooth installation and the establishment of an appropriate clinical service.

### 5.1.3 Government organisations with expertise to assist the project team

There are several government organisations that may be able to assist the project team:

- NHS Supply Chain: for contractual and purchasing procedures.
- in Scotland contact Scottish Healthcare Supplies.
- in Wales contact Welsh Health Supplies for procurement matters and Welsh Health Estates for Technical and Estates related issues.
- in Northern Ireland contact the Department of Health, Social Services and Public Safety (DHSSPS).
- the MHRA
- estates and facilities management section at the Department of Health for information on planning and preparing a site for MR installation.

See the [website list](#) for contact details.

### 5.1.4 Safety of CE marked medical devices

The Medical Devices Regulations [99] stipulate that the manufacturer of a device is responsible for establishing that the device is safe and that it is suitable for its intended purpose. To establish this, manufacturers implement appropriate controls on the device design and manufacture, and evaluate the safety and performance of the device in its intended application. This involves an analysis of risks that could arise during use, an assessment of relevant pre-clinical and clinical data, the preparation of appropriate instructions for use and, if necessary, specific training schemes. From such activities,

manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

Failure to follow the manufacturer's instructions is considered 'off label' use. As well as the possible risks to the patient and user, there is the potential for litigation against the hospital or healthcare professional. Liability for off-label use rests with the user, not the manufacturer of the medical device or product in question [100].

On the rare occasions when there is no appropriate medical device for a particular procedure, then you must make a decision whether to use a medical device off-label, to modify an existing device or to use a product for a medical purpose although it is not CE-marked as a medical device.

You must balance the risks and benefits to the patient, taking into account the following recommendations:

- carry out a risk assessment and document it
- consider the ethical and legal implications
- implement suitable precautions to minimize the risk
- review the risk assessment at suitable periods
- consider getting approval from the MHRA for exceptional use of non-complying devices.

The patient must be fully informed during the consent procedure and a note made in their records if a device is going to be used off-label.

MR imaging equipment that is CE marked as a medical device will usually have the IEC levels incorporated into its design. However manufacturers are not required to do so and they may also offer limitation of exposure in line with other recommendations.

### 5.1.5 Equipment conformity

All equipment placed on the market within the European Union must carry the CE marking.

The equipment may comply with the following standards:

- EN 60601-1: Medical electrical equipment Part 1: - General requirements for basic safety and essential performance [101].
- EN 60601-1-1: Medical electrical equipment – Part 1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems [102].
- EN 60601-1-4: Medical electrical equipment – Part 1-4: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems [103].
- IEC 60601-2-33: Medical electrical equipment – Part 2-33: Particular requirements for safety of magnetic resonance equipment for medical diagnosis [6].

## 5.2 Installation

### 5.2.1 General



The installation of an MR unit requires a number of issues to be carefully considered by all those responsible for planning the supply and installation of the equipment and its immediate environment. The Department of Health's Estates and facilities management (formerly NHS Estates) has published comprehensive guidance on these matters [104, 105, 106]. Potential purchasers are strongly recommended to refer to these documents and to take advice from appropriate professional staff.

The interactions between the equipment and the environment will affect both equipment and personnel. For optimum safety and performance, the interactions must be properly controlled. In certain cases, the environment will determine the type of MR diagnostic equipment that can be housed. Technical advice should be sought from the potential suppliers and appropriate professionals at an early stage.



It is strongly recommended that before considering an installation, all sections of these MHRA guidelines are reviewed in order to appreciate the issues involved and the range of professional advice needed to be sought.



The MHRA's Medical Electrical Installation Guidance Notes 'MEIGaN' [107] document has been archived. However, it remains accessible as a useful reference document.

## 5.2.2 Shielding of static magnetic fringe fields

There are a number of approaches designed to contain the stray magnetic field, which is particularly important when installing higher field equipment in confined spaces. These include active shielding, passive cladding (an iron shield that is on the magnet) and room shielding (an iron shield that is separate from the magnet). In certain cases, the field distribution has an unusual geometry. Full details, floor plans, magnetic stray field plots and diagrams should be made available from the manufacturers and suppliers of the MRI equipment.

## 5.2.3 Static magnetic fringe fields and their influence on other ferromagnetic equipment

In planning a new MR installation, it is necessary to consider the fall off in the stray field of the magnet relative to the position of any ferromagnetic equipment. A very hazardous aspect of the stray magnetic field is the magnetic attraction exerted on any ferromagnetic object. This can include a pair of scissors, a bunch of car keys, a spanner, a gas cylinder, etc. The force of attraction at any point increases with the degree of non-uniformity of the field intensity. If this force exceeds a critical value the ferromagnetic object will move, continue to accelerate towards the magnet and effectively become a 'projectile'. This 'projectile effect' can be an extremely serious hazard not only to anyone in the magnet or close to it but also to the magnet itself. Especially in the case of large objects and high field magnets, there is the possibility of damage to the magnet windings when removing the object.

## 5.2.4 Static magnetic fringe fields and their influence on sensitive hospital devices

In planning a new MR installation, it is necessary to consider the fall off in the stray field of the magnet, **in all directions**, in relation to the position of any equipment that is sensitive to external magnetic fields. Examples of such devices include:

- disc and tape storage devices
- credit cards, watches and clocks, telephone switch gear
- main electrical distribution transformers, power transformers
- patients with cardiac pacemakers and other implantable medical devices
- CT Scanners, TV monitors, Video terminals, Ultrasound equipment
- radionuclide imaging cameras, PET scanners
- radiotherapy equipment
- X-ray tubes, computed radiography equipment, image intensifiers.

The minimum recommended distance from the iso-centre (the magnetic centre) of a magnet would depend very much on the type of magnet and any shielding that is involved. Information on fringe fields must be obtained from the manufacturer.

## 5.2.5 The influence of external objects on static magnetic field homogeneity

Ferromagnetic objects present in the stray field of the magnet may distort the field distribution within the magnet. This could affect the homogeneity of the field at the iso-centre to the extent of degrading the performance of the equipment. The degradation of the field homogeneity at the centre of the magnet is not necessarily linear with field intensity. Examples of ferromagnetic objects that could affect the homogeneity of the static field include:

- steel reinforcement in floor
- steel girders, reinforced columns, air conditioning ducts

- power lines, transformers
- cars, electric transport carts, dumbwaiters
- lifts, large vehicles, electric trains.

Further information should be obtained from the manufacturer.

### 5.2.6 Radio frequency interference and shielding

The level of radio frequency power emitted from the MRI equipment can give rise to interference with other equipment. In addition, it is necessary to ensure that external radio frequency emissions are sufficiently low not to be detected by the MR system so that artefacts do not appear in the images or spectra.

The Home Office regulations [108] set an upper limit to the level of radio frequency emitted from industrial, scientific and medical equipment. It is the responsibility of both the manufacturer and the user to ensure, by suitable screening where necessary, that these limits are not exceeded.

It will be necessary to provide a radio frequency shield to prevent external interference by both local and distant sources.

A local site radio frequency survey should be carried out. Many suppliers will provide this service. The level of radio frequency interference is typically measured in  $\text{dB Vm}^{-1}$ . In order to guarantee that the level of radio frequency interference in the centre of the magnet is not discernible in the background noise of the receiver coil, manufacturers typically require that the shield give 90–120 dB attenuation.

The RF enclosure should be designed according to the MRI equipment manufacturer's specification. There are specialist organisations that will advise and provide the necessary screening.



Interlocks to stop scanning when the door is opened should not be bypassed by users. This is to prevent any stray RF from entering the scan room that might be picked up by the receive coil and give rise to artefacts.

### 5.2.7 Co-siting

On sites with more than one MR system of the same field strength cross-talk has to be taken into consideration. This is where the RF generated in one system is picked up as signal by the other and overlaid onto the image. Co-sited systems should be ramped such that the resonant frequency of the B0 field is separated by at least 100KHz.

## 5.3 Commissioning and acceptance

### 5.3.1 Acceptance testing – by the manufacturer

Acceptance testing of engineering services, including shielding, should be carried out in conjunction with the MR supplier prior to installation of the equipment [104, 105, 106].

The manufacturer or supplier should provide written evidence for the compliance of the equipment with the procurement specifications and with their own performance specifications. Arrangements may be made for a hospital technical representative to be present during commissioning procedures.

### 5.3.2 Acceptance testing – independent of the manufacturer

Project teams are strongly advised to arrange for independent acceptance testing of the MR scanner by an MR physicist. The benefits of this are that:

- it provides an independent assessment of performance
- it provides a baseline for further regular quality assurance
- it identifies any corrective action required before clinical use commences.

The acceptance process may also include:

- independent electrical safety testing
- independent confirmation of the 0.5 mT (5 Gauss) line
- independent confirmation of noise levels

### 5.3.3 Quality assurance programme

The hospital or clinical institution should have a written policy for MRI equipment image quality testing as part of its broader quality assurance programme. This should include the monitoring of both signal and geometric parameters. MR units should not rely solely on the manufacturer's daily quality assurance (QA) programme unless they are fully aware of the tolerance levels. For more information on MR QA and training, please contact your [MR SAFETY EXPERT](#).

An audit of all the policies and procedures used in relation to the MR service should be a regular part of the broader QA programme.

### 5.3.4 Test objects

All QA measurements whether at acceptance test levels or on a regular basis should be undertaken using good quality test objects. If using the manufacturer's own test objects, MR units should ensure that these are testing to a known level and that the results will allow trends to identify levels for action before image quality is compromised.

### 5.3.5 Training on new MRI equipment

Sufficient time and funding must be allowed in the planning process to ensure adequate training of all personnel before using the equipment for clinical imaging. This will include the need to read the user manuals provided by the manufacturer. Training will also be important when upgrades are acquired.

### 5.3.6 Maintenance

The recommendations of the manufacturer should always be followed with regard to maintenance.

A formal handover procedure should be agreed and followed when equipment is passed in and out of maintenance.

## 5.4 MR suite recommendations

Please refer to section 4, where the key points in this section have already been covered in some detail.

### 5.4.1 MR CONTROLLED ACCESS AREA



Irrespective of operating field strength, it is recommended that the MRI equipment is housed in a [MR CONTROLLED ACCESS AREA](#), [MR ENVIRONMENT](#) and, if necessary, an associated [MR PROJECTILE ZONE](#) with access limited to [MR AUTHORISED PERSONNEL](#) or those under supervision. Details of the recommendations are given in section 4.

### 5.4.2 Number of entrances

The number of entrances should be kept to a strict minimum. Normally, there should be a single door large enough for staff, patient access on a trolley or bed, equipment replacement and dewars in the case of superconducting magnets. All doors to the MR suite should be self-closing and locking with security locks that can be operated by [MR AUTHORISED PERSONNEL](#) only from the outside, but freely opening from the inside in case of emergency. Naturally, any device used for unlocking doors must not be ferromagnetic.

Entrance doors to the [MR ENVIRONMENT](#) should not open directly onto public areas and should be visible from the operator's console. The door into the MR scanner room should swing in a direction that does not block the operators' view of the entrance.

### 5.4.3 Lockers

Adequate security lockers should be provided to accommodate personal belongings that will be either attracted by the static magnetic field or suffer damage. Any devices used for locking/unlocking doors to these lockers must not be ferromagnetic.

#### 5.4.4 Nurse call / panic alarms

Suitable alarms should be incorporated into the scan room, control room, and anaesthetic areas to warn others of an emergency which may be medical or non-medical in origin. Telephones should be provided in the control room and anaesthetic areas.



Staff should not work alone, especially out of hours. Where it is considered essential that staff do work alone, the Lone Worker Policy of the Trust should be considered.

#### 5.4.5 Venting cryogenes

In the case of superconducting magnets it will be necessary to duct the cold vapours produced by boil-off out of the [MR ENVIRONMENT](#) (see [Appendix 1](#)) to the outside of the building. Note that 100 litres or more of liquid cryogen can boil off during filling. Access will be necessary to bring dewars to the point of filling and adequate ventilation must be provided during the filling process. Dewars and ducting must be made from non-ferromagnetic material.

The chemical industry is highly conversant with the need for the control of venting systems and its safety aspects. It is strongly advised that a request is made to an appropriate part of the industry or to the Institute of Chemical Engineers for advice and to carry out a Hazard and operability study at the design stage of the installation.

MR equipment manufacturers typically call for three protections, the cryogen ventilation path (quench vent), an active exhaust fan, and a passive overpressure relief (exclusive of the RF door), built into MR installation requirements.

#### 5.4.6 Oxygen monitors



It is essential that an adequate number of oxygen monitors are installed and that they are regularly maintained.

Death by asphyxiation has occurred from the leaking of helium, which displaces oxygen in the room. Monitors and their alarms should be able to be seen and heard at all times and they should be checked regularly as part of a planned preventative maintenance programme. Monitors should be set to sound an alarm if the oxygen concentration goes below a specified level (19% would be a suitable level [6]). The MR unit should then be evacuated immediately in line with the written and approved policy, and only re-entered after inspection by a suitably qualified person or representative of the manufacturer or supplier authorised by the [MR RESPONSIBLE PERSON](#).

#### 5.4.7 Signs

At each entrance to the [MR CONTROLLED ACCESS AREA](#) and [MR ENVIRONMENT](#), adequate, clearly visible warnings must be displayed (an example is shown in [Figure 2](#)). For examples of recognised warning and prohibitive signs users should refer to the Health & Safety (Safety Signs & Signals) Regulations 1996 [109], IEC 60601-2-33 [6] and BS ISO 7010 [110].

#### 5.4.8 Equalising wave guides

Where fitted consideration should be given to acoustic noise transmission that may occur through wave guides.

#### 5.4.9 Temperature and humidity measurement

It is essential that temperature and humidity are measured in the scan room. The protection of the patient from heat stress and burns due to RF exposure is only limited by the room being maintained at moderate levels (see appendix [A2.1.4.1](#)). For advice on how to operate outside these limits, please refer to the manufacturer for advice as discussed in appendix [A2.1.4.1](#).



**Figure 2 MRI door entry sign**

#### 5.4.10 Conventional metal detectors

The use of conventional metal detectors which do not differentiate between ferromagnetic and non-ferromagnetic materials is not recommended [54].

#### 5.4.11 Ferromagnetic material detectors

ACR [54] recommends that:

‘the use of ferromagnetic detection systems is recommended as an adjunct to thorough and conscientious screening of persons and devices approaching Zone IV. It should be reiterated that their use is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage.’

The ferromagnetic detection systems have a number of advantages over conventional metal detectors including being totally passive systems and allowing non-ferromagnetic metal objects to pass by without alarming.

Ferromagnetic detection systems are designed to be operated in two different modes; for pre-screening patients or for guarding a room entryway. In the pre-screening mode the system is typically located in a patient preparation area and will allow a patient to be scanned for small ferromagnetic items in advance of entering the [MR ENVIRONMENT](#).

Ferromagnetic detection systems come in different formats, and are suitable for different uses. Pass-through systems, which may be located at a doorway entry, provide a degree of automated ferromagnetic screening for all persons and materials passing through the effective aperture. Pass-by systems are typically single-sided ferromagnetic screening tools which, for optimum effectiveness, involve moving the patient past in two directions, or rotating in front of the detector. Pass-by systems, by virtue of the subject proximity to the detector sensors, may be more sensitive than a pass-through system set at a doorway width. Handheld ferromagnetic detectors are effective for manually screening patients for ferromagnetic material, and may even be used for non-ambulatory patients on transports that contain ferromagnetic material that would alarm pass-through or pass-by systems.



The layout configuration of the MRI Suite should include provision for the siting of ferromagnetic detection systems [111].



Ferromagnetic detection systems are intended as **ancillary screening devices** and are not intended to be used as a replacement for traditional safety programmes, training or primary screening methods but as a complimentary tool.

## 5.5 Potential equipment failure

### 5.5.1 Equipment modifications

Hospitals and clinical institutions must ensure that any modifications to MR diagnostic equipment are carried out by the manufacturer or supplier or a suitably qualified person or group who will take on the responsibility of any ensuing defect or hazard to the health or safety of personnel. This is usually the role of the design authority. Adequate records of the changes together with test results should be provided to the hospital or clinical institution. Particular attention should be paid to changes in exposure to the subject both in normal use and in a fault condition. An appropriate entry should be made in the patient and equipment log (see 4.15).

Manufacturers will occasionally offer modifications that have been developed to improve the performance or safety of their equipment. These modifications are sometimes devised as a result of defects reported to MHRA by either the user or the manufacturer and may have been notified to the NHS as a Field Safety Notice or in a Medical Device Alert.

### 5.5.2 Equipment incident reports

Incidents and near misses involving MR diagnostic equipment should be reported to MHRA (or the equivalent organisation in the devolved administrations). Electronic reporting of these incidents is now available via the MHRA website. Guidance on what to report is given in [Appendix 4](#). An appropriate entry should be made in the patient and equipment log.

### 5.5.3 Effects that have an impact on patients

This section primarily discusses MRI equipment system failures that are likely to affect the patient. To a large extent equipment failures that can cause hazards must be the responsibility of the manufacturer or supplier of the equipment, those installing the equipment and those maintaining it. There is also a need to check interlocks and other safety functions.

The main aspects of equipment failure that can directly affect the patient are:

- the magnet ( $B_0$ )
- the gradient systems (dB/dt)
- the radio frequency amplifier, transmitter or receiver ( $B_1$ )
- the patient handling system
- the cooling systems
- the computer.

### 5.5.4 Superconducting magnet quench

Superconducting magnets may occasionally lose field abruptly due to a process known as 'quenching'. If the magnet is properly installed and the cryogen levels are adequately maintained, this will be an extremely rare event.

Inductance of superconducting magnets is such that, in the event of a collapse of the field, dB/dt is small compared with the recommended safety levels (see section 3).

In normal operation, the highest risk of a quench is when the current probe is inserted in order to change the field, or when liquid helium is being fed to the cryostat. Only suitably trained staff may carry out these operations.

It is a misconception that there can only be total quenches. For certain magnets one must allow for an emergency quench which produces only a partial quench, a second operation is required before the field is completely eliminated. Thus, even when a quench has occurred, care must still be taken in handling ferromagnetic objects near the magnet.



A quench will in general be accompanied by a loud bang and the **emission** of large quantities of cold gas.

The gas outlet for the normal boil-off and the emergency bursting discs should be vented directly to a suitable point on the outside of the building.



A **minimum** three metre exclusion zone is recommended for the quench vent exhaust [112]. Specific requirements should be obtained from the manufacturer.

If there is inadequate venting, cold gas may spread through the patient area. It will form a white fog that eventually clings to the ceiling. The patient should be removed at once, since there may be oxygen depletion and the presence of very cold gases may cause a cold burn, frostbite or hypothermia.



In accordance with the recommendations of superconducting MR manufacturers, the MHRA recommends annual inspections of all vent piping, **this should include, at least, a visual inspection of the external piping**. A basic guide to the installation and specification is detailed in appendix **A1.3**.

**Emergency quench buttons** to switch off the field should be provided, not only near the magnet but also near the entrance of the MR unit. Such buttons should be easily depressed in the case of an emergency and provided with a protective cover or box fitted over them. Each button should be accompanied by a notice indicating its purpose and noting the time required for the field to fall to a safe level following activation of the switch. This time is generally about 30 seconds.

Where relevant, the fire ratings for wiring systems given in BS 7671:2008 [113] 'Requirements for electrical installations'. Clause 422.2.1 will apply:

In conditions where BD2, BD3, and BD4, exist wiring systems that are supplying SAFETY CIRCUITS shall have a resistance to fire rating of either the time authorised by regulations for building elements or one hour in the absence of such regulations.

BD2 is defined as low density occupation, difficult conditions of evacuation.

BD3 is defined as high density occupation, easy conditions of evacuation.

BD4 is defined as high density occupation, difficult conditions of evacuation.

### 5.5.5 Active magnet shimming

Loss of current in an active shimming system will be obvious from a drop in equipment performance. Loss of a portion of shimming may be less obvious. Shimming loss should not affect patient or volunteer safety, but it will affect the performance.

### 5.5.6 Time-varying magnetic field gradients

Gradient systems are the source of many of the artefacts in images. In two-dimensional Fourier transform image reconstruction, any gradient instabilities result in artefacts similar to those that are common with abdominal motion. In back-projection, reconstruction gradient errors often manifest themselves as distortions and breaks in the boundaries of structures in the images. Loss of a gradient in either system causes gross and obvious image artefacts.

### 5.5.7 Radio frequency system

The radio frequency (RF) coils are generally close to the patient and require great care in preparation and maintenance, particularly the provision of adequate insulation. In general, safety problems are more

likely to arise from the transmitter system than from the receiver. However, in some cases the transmitter and receiver coils are combined.

Coil positioning errors and damage due to twisting coil cables during positioning etc, can all result in failed examinations.

It is essential to ensure that the total RF exposure of the patient remains within the recommended limits (see section 3). With advanced sequences exposures can rapidly approach the recommended safe levels.

### 5.5.8 Patient handling system

The main problems are due to:

- failures of the drive system to move the patient couch
- trapping of the patient, patient attachments and patient support systems
- failures of the table to dock and undock correctly.

It is essential that a patient can be removed from the machine as quickly as possible following a power failure. The patient couch must be free to move during a power failure. Mechanical design should be as simple as possible. All clearances should be as large as possible to avoid any trapping of tubes, ties, straps, fingers, etc. Where there are sliding seals they should be covered as far as possible. Any patient weight restrictions imposed by the manufacturer must be observed.

### 5.5.9 Patient monitoring equipment

Patient monitoring equipment should be examined at regular intervals, paying particular attention to the condition of the cabling. The manufacturer's recommendations for maintenance should be followed.



Sites should have systems in place to ensure that MRI dedicated equipment can be used appropriately, this may be an issue at sites that have different models in the department to outside the department. Particular issues are:

- Availability of consumables
- Training / familiarity of staff with the device

### 5.5.10 The cooling system

Air conditioning in the magnet is often helpful in providing patient comfort. Loss of the air conditioning system could affect patient safety.

In the case of resistive magnets, the cooling system must be securely interlocked with the power supply to cut the power in the event of a failure of the cooling system.

If fitted, the loss of the active shims cooling system, could give rise to excessive heating of the patient or volunteer being scanned. Cooling system interlocks must be fitted and operate effectively.

### 5.5.11 Interlocks and safety functions

Checks of the correct functioning of all safety interlocks and safety functions should be conducted periodically. Records should be kept, including details of any defects and remedial action taken, etc.

## 5.6 Emergency procedures

### 5.6.1 General

An emergency can relate to the well-being of patients and volunteers being scanned, to an environmental emergency such as a fire or a threat to a member of staff. Careful consideration must be given to setting up the correct form of training for the specialist staff involved in any form of emergency which needs their entry into the [MR CONTROLLED ACCESS AREA](#), and the necessary liaison with the appropriate groups both within and outside the establishment. Sections 4.2 and 4.4 cover access to the [MR CONTROLLED ACCESS AREA](#).

It is during an emergency that the training of personnel is often put to the test.

**DO NOT BECOME COMPLACENT.** A simple incident can easily be escalated by thoughtless action.

Written procedures should be available to cover at least the following emergencies:

- cardiac arrest
- fire
- a quench in the MR unit
- a decreased oxygen level
- a loss of electrical power/lighting.

These procedures should be reviewed and audited at regular periods. Procedures should be well known and understood by all **MR AUTHORISED PERSONNEL** and practised from time to time.



Procedures should be in place to cover emergency access to the **MR CONTROLLED ACCESS AREA** when an **MR AUTHORISED PERSON** is not available eg formation of an emergency MR team so that more than one person should be contactable to supervise emergency access.



Consideration will need to be given to the provision of the necessary supervision and control should an emergency such as a fire occur out of hours.

### 5.6.2 Cardiac arrest

Given the time required for many multi-slice sequences, coupled with the enclosed nature of the MR diagnostic equipment system, ECG monitoring should be performed on any patients who may be at risk with the possible exception of the patient being under the constant supervision of a suitably qualified person. Standard ECG monitoring equipment will not be suitable for use in a MR diagnostic system. Specially developed ECG monitoring systems are available for MR and must be used. Care should be taken not to misinterpret additional signals, which are generally present on an ECG monitor during image acquisition. Radiofrequency pulses and the time-varying gradient field cause these additional signals.

Following an arrest, resuscitation – in the form of keeping airways open as well as cardiac massage – should begin immediately. At the same time the assistance of the resuscitation team should be sought. The patient should be removed from the magnet and the **MR PROJECTILE ZONE** as quickly as possible. Resuscitation should then take place outside the **MR PROJECTILE ZONE** by a qualified resuscitation team, as is normal hospital practice. Procedures will need to ensure that a non-ferromagnetic trolley is available at all times if the couch is not able to undock and be used to transport the patient.



Resuscitation equipment must never be taken to the patient in the **MR PROJECTILE ZONE** when the magnet is energised unless it is either **MR SAFE** or **MR CONDITIONAL** and the conditions are met.



The patient should be taken to the resuscitation area outside the **MR PROJECTILE ZONE**.



It is recommended that the hospital conduct an MR evacuation / resuscitation drill at least annually.

### 5.6.3 Fire



It is strongly recommended that sites invite the local fire brigade, via the hospital fire officer, to visit the MR unit in order to familiarise themselves with the local situation.

**Access:** Ideally, only **MR AUTHORISED PERSONNEL** should enter the **MR ENVIRONMENT** unless the magnetic field has been fully quenched or turned off.

**Superconducting magnet systems:** The magnet must be quenched if the emergency services wish to enter the **MR ENVIRONMENT** with ferromagnetic equipment. Warning notices must be provided. In exceptional cases it may not be necessary to quench the magnetic field if it is not necessary to enter the **MR ENVIRONMENT**.



It is recommended that **MR CONDITIONAL** extinguishers are provided within the controlled access portion of the MR suite.

### 5.6.4 Superconducting magnet quench

In the event of the magnet quenching, the MR diagnostic unit should be evacuated until a suitably qualified person or a representative of the supplier authorised by the **MR RESPONSIBLE PERSON** has inspected the system.

If the quench is initiated on purpose, the door to the scan room should be fixed open before initiating the quench. A build-up of pressure in the scan room could make an inward opening door difficult to open.



It will be very difficult to break the control room window as it may consist of four layers of glass with mesh bonded between each of 2 layers.



Safety measures should be in place to allow exit from the scan room in case of a quench.

## 5.7 Planning for replacement

Advice on equipment management is given in 'Managing Medical Devices' [114].

A policy on removal from service is an essential part of equipment management. At some point all equipment will need to be replaced.

The expected life cycle of a device/piece of equipment should be held in the inventory record and regularly reviewed against the usage, maintenance and repair record to see if the end date needs to be adjusted. Heavy use or irregular maintenance may reduce the life cycle; limited use may extend it.

### 5.7.1 Replacement criteria

Factors to consider include:

- whether the device is damaged or worn out beyond economic repair
- its reliability (check service history)
- clinical or technical obsolescence
- changes in local policies for device use
- absence of manufacturer/supplier support
- non-availability of correct replacement parts
- non-availability of specialist repair knowledge
- users' opinions
- possible benefits of new model (features, usability, more clinically effective, lower running costs)
- lifecycle of the medical device.

# Appendix 1 Cryogenics and venting issues

## A1.1 Cryogenics

### A1.1.1 Asphyxiation

Nitrogen and helium may produce local oxygen deficient atmospheres, which will produce asphyxia if breathed. Atmospheres containing less than 18% oxygen are potentially dangerous and entry into atmospheres containing less than 20% oxygen is not recommended. Atmospheres containing less than 10% oxygen can result in brain damage and death. The use of oxygen monitors is recommended.

Asphyxia due to oxygen deficiency is often rapid with no prior warning and the victim may not be aware of the asphyxia. Typical symptoms are:

- rapid breathing and gasping for breath
- rapid fatigue
- nausea
- vomiting
- collapse or inability to move
- unusual behaviour.

### A1.1.2 Cold burns, frostbite and hypothermia

Liquid helium and nitrogen or even their cold gases can damage the skin producing an effect similar to a heat burn. Unprotected parts of the skin that come into contact with un-insulated items of cold equipment may also stick fast to skin, the flesh being torn on removal.

The cold vapours from liquefied gases may cause frostbite given prolonged or severe exposure to unprotected parts. A symptom is local pain but sometimes no pain is felt or it is short-lived.

Transient exposure to very cold gas produces discomfort in breathing and can provoke an attack of asthma in susceptible people.

### A1.1.3 Handling cryogenics

General requirements:

- Training authorised by cryogen suppliers must be undertaken before personnel operate and replenish the cryogenics.
- Maintenance of cryogenic plant must have been authorised by the appropriate senior site engineer, physicist or technician to ensure that it is safe to carry out such work.
- Pipes or metal that is not insulated must not be touched by unprotected parts of the body.
- In the event of unusual venting, immediately inform an authorised cryogenic operator or the site engineer, physicist or technician.
- No unauthorised person, at any time, should operate or tamper with cryogenics, valves, etc.

### A1.1.4 Protective clothing

Protective clothing serves mainly to avoid frost burns. Dry leather gloves should be worn when handling anything that is or may have been in contact with cold liquids. However, even with gloves, cold equipment can only be held for a short time. Gloves should fit loosely so that they may be removed easily in case of liquid spillage. Eyes should be protected with a face shield or goggles. Overalls or similar type of clothing and boots should be worn. The overalls should be worn outside the boots. As far as is practical, use close-fitting overalls without pockets to avoid accumulation of cryogenics in pockets or loose folds. Do not wear watches or jewellery when handling cryogenic liquids.

### A1.1.5 Equipment

Only containers specially designed to hold cryogenic liquids should be used. Although these containers (dewars) are made from materials which can withstand the very large and rapid changes in temperature, for use with MR systems they must also be made from non-magnetic materials. If it is necessary to fill a dewar or transfer cryogenics, it is important that it should be filled slowly in order to minimise the thermal

shocks that occur when any materials are cooled. This also reduces splashing and avoids a rapid build-up of pressure. Wide-necked and shallow containers should be partly covered during filling to reduce splashing and loss of liquid.

Never plug the necks of small liquid containers. When not in use cover the dewars to prevent accumulation of moisture and plugging of the outlet with ice. Large storage containers not open to the atmosphere must be provided with pressure relieving devices. Use only the stopper supplied with the container.

Containers are designed to withstand normal operating pressures. All containers should be open or protected by a vent that allows the vapour to escape. The vent should be inspected regularly to ensure that it is not iced up. Icing up is more likely to occur when the boil-off rate of the liquid is large (eg when the thermal insulation of the dewar has broken down).

Never allow two or more vents to be open to the atmosphere as excess pumping will occur and an ice block will form in the neck of the vessel thus trapping the gas.

### A1.1.6 Signage

Adequate, clearly visible warnings must be displayed where necessary (an example is shown in Figure 3). For examples of recognised warning and prohibitive signs users should refer to the Health & Safety (Safety Signs & Signals) Regulations 1996 [109] and BS ISO 7010 [110].



Figure 3 Cryogen Hazard sign

### A1.1.7 Oxygen enrichment

The cryogen may cause oxygen in the air to liquefy or the air to become oxygen enriched due to the low temperatures – especially during post quench or filling procedures. This is a combustion hazard as liquid oxygen and oxygen enriched air is highly flammable.

 Naked flames should be prohibited, especially post quench and during cryogen transfer.

## A1.2 The Pressure Systems Safety Regulations (PSSR)



The MHRA recommends that users contact the manufacturer of their MR system to ensure that they are complying with the requirements of the PSSR.



It is the employer's responsibility to ensure compliance with the PSSR after installation.

### A1.2.1 Overview of the regulations

The aim of PSSR [115, 116] is to prevent serious injury from the hazard of stored energy as a result of the failure of a pressure system or one of its component parts. A pressure system can be defined as a system comprising one or more pressure vessels of rigid construction, any associated pipework and protective devices. In the case of MRI the system will include the cryostat, cold head and the quench vent pipe to the atmosphere. The application of these regulations to MRI is summarised here.

### A1.2.2 Installation

The employer of the person who installs the equipment is responsible for the overall safety of the installation of the system and must ensure that nothing in the manner of installation gives rise to danger or hinders the operation of a protective device. This includes the following:

- ensure that protective devices are clear of obstruction, operate correctly without hindrance or blockage and that the discharge is routed to a safe place
- provide adequate access for maintenance and examination purposes
- have the installation work checked and approved on completion by a suitably qualified person.

Where the installer is also the designer, manufacturer or supplier of the pressure system, they should comply with the essential safety requirements of the Pressure Equipment Regulations 1999 and any other relevant supply regulations. Where these regulations do not apply PSSR Regulations 4 and 5 will apply

Regulations 4 and 5 of PSSR require that the system should be:

- designed, and constructed from suitable material to prevent danger
- designed and constructed so that all necessary examinations can be carried out
- designed and constructed so that access to the interiors can be gained without danger where such access is provided
- provided with any protective devices necessary to prevent danger. Where the protective devices are designed to release contents, they should do so safely
- must ensure the relevant information and markings are supplied with or on the equipment.

### A1.2.3 The Competent Person

The user of a pressure system will need the services of a 'competent person' to meet the requirements of PSSR. 'Competent person' means a competent individual (other than an employee) or a competent body of persons.

The competent person has 2 principal duties under the regulations:

- drawing up or certifying scheme of examination, and
- carrying out examinations under the scheme.

The competent person should have:

- staff with practical and theoretical knowledge and actual experience of the relevant systems
- access to specialist services
- effective support and professional expertise within their organisation; and
- proper standards of professional probity.

#### **A1.2.4 The written scheme of examination**

The user requires a written scheme of examination, which is certified as suitable by a competent person. The user shall ensure that it is reviewed at appropriate intervals by the competent person and modified in accordance with the competent person's recommendations.

The written scheme of examination shall:

- specify the nature and frequency of examination
- specify the measures necessary to prepare the pressure system for safe examination.

Where appropriate, the user shall provide for an examination to be carried out before the pressure system is used for the first time.

#### **A1.2.5 Examination in accordance with the written scheme**

The user shall ensure that the system is examined by a competent person as specified by the written scheme of examination. The user must ensure that the system is not used after the date specified for re-examination.

#### **A1.2.6 Operation**

There is a duty on the employer to ensure that anyone using, managing or supervising work equipment has received adequate training. The employer must also provide:

- all procedures and information needed for the equipment to be operated safely
- any special procedures to be followed in the event of an emergency.

#### **A1.2.7 Maintenance**

The equipment must be properly maintained and kept in good repair to prevent danger. The type and frequency of maintenance will depend upon a number of factors including:

- the age of the equipment
- reports of previous maintenance or inspection
- any repairs or modifications that have been made
- manufacturer's instructions
- reports of examinations made under the written scheme of examination.

#### **A1.2.8 Precautions to prevent pressurisation of certain vessels**

The purpose of this regulation is to prevent an unintentional build-up of pressure in a vessel, which is provided with a permanent outlet to the atmosphere. In the case of MRI this is the quench vent piping. Users must ensure that this outlet does not become blocked.

### **A1.3 Basic guide to installation and specification of quench piping**

#### **A1.3.1 Terminals**

The terminal should be of such a design and located such that:

- there is no possibility of water or rain ingress into the vent pipe
- the vent terminal is positioned so as not to cause any risk or harm in the event of a quench to personnel.

#### **A1.3.2 Routine inspection**

Routine inspection [117] is undertaken over the entire length of the quench pipe to identify the following:

- adequate expansion provision/components are fitted within the vent system
- all joints within the quench vent system are checked for gas tightness and are in a sound state of repair, including the connection to the magnet.

### **A1.3.3 Construction and checks**

The vent installation company must declare that the installation of the quench vent has been manufactured, designed and installed in accordance with the MRI manufacturer's installation guidance and instructions.

The route of the quench pipe should be clearly marked to prevent accidental breach during maintenance work.

## Appendix 2 Exposure limits

The following section details exposure limits suggested by HPA, IEC and ICNIRP.

### A2.1 Patients, volunteers and carers exposure limits

#### A2.1.1 Modes of operation

The recommended operating modes are summarised below.

##### A2.1.1.1 HPA

The 2008 HPA report [1] recommends:

- **Routine MRI procedures** for all patients are termed the normal operating mode.
- **Specific MRI examinations** outside the normal operating mode range are termed the controlled operating mode and exposures must be carried out with appropriate consideration of the medical circumstances. Here, discomfort and/or adverse effects for some patients may occur, and a clinical decision must be taken to balance such effects against foreseen benefits to the patient.
- **Experimental MRI procedures** at levels outside the controlled operating mode range are termed the experimental operating mode, and are subject to approval by an ethics committee.

##### A2.1.1.2 IEC

The 2010 IEC standard [6] has three levels of operation, which are defined below:

- **Normal operating mode** of operation of the MRI equipment in which none of the outputs have a value that may cause physiological stress to patients
- **First level controlled operating mode** of operation of the MRI equipment in which one or more outputs reach a value that may cause physiological stress to patients which needs to be controlled by medical supervision
- **Second level controlled operating mode** of operation of the MRI equipment in which one or more outputs reach a value that may produce significant risk for patients, for which explicit ethics committee approval is required (ie a human studies protocol approved to local requirements).

##### A2.1.1.3 ICNIRP

The ICNIRP 2004 and 2009 [12,13] publications also recommend three operating modes for patient scanning:

- **Normal operating mode** for routine scanning of patients
- **Controlled operating mode** for specific examinations above normal operating mode output level, carried out under medical supervision
- **Experimental operating mode** carried out at levels above the controlled operating mode and for which a [research](#) ethics committee approval has been obtained.

#### A2.1.2 Static magnetic fields (B0)

All three organisations recommend that patients and volunteers are moved slowly into the magnet bore, to avoid the possibility of vertigo and nausea.

The IEC/ICNIRP requires 'medical supervision' of the patient, and the HPA requires 'appropriate physiological monitoring of pulse rate' working in the experimental mode (see section 4.13). The whole body limits are given in

[Table 5](#).

**Table 5 Static field whole body limits**

	NORMAL MODE	CONTROLLED MODE	RESEARCH / EXPERIMENTAL MODE	Movement dB/dt limit
HPA	≤ 4 T	4-8 T	> 8 T	1 Ts <sup>-1</sup>
IEC 2002 †	< 2 T	2-4 T	> 4 T	-
IEC 2010 *	≤ 3 T	3-4 T	> 4 T	3 Ts <sup>-1</sup>
ICNIRP 2009	≤ 4 T	4-8 T	> 8 T	1 Ts <sup>-1</sup>

† Older systems are likely to be built to this standard

\* IEC now consider 3T systems to be Normal mode

### A2.1.3 Time-varying magnetic field gradients

#### A2.1.3.1 IEC/ICNIRP/HPA guidance

These provide a very comprehensive explanation on the restrictions for time-varying magnetic field gradients to be incorporated in MR scanners; it is summarised in Table 6. Fundamentally, they state that the system must not have gradient output that exceeds the limit for peripheral nerve stimulation (PNS). This will also protect against cardiac fibrillation. The PNS threshold may be determined by human studies or the default values shown in Table 6 may be used.

- **IEC/ICNIRP/HPA normal operating mode** The gradient system shall operate at a level that does not exceed 80% of the directly determined mean threshold for PNS, where the threshold for PNS is defined as the onset of sensation.
- **IEC/ICNIRP/HPA first level controlled operating mode:** the gradient system shall operate at a level that does not exceed 100% of the directly determined mean threshold for PNS.
- ICNIRP has no limit for experimental mode exposures, IEC has a limit to prevent cardiac stimulation and HPA has suggested that a limit of 120% of the directly determined mean threshold for PNS, should apply; this is also shown in Table 6.

**Table 6 IEC/ICNIRP/HPA patient and volunteer exposure limits to time-varying magnetic fields**

	NORMAL MODE	CONTROLLED MODE	RESEARCH / EXPERIMENTAL MODE
Limits for gradient output: Expressed as a percentage of the median perception threshold, $\text{dB}/\text{dt}=20(1+0.36 / t_{s,\text{eff}})T \text{ s}^{-1} (\%)$ *	<80	80 - 100	100 – 120 ‡
IEC limit to prevent cardiac stimulation. For all modes of operation ( $Ts^{-1}$ ).	$\frac{dB}{dt} < \frac{20}{\left\{1 - \exp\left(-\frac{t_{s,\text{eff}}}{3}\right)\right\}} *$		

\* - ( $t_{s,\text{eff}}$  is the effective stimulus duration, in ms.)

‡ - No limit for IEC

### A2.1.4 Specific absorption rate (SAR) limits

#### A2.1.4.1 IEC/ICNIRP

IEC/ICNIRP SAR limits are listed in Table 7 and Table 8. IEC 2002 required scanners to reduce SAR if ambient temperature is above 25°C or if relative humidity is above 60%. The requirement to reduce SAR in high humidity was removed in IEC 2010.

It is recommended that sites make themselves familiar with the SAR limits used by their system from both the applicable IEC standard and the manufacturer’s user manual.

**Table 7 IEC/ICNIRP patient and volunteer SAR limits (Wkg<sup>-1</sup>) for RF field exposure**

	Whole body	Partial body		Head <sup>b</sup>	Local Trunk	Extremities
		Head	Not head <sup>a</sup>			
NORMAL MODE	2	3*	2–10	10	10	20
CONTROLLED MODE	4	3*	4–10	10	10	20
RESEARCH / EXPERIMENTAL MODE	>4 (8 HPA)	>3*	>(4–10)	10 (15 HPA)	>10 (15 HPA)	>20 (25 HPA)

a Partial-body SAR scales dynamically with the ratio  $r$  between the patient mass exposed and the total patient mass:

– normal operating mode:  $SAR = (10-8 \times r) \text{ Wkg}^{-1}$

– controlled operating mode:  $SAR = (10-6 \times r) \text{ Wkg}^{-1}$

b In cases where the eye is in the field of a small local coil used for RF transmission, care should be taken to ensure that the temperature rise is limited to 1°C.

Averaging time = 6 min.

\*IEC state 3.2 Wkg<sup>-1</sup>

**Table 8 IEC 2010 patient and volunteer SAR limits (Wkg<sup>-1</sup>) for RF field exposure**

	Whole body	Partial body		Head <sup>b</sup>	Local Trunk	Extremities
		Head	Not head <sup>a</sup>			
NORMAL MODE	2	3.2	2–10	10	10	20
CONTROLLED MODE	4	3.2	4–10	20	20	40
RESEARCH / EXPERIMENTAL MODE	>4	>3.2	>(4–10)	>20	>20	>40

a Partial-body SAR scales dynamically with the ratio  $r$  between the patient mass exposed and the total patient mass:

– normal operating mode:  $SAR = (10-8 \times r) \text{ Wkg}^{-1}$

– controlled operating mode:  $SAR = (10-6 \times r) \text{ Wkg}^{-1}$

b In cases where the eye is in the field of a small local coil used for RF transmission, care should be taken to ensure that the temperature rise is limited to 1°C.

Averaging time = 6 min.



HPA and IEC SAR limits are set assuming moderate environmental conditions of relative humidity and ambient temperature. There is a risk of overheating the patient if SAR is not reduced in adverse conditions.



The MHRA recommends that MR users ensure that environmental conditions are monitored. The MHRA also recommends that those MR users that wish to operate outside these conditions should refer to the manufacturer for guidance.

The variance between manufacturers and systems of different field strengths can only be ascertained by obtaining information from the manufacturer. For example:

- Some systems may monitor ambient humidity and temperature and adjust the SAR system limits accordingly.
- Some systems may have no such mechanism and it may be necessary to stop scanning if the ambient conditions exceed these limits.
- Some low field systems may operate well within SAR limits even outside these ambient conditions.

### A2.1.5 Temperature rise limits

The HPA (2008), IEC (2010) and ICNIRP (2004) all have the same limits with respect to temperature rise (except the foetus in ICNIRP and experimental mode in HPA). They are presented here.

- **NORMAL MODE** of operation. Exposure of extended volumes of the body should be such as to avoid a rise of more than 0.5°C in the body temperature of patients and volunteers, including those compromised with respect to their thermoregulatory ability.
- **CONTROLLED MODE** of operation. A relaxation of the basic restrictions on the rise in body temperature to 1°C can be envisaged if the patient or volunteer is monitored as appropriate (see section 4.13).
- **RESEARCH / EXPERIMENTAL MODE** of operation. Any scanning in this mode, which may result in a whole body temperature rise above 1°C, requires ethics committee approval. HPA recommend limiting the temperature rise to 2°C.

**Table 9 Basic restrictions of whole body temperature rise for the body**

Mode	Temp °C
NORMAL MODE	0.5
CONTROLLED MODE	1.0
RESEARCH / EXPERIMENTAL MODE	>1.0 (<2 HPA)

**Temperature rise limits for limited regions of the body:** In certain applications when small or surface coils are being used for transmission, as well as reception, exposure to radiofrequency can be limited to relatively small regions of the body. In such cases, restriction of the average SAR in different regions of the body should be such as to prevent the local temperature rising above 38°C in any tissue in the head or fetus, or above 39°C in any tissue in the trunk, and 40°C in any tissue in the limbs.

**Table 10 Basic restrictions of maximum temperature for the body**

Mode	Head	Fetus	Trunk	Limbs
NORMAL MODE	38°C	38°C*	39°C	40°C
CONTROLLED MODE	38°C	38°C*	39°C	40°C
RESEARCH / EXPERIMENTAL MODE	>38°C	-	>39°C	>40°C
HPA upper limit	39°C		40°C	41°C

\* only ICNIRP has a specific limit for the fetus

### A2.1.6 Acoustic noise

The HPA recommends [1] that

‘Noise levels can exceed 85 dB(A) in almost all commercial MRI scanners, and it is difficult in practice to measure or predict noise levels for each pulse sequence. Therefore, it would be prudent at present, to fit hearing protection on all patients and volunteers as a matter of course. Hearing protection should be selected that reduces the noise at the ear drum to below 85 dB(A). For particularly intense exposures, above 115 dB(A), the use of both ear plugs and ear muffs would be advisable, although it is recognised that the extra attenuation provided may be difficult to quantify.’

The ICNIRP recommends that users:

‘offer hearing protection to the patients, when a noise level of 80 dB(A) is exceeded; hearing protection should always be worn by patients undergoing MR procedures at levels exceeding 85 dB A, at best by headphones allowing verbal communication. Other devices such as earplugs hamper verbal communication with patients during the operation of the MR system and offer non-uniform noise attenuation over the hearing range; however, earplugs are often used to prevent problems from acoustic noise associated with MR procedures. For adolescents and infants, smaller earplugs are required to attenuate acoustic noise associated with MR procedures.’

The IEC standard 60601-2-33 [6] requires that for patients and volunteers hearing protection is required above 99 dB(A).

The type of hearing protection must be chosen to ensure that the noise level at the eardrum is less than the above figure. Earplugs can offer 10–30 dB(A) noise reduction. Correct selection and use of hearing protection is necessary to obtain optimal reduction, therefore staff should be trained in the selection and fitting of hearing protection.

Please note that clear information should be obtained from the supplier or manufacturer of the MR scanner on its noise frequency spectrum and maximum noise level which the patient or volunteer will experience under normal and fault conditions.

Where sites are able to demonstrate that noise levels are significantly lower than 80 dB(A) the requirement for hearing protection may be relaxed.

## A2.2 Occupational exposure limits in MR

### A2.2.1 Occupational exposure limits for EMF

Until the Physical Agents Directive comes into force in the UK, the guidelines of the ICNIRP for occupational and public exposure should be used.

### A2.2.2 Occupational exposure limits for noise

The regulations require that employers make hearing protection freely available to employees when exposure exceeds the **lower exposure action level**. The regulations also state that hearing protection **must** be worn by all employees when the **upper exposure action level** is exceeded. Exposure action values and limits are given in Table 12.

Daily and weekly personal exposure values can be calculated by using the HSE noise calculator [118] or by using the ready reckoner in Table 11.

**Table 11 Relation between sound level and time to reach daily action values**

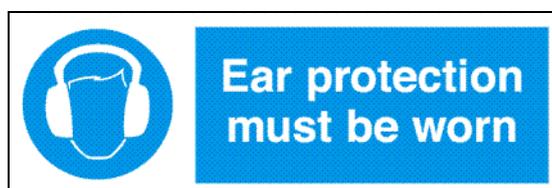
Sound level db(A)	Time to reach action value ( hh:mm:ss or mm:ss)		
	Lower action value 80 dB(A)	Upper action value 85 dB(A)	Limit value 87 dB(A)
80	8:00:00	-	-
82	5:02:52	-	-
84	3:11:05	-	-
86	2:00:34	6:21:17	-
88	1:16:04	4:00:34	6:21:17
90	48:00	2:31:47	4:00:34
92	30:17	1:35:46	2:31:47
94	19:07	1:00:26	1:35:46
96	12:03	38:08	1:00:26
98	7:36	24:03	38:08
100	4:48	15:11	30:17
102	3:02	9:35	24:03
104	1:55	6:03	15:11
106	1:12	3:49	9:35
108	0:46	2:24	6:03
110	0:29	1:31	3:49
112	0:18	0:57	2:24
114	0:11	0:36	1:31

For example, a personal exposure of 16 minutes to 100 dB(A) will place a person above the upper exposure action value of 85 dB(A).

**Table 12 Occupational noise action values and limits**

	Daily or weekly personal exposure dB(A) (average value)	Peak sound pressure dB
Lower exposure action values	80	135
Upper exposure action values	85	137
Exposure limit values	87	140

Where an employee is likely to be exposed above an **upper exposure action value** in the work place, the employer shall designate the area a **hearing protection zone**, restrict access to the area and identify the area with suitable signs (example shown in Figure 4).



**Figure 4 Hearing protection required sign**

The type of hearing protection must be chosen to ensure that the noise level at the eardrum is less than the above figure. Earplugs can offer 10–30 dB(A) noise reduction. The type of hearing protection should be chosen to match the noise frequency spectrum of the MR system in use.

Correct selection and use of ear protection is necessary to obtain optimal reduction, therefore all staff should be trained in the selection and fitting of hearing protection.

 The MHRA recommends that noise evaluation is included in the site risk assessment. Only appropriately trained staff should undertake noise measurements.

The use of hearing protection is regulated by the Personal Protective Equipment at Work Regulations 1992 [91]. Key points to remember about PPE are:

- it must offer adequate protection for its intended use
- those using it must be adequately trained in its safe use
- it must be properly maintained and any defects need to be corrected before re-use
- it must be returned to its proper storage after use.

**A2.3 Exposure limits for general public**

**A2.3.1 Introduction**

The general public comprises individuals of all ages and of varying health status, and may include particularly susceptible groups or individuals. In many cases, the general public is unaware of their exposure to EMF. Moreover, individual members of the public cannot reasonably be expected to take precautions to minimise or avoid exposure.

In 2004 the NRPB recommended that ‘the ICNIRP exposure guidelines should be used for restricting occupational and general public exposure to static magnetic fields’.

**A2.3.2 General public exposure limits for static magnetic fields**

ICNIRP recommends that acute exposure of the general public should not exceed 400 mT (any part of the body) [9].

**Table 13 Limit of exposure to static magnetic fields.**

Exposure characteristics	Magnetic flux density
Exposure of any part of the body	400 mT

<sup>a</sup> ICNIRP recommends that this limit should be viewed operationally as spatial peak exposure limit.

<sup>b</sup> Because of potential indirect adverse effects, ICNIRP recognizes that practical policies need to be implemented to prevent inadvertent harmful exposure of persons with implanted electronic medical devices and implants containing ferromagnetic material, and dangers from flying objects, which can lead to much lower restriction levels such as 0.5 mT.

### A2.3.3 General public exposure limits for time-varying magnetic fields

The exposure levels to the root mean square values of predominantly sinusoidal field variations at various frequencies are given in Table 14 below.

**Table 14 Reference levels for general public exposure to time varying magnetic fields (unperturbed rms values).**

Frequency range	Magnetic flux density (T)
1 – 8 Hz	$4 \times 10^{-2} / f^2$
8 Hz – 25 Hz	$5 \times 10^{-3} / f$
25 Hz – 50 Hz	$2 \times 10^{-4}$
50 Hz – 400 Hz	$2 \times 10^{-4}$
400 Hz – 3 kHz	$8 \times 10^{-2} / f$
3 kHz – 10 MHz	$2.7 \times 10^{-5}$

Note: In the frequency range above 100 kHz, RF-specific basic restrictions need to be considered additionally.

### A2.3.4 General public exposure limits for specific absorption rate

The ICNIRP basic restrictions for general public exposure to RF fields is given below.

**Table 15 Basic restrictions for general public exposure to RF fields**

Body part Units	SAR limit $Wkg^{-1}$	Tissue mass Grams	Time period Minute
Whole body average	0.08	-	6
Localized SAR (head and trunk)	2	10	6
Localized SAR (limbs)	4	10	6

Note 1) These apply for RF fields from 100 kHz to 10 GHz

Note 2) SAR is averaged over the tissue mass and over the time period.

## Appendix 3 Skills for health

### A3.1 HCS MR1: Develop safety framework for magnetic resonance imaging

#### A3.1.1 Summary

This standard concerns scientific and technical support for the development of a safety framework for the safe use of magnetic resonance equipment in compliance with relevant guidelines on MR safety. Users of this competence will need to ensure that practice reflects up to date information and policies.

#### A3.1.2 Performance criteria

- 1) Identify safety requirements for proposed MR services through consultation with other healthcare professionals
- 2) Specify roles, responsibilities and authority levels of relevant staff at appropriate level of detail to facilitate implementation and management of the framework
- 3) Develop a complete and accurate set of local rules for MR safety
- 4) Clearly specify potential risks and methods of management
- 5) Incorporate establishment and review of electromagnetic compatibility of implants and devices
- 6) Obtain necessary approval of the framework prior to implementation
- 7) Specify the record-keeping requirements regarding staff training, staff and patient exposure, contrast media and equipment modifications.
- 8) Formulate contingency plans for the management and control of incidents and emergencies

#### A3.1.3 Knowledge and understanding

- 1) Relevant national, international standards and guidelines on MR safety and their interpretation
- 2) The physical principles of NMR and MRI
- 3) The physical theory and technology underpinning clinical applications of MR
- 4) The operational dynamics of a clinical MR facility
- 5) The clinical case-mix relevant to the MR system
- 6) The organisational culture of the institution
- 7) Types of risk and methods of risk management
- 8) The impact of stray magnetic fields on the environment
- 9) The nature and biological effects of electromagnetic fields encountered in MRI
- 10) Electromagnetic compatibility in the context of MRI and associated equipment
- 11) The dangers associated with liquefied gases
- 12) The principles and limitations of MR compatibility
- 13) The implications for safety and equipment selection
- 14) Roles, responsibilities and levels of authority of personnel involved in MR services
- 15) Risks associated with MR services
- 16) Relevant legislation and its interpretation

# Appendix 4 Incidents to report to MHRA

Report these types of problems online to [MHRA](#).

## A4.1 Device failures (adverse incident)

The following issues if they result in, or may result in, harm\* to the patient or users:

- burns and overheating
- software errors
- unexpected and/or serious artefacts
- inadequate / inaccurate instructions for use
- unexpected interactions between devices and the MRI system:
  - projectile incidents
  - change of device function
- cryogen and quench issues
- noise issues
- mechanical failures
- contrast injector failures
  - failure of contrast injector consumables.

\* Harm includes misdiagnosis, delayed diagnosis, delayed treatment, inappropriate treatment, absence of treatment and transfusion of inappropriate materials.

Report online [here](#).

## A4.2 Defective medicines

- issues with medicinal gasses
- failures of pre-filled syringes containing contrast agents.

Report online [here](#).

## A4.3 Side effect with a medicine (adverse drug reaction)

- side effects from contrast agents.

Report online [here](#).

## Appendix 5 Example labels

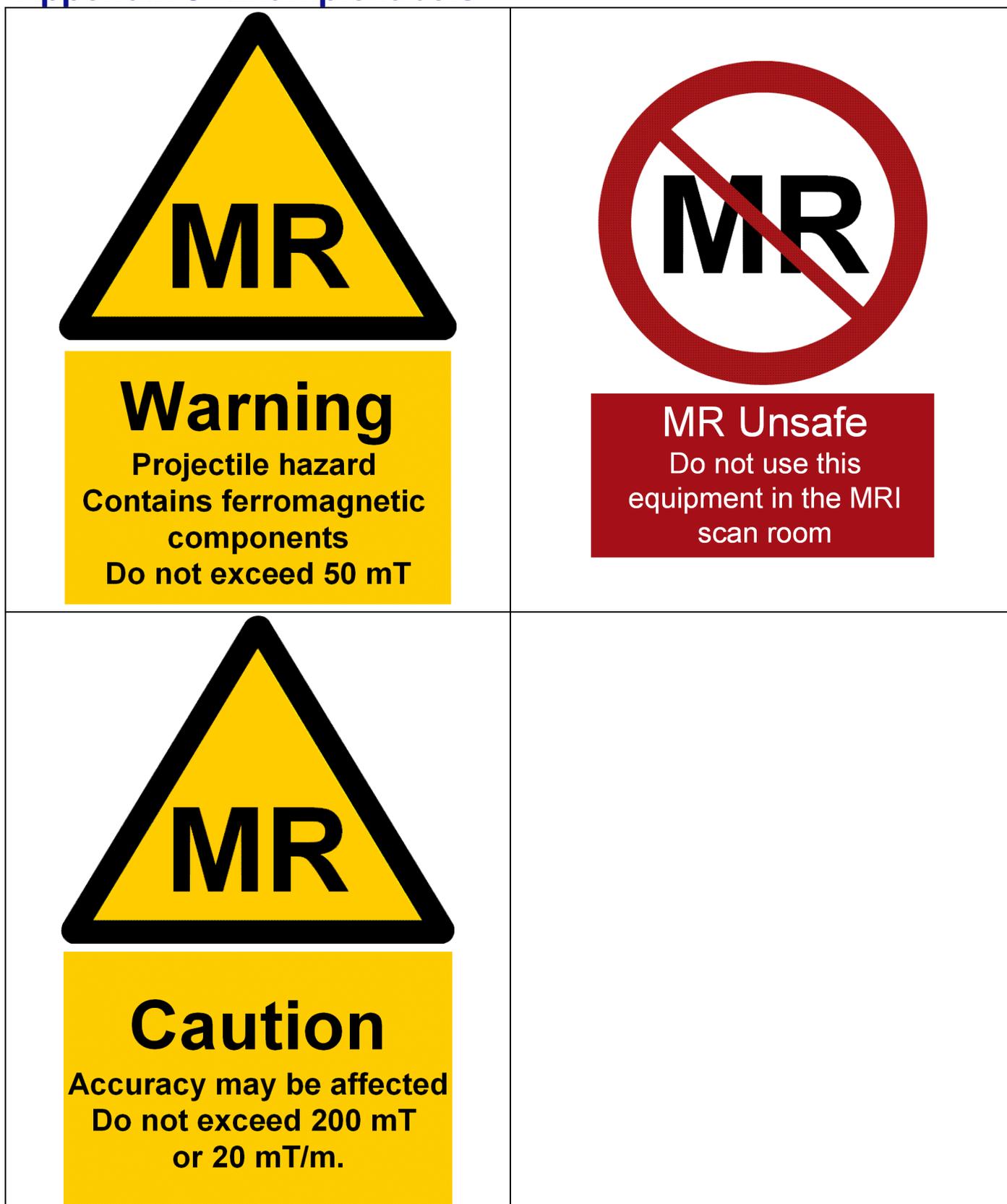


Figure 5 Example labels

## Websites list

Name	Site
Association of Anaesthetists of Great Britain and Ireland	<a href="http://www.aagbi.org">www.aagbi.org</a>
British Association of MR Radiographers (BAMRR)	<a href="http://www.bamrr.org/">www.bamrr.org/</a>
British Institute of Radiology (BIR)	<a href="http://www.bir.org.uk">www.bir.org.uk</a>
British Standards Institute (BSI)	<a href="http://www.bsigroup.com">www.bsigroup.com</a>
Department of Health (DH)	<a href="https://www.gov.uk/government/organisations/department-of-health">https://www.gov.uk/government/organisations/department-of-health</a>
Department of Health, Social Services and Public Safety for Northern Ireland (DHSSPS)	<a href="http://www.dhsspsni.gov.uk/">www.dhsspsni.gov.uk/</a>
European Committee for Electrotechnical Standardization (CENELEC)	<a href="http://www.cenelec.org">www.cenelec.org</a>
Food and Drug Administration (FDA)	<a href="http://www.fda.gov">www.fda.gov</a>
Health and Safety Executive (HSE)	<a href="http://www.hse.gov.uk">www.hse.gov.uk</a>
Institute of Chemical Engineers (IchemE)	<a href="http://www.icheme.org">www.icheme.org</a>
Institute of Physics and Engineering in Medicine (IPEM)	<a href="http://www.ipem.ac.uk">www.ipem.ac.uk</a>
International Commission on Non-Ionizing Radiation Protection (ICNIRP)	<a href="http://www.icnirp.de">www.icnirp.de</a>
International Electrotechnical Commission (IEC)	<a href="http://www.iec.ch">www.iec.ch</a>
International Organization for Standardization (ISO)	<a href="http://www.iso.org">www.iso.org</a>
International Radiation Protection Association (IRPA)	<a href="http://www.irpa.net">www.irpa.net</a>
International Society of Magnetic Resonance in Medicine (ISMRM)	<a href="http://www.ismrm.org">www.ismrm.org</a>
MagNET Evaluation Centre (MagNET)	<a href="http://www.magnet-mri.org">www.magnet-mri.org</a>
Medicines and Healthcare products Regulatory Agency (MHRA)	<a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a>
NHS Supply Chain	<a href="http://www.supplychain.nhs.uk">www.supplychain.nhs.uk</a>
Health Protection Agency (HPA)	<a href="https://www.gov.uk/health-protection/radiation">https://www.gov.uk/health-protection/radiation</a>
Royal College of Radiologists (RCR)	<a href="http://www.rcr.ac.uk">www.rcr.ac.uk</a>
Health Facilities Scotland	<a href="http://www.hfs.scot.nhs.uk/">http://www.hfs.scot.nhs.uk/</a>
Society and College of Radiographers	<a href="http://www.sor.org">www.sor.org</a>
Welsh Health Estates	<a href="http://www.wales.nhs.uk/whe">www.wales.nhs.uk/whe</a>

Sites last checked November 2014

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