Safeguarding public health

MHRA

Device Bulletin

Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use

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Contents

1 Introduction

1.1 Background

These guidelines cover important aspects of magnetic resonance imaging (MRI) equipment in clinical use, with specific reference to safety. They are 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 the National Radiological Protection Board (NRPB), its successor the Health Protection Agency (HPA), the International Electrotechnical Commission (IEC) and the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

1.1.1 Section 2 The hazards in MR

- Hazards with static magnetic fields (B_0).
- Hazards with time-varying magnetic field gradients (dB/dt).
- Hazards with pulsed radiofrequency fields (B_1).
- Acoustic noise.
- Exposure to MRI during pregnancy.
- Hazards with cryogens.

1.1.2 Section 3 Exposure limits and guidance

- Exposure limits and details of guidance relevant to patients, volunteers, staff, and the general public.

1.1.3 Section 4 Management of MR units

- The responsibilities of the hospital or clinical institution, the supplier and the user.
- The control of all personnel having access to the equipment and its immediate environment.
- The management of patients and volunteers for scanning.
- The control and recording of exposures of patients and volunteers.
- The need for special clinical considerations of use with a number of implantable medical devices.
- The need for training all staff associated with the equipment.
- The need for special attention in units operating with high fields, open systems, or undertaking interventional procedures or radiotherapy planning.

1.1.4 Section 5 Equipment Management

- The special considerations required in the purchase, location and installation of equipment.
- The equipment failures that could influence safety.
- The need for special emergency procedures in the case of patient trauma or an accident.

These guidelines are written primarily for healthcare providers but they are valid for other organisations using MRI equipment in clinical applications. They will have some relevance to users of laboratory MR equipment.

1.2 Changes in this edition

1.2.1 Updates to standards, guidance and legislation

There have been a number of updates since edition 2 was published in 2002. These include:

- ASTM International (previously American Society for Testing and Materials) standard on marking of devices in the MR environment and its new definitions; MR safe, MR conditional and MR unsafe (2005)
- update on NRPB guidance for occupational exposures (i.e. use ICNIRP 1998) (2004)
- update on ICNIRP 2004 patient exposure guidance
- update on 2005 noise legislation. Lowering of occupational noise action values/limit in line with new regulations. The MHRA recommends personal protective equipment at 80dB(A)
- noise exposure recommendations in line with ICNIRP guidance.

1.2.2 Feedback on Edition 2

Feedback from users of this document has been incorporated into this edition:

- cryogen issues moved from appendix to body
- addition of pressure safety vessels regulations information
- website amendments incorporated into body of guidance
- simplification of the training section.

1.2.3 New formatting

To make the document clearer, new formatting has been introduced:


Cautions are formatted like this.


The MHRA's recommendations and conclusions are formatted like this.

Essential reading is formatted like this.

Defined terms are formatted in SMALL CAPITALS.

Hyperlinks are formatted in light blue text.

1.2.4 Document status

First published 1993
Second edition 2002 under the title 'Guidelines for Magnetic Resonance Equipment in Clinical Use'.
This new edition has been reclassified as a Device Bulletin.

1.3 Updates due

Readers should note that a number of documents referenced in this document are under review. This includes the following documents (with their review dates):

- NRPB (now HPA) patient exposure guidance – 2008
- ICNIRP static field guidance – 2008
- IEC 60601-2-33 amendment relating to occupational exposure – 2007
- IEC 60601-2-33 (3rd edition) – 2009.

The MHRA will update this guidance once these are published.

1.4 Definitions

The defined terms in this document are summarised here.

MR CONTROLLED AREA
A volume totally enclosed and of such a size to contain the 0.5 mT (5 Gauss) magnetic field contour. Access should be restricted and suitable signs should be displayed at all entrances (see 5.4.7).

INNER MR CONTROLLED AREA
A volume totally enclosed and of such a size to contain the 3 mT (30 Gauss) magnetic field contour.
Where there is only one area (i.e. no INNER MR CONTROLLED AREA) all references in these guidelines to INNER MR CONTROLLED AREA will apply to the whole of the MR CONTROLLED AREA.

MR CONDITIONAL
An item which has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

MR ENVIRONMENT
volume within the 0.50 mT line of an MR system, which includes the entire three dimensional volume of space surrounding the MR scanner. For cases where the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment.

MR SAFE
an item which poses no known hazards in all MR environments

MR UNSAFE
an item which is known to pose hazards in all MR environments.

MR AUTHORISED PERSON
a suitably trained member of staff authorised to have free access to the MR CONTROLLED AREA.

MR OPERATOR
an MR AUTHORISED PERSON who is also entitled to operate the MRI equipment. MR OPERATORS are normally radiographers or radiologists but may include assistant practitioners, physicists, maintenance and research staff.

MR RESPONSIBLE PERSON
a member of staff who is responsible for MR Safety. This 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.

MR SAFETY ADVISOR
a designated professional with adequate training, knowledge and experience of MRI equipment, its uses and associated requirements. The designated professional MR SAFETY ADVISOR should be in a position to adequately cover the necessary engineering and scientific aspects of the safe clinical use of the MR devices.

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 Radiation Protection Division of the **Health Protection Agency** (HPA) (formerly the **National Radiological Protection Board** (NRPB)) publishes guidance on several aspects of exposure to magnetic fields. Publications to date are:

- patient MR exposure guidance in 1991[1] (under review)
- 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 HPA.
The **International Electrotechnical Commission** (IEC) provides a standard (IEC 60601-2-33) for manufacturers of MRI equipment to follow [5]. 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 (currently under review).

The **International Commission on Non-Ionizing Radiation Protection** (ICNIRP) published guidance on general exposure to static fields in 1994 [6] (currently under review) and to time-varying electromagnetic fields in 1998 [7] (currently under review). This guidance is for occupational and general public exposure. For MRI clinical exposure to patients, ICNIRP published a statement in 2004 [8].

2.1.2 MR safety marking

ASTM International published a standard in 2005 [9] for the marking of devices brought into the **MR ENVIRONMENT**, which includes new safety definitions. This is as a result of widespread confusion over the previous definitions proposed in 1997 by the Center for Devices and Radiological Health [10].

There have been adverse incidents reported where devices marked as MR safe or MR compatible (under the old definition) have been attracted into the scanner. The users failed to consult the testing conditions and assumed that MR Safe meant that the device was safe under all conditions.

Users should check the safety conditions of all equipment marked as MR safe or MR compatible (using the old definitions) and ensure that all relevant staff are made aware of them.

The new definitions and example labels are given below.

Table 1 Definitions from ASTM International standard F2503-05

MR SAFE 'an item which poses no known hazards in all MR environments'	
MR CONDITIONAL 'an item which has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.'	
MR UNSAFE 'an item which is known to pose hazards in all MR environments.'	
MR ENVIRONMENT 'volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire three dimensional volume of space surrounding the MR scanner. For cases where the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment.'	

MR ENVIRONMENT is equivalent to the **MR CONTROLLED AREA** as defined in this document.

The MHRA recommends that all equipment that may be taken into the MR CONTROLLED AREA is clearly labelled using these new markings and where possible, the appropriate descriptive text should be used (see examples in chapter 6, the British standard on safety signs may be useful [11])

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

2.1.2.1 Artefacts

It should be noted that ASTM F2503 does not address image artefact, this is addressed in their standard F2119-01 [12]. The presence of an artefact may indicate a malfunction that needs to be urgently addressed (e.g. 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 unit operating above 3 T. The majority of scanners installed in the NHS for general diagnostic purposes are 1.5 T in strength.

A review [13] 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 i.e. 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 required 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. A test of the 0.5 mT field line should be undertaken if this is not clearly contained within the MR CONTROLLED AREA. These should be shown to staff and explained clearly.

A field strength of 0.5 mT (5 Gauss) was chosen for the MR CONTROLLED AREA to avoid interaction with medical implants. A field strength of 3 mT (30 Gauss) was chosen for the INNER MR CONTROLLED AREA to avoid the projectile hazard [6].

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

Floor marking of the 0.5 mT and 3 mT line should be considered.

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 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 [14] and they noted that:

> 'Short-term exposure to static magnetic fields in the tesla range and associated field gradients revealed a number of acute effects. Cardiovascular responses, such as changes in blood pressure and heart rate, have been occasionally observed in human volunteer and animal studies. However, these were within the range of normal physiology for exposure to static magnetic fields up to 8 T.
>
> Although not experimentally verified, it is important to note that calculations suggest three possible effects of induced flow potentials: minor changes in the rate of heart beat (which may be considered to have no health consequences), the induction of ectopic heart beats (which may be more physiologically significant), and an increase in the likelihood of re-entrant arrhythmia (possibly leading to ventricular fibrillation). The first two effects are thought to have thresholds in excess of 8 T, while threshold values for the third are difficult to assess at present because of modelling complexity. Some 5–10 per 10,000 people are particularly susceptible to re-entrant arrhythmia, and the risk to such people may be increased by exposure to static magnetic fields and gradient fields.
>
> The limitations of the available data are such, however, that it is not possible to draw firm conclusions about the effects of static magnetic fields on the endpoints considered above. 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 (e.g. 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 1991 NRPB report conclusions [1] regarding the exposure of patients and volunteers in static magnetic fields are:

> 'The evidence suggests that the acute exposure of humans to static magnetic fields below about 2.5T is unlikely to have any adverse effect on health. In addition, there have been no reports of adverse effects from MR systems operating at 2.35T. Short-

term exposure to fields above about 4T may produce significant detrimental health effects, including vertigo and nausea, reduced aortic blood flow and increased blood pressure; experiments with primates suggest increased cardiac arrhythmia and reduced mental function above 4–5T. These effects are not well established but suggest a degree of caution should be exercised in the exposure of patients to fields above 2.5T.'

The 2004 ICNIRP report conclusions [8] regarding the static field are:

'The literature does not indicate any serious adverse health effects from the whole-body exposure of healthy human subjects up to 8 T. However, it should be noted that, to date, there have been no epidemiological studies performed to assess possible long term health effects in patients, workers, or volunteers. It is important that such research be carried out, particularly on individuals such as workers and volunteers with high levels of exposure.'

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 [15]. 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, and the gradient, dB/dz [16]. Once ferromagnetic materials become magnetically saturated, above say 0.5 T, there will be no B dependence for either displacement force or maximum torque.

The force experienced in MRI scanners is at a maximum just inside the bore 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. 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 CONTROLLED AREA unless it is clearly and suitably labelled.

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. For an implant fixed in the body, the torque will be at a maximum when it is in the **centre of the imaging volume**. It has been calculated that the twisting force experienced by a 1 cm long needle shaped object will be up to 90 times the magnitude of the attractive force. Torque is largely shape dependent and is proportional to the field strength, B, and to the angle the object is away from alignment with the field [16].

For some implants, this may be the limiting effect when assessing its 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. [17] 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%. The Lenz effect can also be caused by switching gradients.

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 (i.e. the device will try to move to the iso-centre) and/or a torque force (i.e. 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 [18].

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. Static magnetic fields as low as 1.0 to 1.7 mT can alter the operating mode of some pacemakers in certain circumstances. Permanent damage to some components (such as the reed switches) may occur when exposed to certain magnetic fields. 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.

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 [18]. 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 only monitoring equipment intended for use in an MR environment be used. Examples of monitoring equipment are: Electrocardiography (ECG) monitors, heart rate monitors, blood pressure and blood oxygen monitors. If the monitoring equipment is modified in any way, its compatibility needs to be re-examined. Staff should know any conditions (e.g. 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 e.g. ECG leads and electrodes.

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

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.
In the late 1980s and early 1990s, MR scanners typically operated with gradients of approximately 10 to 15 mT/m with slew rates of 12 mT/m/ms. By 2006, gradient strengths in the region of 80 mT/m and slew rates of up to 400 mT/m/ms were available on clinical systems [19].

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. At frequencies above 1 MHz, a reactive element begins to be significant and at frequencies above about 30 MHz, the wavelength begins to influence the electric field and current distribution. 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 [5].

An overview into the biological effects of time-varying magnetic field gradients is given in references [20] and [18].

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 [21]. 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.

There have been reported incidents of patients and volunteers experiencing PNS whilst undergoing MR examinations.

The 1991 NRPB report [1] concludes:

> 'The threshold current density for peripheral nerve or cardiac muscle stimulation is about 1.2 Am^{-2} at stimulation frequencies below about 100 Hz. Both can be avoided adequately by restricting induced current densities to less than 400 mAm^{-2}. In most cases, this can be achieved by restricting exposure to rates of change of magnetic flux density to less than 20 Ts^{-1}. Some relaxation can be considered for gradient fields orthogonal to the static field vector. In addition, relaxation of this value can be envisaged for short periods of magnetic field change (< 3 ms for cardiac stimulation and < 120 μs for peripheral nerve stimulation). It should be noted that, for periods of flux density change longer than 3 ms, peripheral sensation does not adequately protect against cardiac stimulation. Individuals are likely to vary in their sensitivity to induced currents; some, under neuroactive medication or with neurological disorders, may be particularly sensitive although this is not well established. It would seem reasonable to monitor people exposed above the lower level of restriction until further information becomes available.'

For information on the restriction levels see Appendix A2.1.3

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 frequencies of RF pulses are given in Table 2. 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.

Table 2 Typical field strengths and RF transmit frequencies for MR systems

Field strength (T)	Transmit frequency (MHz)
0.2	8.5
0.5	21
1.0	42
1.5	63
3.0	126

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 [22].

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 [22].

The NRPB 1991 report [1] conclusion on heat stress is:

> ‘It can be concluded that resting humans in moderate environment exposed for short periods to radiofrequency electromagnetic fields at Specific energy Absorption Rate (SAR) of 1 Wkg^{-1} up to 4 Wkg^{-1} will experience a tolerable heat load and rise in temperature of less than 1°C. It is also clear that some people are less heat tolerant than others; it is advised that the rise in body temperature for such people should be restricted to less than 0.5°C and that whole-body SARs should be restricted to a lower part of the above range. The less heat tolerant group is not well defined; therefore, it may be prudent to monitor blood pressure, heart rate and body temperature during exposure above the lower level.’

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 [23].

2.4.3.1 Contact burns

A review of burns in MR is given in reference [24]. 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 discuss 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 [25].


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 discuss 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 [26]. 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 MHRA has received reports of staff, carers and patients suffering a temporary threshold shift after exposure to MR noise without ear protection.

The use of earplugs, ear defenders, or other means of hearing protection is highly recommended [27]. Staff training in the use and selection of ear protection is also necessary. See the section on acoustic noise levels in reference [27] and sections 2.6.2, 3.2.5, 3.3.2 and 4.12.9 in this document.

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.

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 1991 NRPB report conclusions [1] regarding pregnancy and the static field are:

> 'The prolonged exposure of animals and cells to static fields of about 1 T had no effect on pre- or post-natal development and did not result in damage to chromosomes in germ cells or in somatic cells. Thus, development genetic (including hereditary) effects are unlikely.'

The 2004 ICNIRP report conclusions [8] regarding the pregnancy and the static field are:

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

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 [28]. The 1991 NRPB report conclusion [1] on pregnancy and the gradient fields is:

> 'There is some equivocal data suggesting that the developing chicken embryo is sensitive to prolonged exposure to weak extra-low frequency magnetic fields. The results from mammalian studies are mostly negative. It may be considered prudent, however, to avoid exposure of pregnant women during organogenesis (the first trimester of pregnancy) until the consequences are more clearly established. Such exposure does not seem to affect chromosome structure, and is therefore unlikely to have mutagenic or hereditary effects.'

The 2004 ICNIRP report conclusions [8] 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 NRPB 1991 report conclusion [1] on radiofrequency exposure in pregnancy:

‘The developing embryo or foetus should be regarded as particularly sensitive to raised temperatures. It is worth noting that heat loss from the embryo and foetus across the placental barrier may be less efficient than heat dissipated in other well vascularised tissues. Adverse effects on embryo or foetal development will be avoided if temperatures in tissues do not exceed 38°C, although other factors such as maternal tolerance in the increased heat load should be taken into account in this context. The data for acute exposure is unlikely to result in chromosome damage provided that temperatures are kept within physiological limits.’

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 NRPB conclusion on clinical exposure during pregnancy

‘Although there is no good evidence that mammalian embryos are sensitive to the magnetic fields encountered in MR systems, it is prudent, until further information becomes available, to exclude pregnant women during the first three months of pregnancy. However, MR diagnostic procedures should be considered where the only reasonable alternative to MR diagnosis requires the use of X-Ray procedures. There is no need to exclude women for whom a termination of pregnancy has been indicated. It is advised that pregnant women should not be exposed above the advised lower levels of restriction.’

2.6.1.5 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. The procedure should be conducted using a verbal and written informed consent procedure. The pregnant patient should be informed on the potential risks, also compared with those of other alternatives. 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. In addition, large doses of MRI gadolinium-based contrast agents have been shown to cause postimplantation fetal loss, retarded development, increased locomotive activity, and skeletal and visceral abnormalities in experimental animals. Such agents should only be used during pregnancy if the potential benefit justifies the risk to the fetus.

The few studies on pregnancy outcome in humans following MRI have not revealed any adverse effects, but are very limited because of the small numbers of patients involved and difficulties in the interpretation of the study outcomes.

In 1991, the Safety Committee of the Society for Magnetic Resonance Imaging (Shellock and Kanal 1991) recommended that ‘MR imaging may be used in pregnant women if other non-ionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would be otherwise require exposure to ionizing radiation (e.g. fluoroscopy, CT, etc.).’’

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 [29]; HSE 1999 [30] and American Academy of Paediatrics 1997 [31] remain inconclusive regarding effects on prematurity or fetal hearing following exposure to noise.

2.6.3 Pregnant patients conclusion

The MHRA recommends that, where possible, the decision to scan should be made at the time by the referring clinician, an MR radiologist and the patient, based on the information above about risks weighed against the clinical benefit to the patient.

See 'Team working within Clinical Imaging Dept, a contemporary view of skill mix RCR/SCoR joint guidance' [32] and the General Medical Council 'Good Medical Practice Guidance for Doctors' [33] 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. 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 (see section 3).

2.6.4 Pregnant staff conclusion

The MHRA recommends that each site should undertake a risk assessment analysing staff movement and location in relation to the levels of the magnetic fields and the total length of time that they will be exposed.

The Management of Health and Safety at Work Regulations [37] 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, dB/dt, and the radio frequency will be relatively low except in the immediate vicinity of the scanning aperture. This may be of concern in the interventional situation [18]. The level of the static magnetic field exposure is dependent on the field strength and shielding incorporated into the design of the magnet.

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.

2.7 Cryogens

2.7.1 Overview

There should be no hazards from cryogens 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 cryogens.

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 cryogens

See appendix A1.1 for more information on working with cryogens.

2.7.3 Quench pipe safety

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 [34].

The first incident involved the design of the external section of the pipe carrying the gas to the outside of the building. Water had been blown into the pipe during a rainstorm, had collected in a bend and had subsequently frozen. The ice blocked the pipe and, when a quench occurred, helium gas was vented into the scan room. In the second incident the quench pipe was found to be of a narrower internal diameter than that specified by the scanner manufacturer. In the event of a quench this would have increased the pressure within the system to above the design value and the pipe could have ruptured.

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.

The MHRA recommends annual inspections of all vent piping. A basic guide to the installation and specification is detailed in appendix A1.3.

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:

- patients for diagnosis
- volunteers engaged in clinical trials (where ethics approval is always needed)
- carers
- staff
- general public.

3.1.2 Sources of advice

The primary sources of information for exposure limits for patients and volunteers in the UK are the 1991 NRPB report [1] , IEC standard 60601-2-33:2002 [5] and the ICNIRP statement of 2004 [8]. All three organisations recommend an approach based on restriction levels. Care must be taken not to confuse the terminology for levels between these documents.

3.1.3 Safety of CE marked medical devices

The Medical Devices Regulations [35] 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 [36].

Where the healthcare organisation or healthcare professional judges that there is no alternative but to use a medical device off-label or to modify an existing medical or non-medical device, they should carry out and document a full risk assessment, and consider the ethical and legal implications.

Where a healthcare professional judges there is no alternative to off-label device use, the patient must be fully informed during the consent procedure and a note made in the patient's records.

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.

3.2 Patients, volunteers and carers exposure

The MHRA recommends using the three-mode approach to the clinical operation of MRI equipment.

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 pain 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 the local ethics committee and patient monitoring 4.12.13.

For a summary of NRPB, 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 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 NRPB, 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 – painful PNS is prevented.
- CONTROLLED MODE – some patients may experience painful PNS.
- RESEARCH / EXPERIMENTAL MODE – exposure is restricted to prevent cardiac stimulation.

For a summary of NRPB, 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°C will be prevented.
- CONTROLLED MODE – a whole body temperature rise of >1°C will be prevented.
- RESEARCH / EXPERIMENTAL MODE – exposure is unrestricted.

For a summary of NRPB, 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.
For a summary of IEC and ICNIRP guidance on limitation of acoustic noise see appendix A2.1.6.

3.3 Occupational exposure limits in MR

3.3.1 Introduction

Exposure to EMF shall be managed within the framework of the Management of Health and Safety at work regulations [37]. 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 ADVISOR should be familiar with the Management of Health and Safety at Work Regulations 1999 and its Approved Code of Practice and Guidance [38].

Application of NRPB guidance [2] on occupational exposure will aid in this process. However, as the limits set incorporate a safety factor, exceeding a limit will not necessarily result in harm [39]. 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 [5]).

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

3.3.1.1 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. For a summary of the occupational limits for static field see appendix A2.2.2.

3.3.1.2 Time-varying magnetic field gradients

Prevention of PNS. PNS is unlikely to occur in staff outside the imaging volume as the field decreases rapidly. For a summary of the occupational limits for the time-varying magnetic field see appendix A2.2.3

3.3.1.3 Specific absorption rate

Prevention of heat related disorders. Heating is unlikely to occur in staff outside the imaging volume as the field decreases rapidly. For a summary of the occupational limits for SAR and temperature rise see appendix A2.2.4

3.3.2 Acoustic noise

Occupational exposure to noise is now specifically regulated by the Control of Noise at Work Regulations 2005 [40]. For a summary of the Control of Noise regulations see appendix A2.2.5.

3.3.3 Occupational Exposure under the Physical Agents (EMF) Directive

In 1992 the European Commission submitted a proposal for a directive, on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (mechanical vibration, noise, EMF and optical radiation).

In 2004 Directive 2004/40/EC of the European Parliament and of the Council on the on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) [41] was adopted. The Directive aims to protect workers from **known short-term adverse effects** in the human body caused by the circulation of induced currents and by energy absorption as well as by contact currents. It does not address any suggested long-term effects.

- It introduces a set of 'Action values' and 'Exposure limit values'. These values are based on guidance published by the International Commission on Non-Ionising Radiation Protection [ICNIRP] in 1998.
- Employers must carry out action to reduce exposure to EMF if the action value is exceeded by an employee. **Employees must not be exposed above the exposure limit values.**
- The Directive does not cover exposure to patients.

Evidence is mounting that implementation of the directive in its current form will restrict current working practices.

Movement through the static magnetic field is likely to induce currents above the limit set unless movement speed is restricted [6, 42].

Exposure to the time varying field when standing within a metre of the bore of the magnet is likely to result in induced currents above the limits set [43] unless low gradient field are used.

The European Commission has accepted that implementation of the directive in its current form may have an impact on medical use of MRI and has proposed an amendment to delay the implementation of the directive until 2012. This is to allow time to review new evidence and guidance that is due to be published in 2008 by ICNIRP and WHO [44].

For details of its implementation into UK legislation see the HSE website [45].

3.4 Exposure limits for general public

The Management of Health and Safety at work regulations [37] covers risks to the general public, however they will not have access to the MR CONTROLLED AREA and it is therefore unlikely that any member of the public 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 ferromagnetic 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 e.g. 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 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) white paper [46] on MR safety is a useful reference document which has recently been updated [47], however it is aimed at users in the USA.

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. Clear, written instructions detailing the extent of the delegation and the ensuing 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 ADVISOR. 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 the local 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 National Occupational Standard HCS MR1 [48].

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 ADVISOR 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.

4.1.5 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 ADVISOR. The advisor should be a designated professional with adequate training, knowledge and experience of MRI equipment, its uses and associated requirements. Ideally he/she will be a physicist with expertise in MRI, who in view of the potential for harm to patients will normally be a clinical scientist.
The MR SAFETY ADVISOR 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. The MR SAFETY ADVISOR should be able to demonstrate compliance with the National Occupational Standards HCS MR1, 2, 3 & 4 [48].

4.1.6 Referring clinicians

Referring clinicians should be made fully 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.

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 4.6.3 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. 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 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 ADVISOR(s) and representatives of all MR AUTHORISED PERSONNEL who have access to the equipment.

4.1.9 Mobile 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 5).

4.1.10 Extremity MR units

As they gradually become more available, these units will also be special cases in terms of responsibility and location. These units may be located in areas such as outpatient clinics away from the main MR unit.

4.1.11 MR AUTHORISED PERSONNEL and the MR CONTROLLED AREA

It is strongly recommended that the MRI equipment be contained within a designated MR CONTROLLED AREA.

Free access to the MR CONTROLLED AREA should be given only to MR AUTHORISED PERSONNEL. Other personnel should have access only if accompanied by an MR AUTHORISED PERSON who will take on the full responsibility for the presence of that person for the duration of their presence in the MR CONTROLLED AREA.

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 ADVISOR(s) and MR OPERATOR(s).

4.2 UK Health and Safety at Work etc Act 1974

4.2.1 Overview of the 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 [49]. 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.

4.2.2 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.

4.2.3 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.

4.2.4 Duty for designers, manufacturers, suppliers etc under the Act

There is a duty under the Act on any person who designs, manufactures, imports or supplies any article for use at work to:

- ensure, so far as is reasonably practicable, that the article is designed and constructed to be safe and without risks to health and safety at all times, when it is being set, used, cleaned or maintained by a person at work
- carry out or arrange for such testing and examination as may be necessary for the performance of the duty imposed above
- ensure that the person to whom the article is supplied is provided with adequate information about the use for which the article is designed or tested and any conditions necessary to ensure that it will be safe and without risk to health when it is used, when being dismantled and when disposed of
- ensure that revised information is provided if anything becomes known that gives rise to a serious risk to health and safety.

4.2.5 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.

4.2.6 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 [50]
- the Provision and Use of Work Equipment Regulations [51]

- manual Handling Regulations [52]
- patient handling assessments
- workplace (Health, Safety and Welfare) Regulations [53]
- display Screen Equipment Regulations [54]
- Personal Protective Equipment (PPE) Regulations [55]
- Electricity at Work Regulations [56]
- Control of Substances Hazardous to Health Regulations (COSHH) [57]
- Pressure Vessels Regulations [58]
- The Provision of First Aid [59]
- 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 [60,61,62].

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.

4.2.7 Conclusion

From time to time one can expect the Act to be amended so that reference to the latest version is desirable. A guide to this Act is available [27].

4.3 Control of access

It is absolutely vital to control access of personnel and equipment to the MR CONTROLLED AREA and to control those individuals who are scanned.

4.3.1 Supervision of exposed persons

All unauthorised persons should be supervised by an MR AUTHORISED PERSON whilst in the MR CONTROLLED AREA. Supervision of staff will normally be undertaken by an MR OPERATOR following standard procedures.

Section 4.4 describes all categories of exposed people. Particular attention should be paid to pregnant women (see section 2.5) and to individuals with implanted medical 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 CONTROLLED AREA they should have a negligible effect.

4.4 Categories of exposed persons

4.4.1 Patients for diagnosis

Patients should be screened 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 MR OPERATOR. 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.

4.4.2 Volunteers enrolled in clinical trials

The scanning of all volunteers requires prior approval from the local 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).

4.4.3 Staff

Only MR AUTHORISED PERSONNEL should have free access to the MR CONTROLLED AREA. Unauthorised staff must be screened for a wide range of factors (see section 4.12) and seek authority to enter the MR CONTROLLED AREA.

4.4.4 General public

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

4.4.5 Carers

A relative, friend or other person providing support or care for the patient and not employed to do so. They should be screened in a similar way to patients if they are to enter the MR CONTROLLED AREA.

4.5 MR CONTROLLED AREA

4.5.1 Definition of MR CONTROLLED AREA

These guidelines recommend that the MR diagnostic equipment be contained in a designated MR CONTROLLED AREA totally enclosed and of such a size to contain the 0.5 mT (5 Gauss) magnetic field contour. This limit is to prevent harm to those fitted with medical implants that may be affected by the static magnetic field.
Access should be restricted and suitable signs should be displayed at all entrances. An example of the layout is given in Figure 1.

4.5.2 Access to MR CONTROLLED AREA

Access to the MR CONTROLLED AREA should be provided by the minimum number of self-locking doors that is practicable. 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 AREA should be given only to MR AUTHORISED PERSONNEL. All other personnel, including unauthorised staff and visitors must be screened and seek authority to enter the MR CONTROLLED AREA.

4.5.3 Screening for entry to MR CONTROLLED AREA

It is recommended that screening for entry includes verbal questioning, a written questionnaire and provision of information about potential hazards, before authorisation to enter the MR CONTROLLED AREA 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 [63].
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 [64].

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

4.5.4 Warnings for those entering the MR CONTROLLED AREA

All those seeking to enter the MR CONTROLLED AREA must be warned of:

- the possible hazards of the magnetic field, in particular to the operation of 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 65, 66, 67, 68).

A person fitted with a heart pacemaker and/or other implantable medical devices that could be affected (see section 4.10) must not enter the MR CONTROLLED AREA

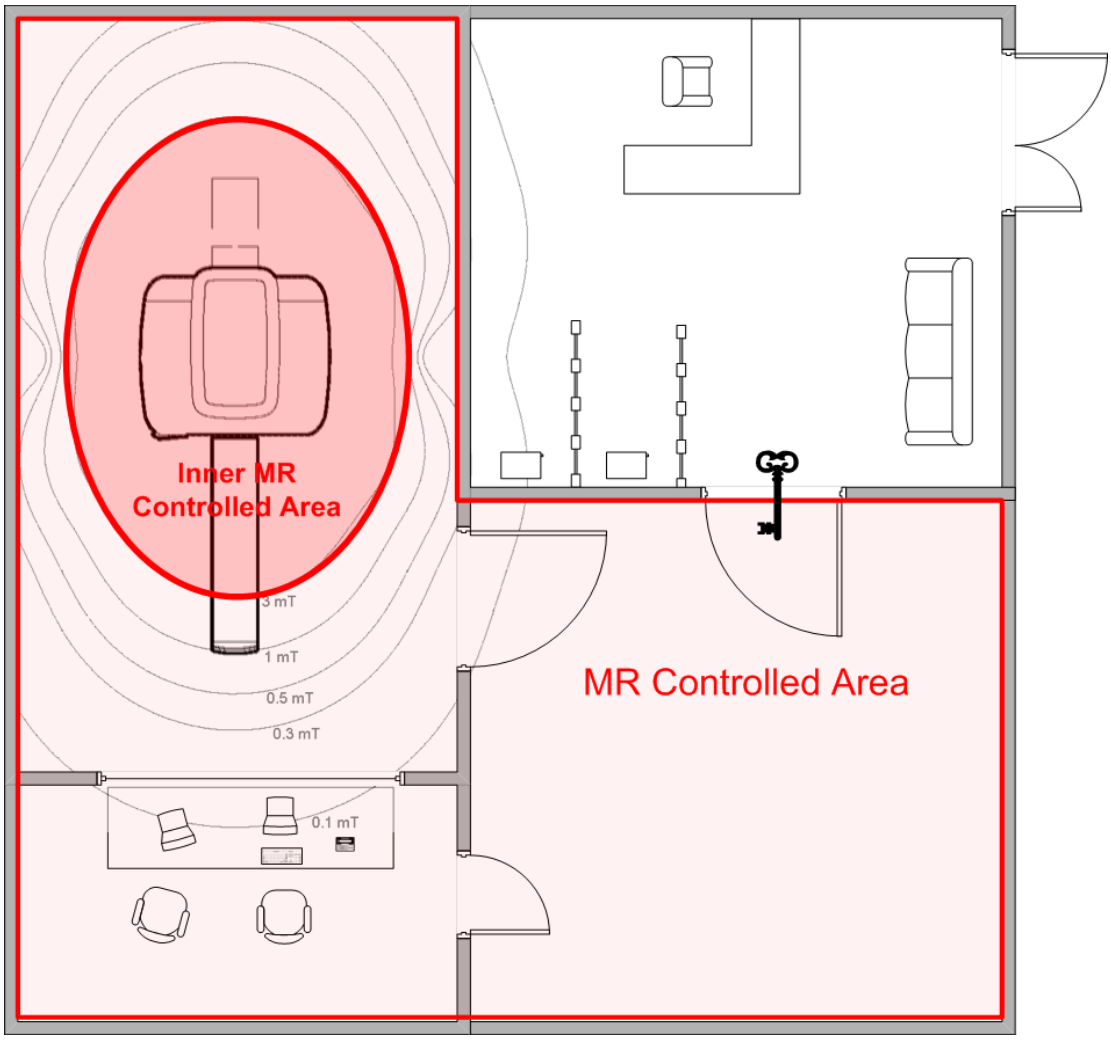

Figure 1 Example layout of an MRI unit

4.6 INNER MR CONTROLLED AREA

4.6.1 Definition of INNER MR CONTROLLED AREA

It may be convenient to define an INNER MR CONTROLLED AREA within the confines of the MR CONTROLLED AREA containing the 3 mT (30 Gauss) magnetic field contour. Where there is only one area (i.e. no INNER MR CONTROLLED AREA) all references in these guidelines to INNER MR CONTROLLED AREA will apply to the whole of the MR CONTROLLED AREA.

A field strength of 3 mT was chosen for the INNER MR CONTROLLED AREA to avoid the projectile hazard [6].

4.6.2 Precautions for the Inner Controlled Area

During their presence in the INNER MR CONTROLLED AREA, unauthorised staff and visitors must be under continuous supervision by an MR AUTHORISED PERSON who is either in the INNER MR CONTROLLED AREA or can see the visitor at all times by some means.

Before entering the INNER MR CONTROLLED AREA everyone must take the following precautions:

- they must deposit mechanical watches, credit cards, magnetic tapes, other magnetic recording media and ferromagnetic objects in the reception area by handing them to a receptionist or by placing them 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. It is not always obvious that an object is ferromagnetic so it may be more appropriate to remove all unattached objects outside the MR Controlled Area
- ferromagnetic objects such as tools, gas cylinders, trolleys, life support systems etc must not be allowed into the Inner MR Controlled Area.

4.6.3 Access to INNER MR CONTROLLED AREA

The access of patients and volunteers to the INNER MR CONTROLLED AREA 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 to the MR Controlled Area, are adequately informed of the safety requirements and abide by them
- all those entering the MR Controlled Area have been adequately screened in person and in terms of what they will be carrying into the MR Controlled Area.

4.7 MR AUTHORISED PERSONNEL

4.7.1 Definition

An MR AUTHORISED PERSON is a suitably trained member of staff authorised to have free access to the MR CONTROLLED AREA. In some cases this may be an external member of staff e.g. maintenance staff.

4.7.2 Authorisation of personnel

Ideally, the selection and certification of a person for authorisation should rest with the MR RESPONSIBLE PERSON and be endorsed by the chief executive. Certification of an individual should only be authorised after satisfactory completion of training in the individual's responsibilities and an appropriate appreciation and understanding of the MR diagnostic equipment and its safety requirements (see section 4.17).

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 AREA and personally behave in such a manner as not to endanger his or her own health or safety or that of others.

4.7.4 Screening of MR AUTHORISED PERSONNEL

All MR AUTHORISED PERSONNEL must have satisfactorily passed the screening process. 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 Area, all MR Authorised personnel must at all times comply with the safety recommendations given in section 4.6.
- 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 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.

4.9 Control of equipment taken into the scan room

4.9.1 Equipment policy

The MR RESPONSIBLE PERSON should ensure that there is a clear policy for the purchasing, testing and marking of all equipment that will be taken into the INNER MR CONTROLLED AREA.

4.9.2 Responsibility for entry

Control of equipment entering the INNER MR CONTROLLED AREA 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 INNER MR CONTROLLED AREA.

4.9.3 Labelling of equipment

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 and RF heating.
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 6.

4.9.4 Ancillary equipment

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.

Exceptions exist. There are circumstances in which ferromagnetic equipment is brought into the scanner room under carefully controlled conditions – e.g. 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 [69].

4.9.5 Testing magnet

It is recommended that users have access to a strong > 0.1T handheld magnet for testing items [46] to be taken into the MR CONTROLLED AREA.

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.
- The approval of the local ethics committee should be obtained [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 e.g. maximum number of scans that may take place per annum.

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.

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 magnetic field should be certain that all departmental safety checklists have been carried out and is entirely confident that is safe to so do.
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 the local ethics committee.

4.10.3 Responsibility for patients/volunteers whilst in the unit

While the patient is within the MR CONTROLLED 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 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 (MR OPERATORS).

4.10.4 Pregnancy and MR imaging

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.

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. 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, are important.
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.

Since the potentially sensitive categories of patients are not well defined, the NRPB recommended that all patients exposed above the lower level of restriction, i.e. in the controlled mode, have simple physiological parameters such as body temperature, blood pressure and heart rate routinely monitored (see section 2.4.2. and [1]). Users should follow their local policy on the matter (see section 4.13).

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 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 [68] with details of tested devices and a 'Reference Manual for Magnetic Resonance Safety, Implants and Devices' on an annual basis [70]. Care should be taken when referring to this document as devices may be different in the USA to those in use in the UK.

4.11.1 Examples of active implantable medical devices

4.11.1.1 Cardiac pacemakers/cardioverter defibrillators

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.
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 e.g. 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.

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 CONTROLLED AREA.

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 [18], [65] 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.

However some manufacturers are suggesting that MR examinations may be safe if strict guidelines relating to scanning parameters are followed. These guidelines will

require detailed knowledge of the scanner and scanning sequences to be used by the staff in the unit, discussion with the manufacturers of the MRI equipment and the implanted device, as well as the respective clinical departments managing the patients [18, 65].

4.11.1.3 Implanted 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 [18, 65].

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) [72] 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 (e.g. 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 tesla 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 are usually ferromagnetic, and are activated by electronic and/or magnetic mechanisms. As such, they are a contraindication to MR exposure.

Some studies have been successfully completed at 0.2 T when special conditions have been satisfied [73]. In this case it is also imperative that the user refers to the manufacturer for advice relating to the MR safety of the device [18, 65].

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 e.g. 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.

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 [18, 65]. 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, the MR procedure should be deferred until the metal has been identified [18, 65].

Aneurysm clips [74] 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 scan room.

For further information please see references [18] and [65].

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 e.g. certain stainless steels, a period of 6–8 weeks is still recommended to allow for tissue growth [66].

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

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 [18, 65]. 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 [65].

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 [75]. 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 Tesla or less. [65]

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 [18, 65, 66].

4.11.4 Transdermal patches, tattoos and make-up

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

- Transdermal medicinal patches containing metal should be removed and replaced after scanning if this can be done without affecting patient treatment.
- 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. [46]

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

4.11.5 Metallic foreign bodies

The presence of metallic objects such as bullets, pellets, shrapnel, concealed body piercing, rings 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 e.g. aorta or carotid artery.

4.11.5.1 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 CONTROLLED AREA of the MR suite.

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 [18, 65, 66].

4.11.5.2 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.

4.11.6 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.

4.11.7 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 weight

The MHRA recommends that all patients be weighed in the MR unit before scanning. It is important that a current weight measurement is available 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 [18].
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 (e.g. check X-ray, physical examination for pacemaker by referring consultant).
Examples of screening forms are available from the BAMRR [76] and MRI safety website [68].

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 4.5.3).
Screening consent/checklist forms should conform to standards for patient information e.g. plain English, 14-point size font minimum and available in alternative languages

appropriate to local population (Welsh, Urdu, etc.) and will include the following but 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.

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 ferro-magnet detectors is dealt with in section 5.4.10.

4.12.6 Patient clothing

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 [25].

To avoid burns caused by RF heating [67]:

- 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. 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 i.e. 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 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, 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 A2.2.5). 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.

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 [40].

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 controlled and experimental modes [1]. Local policies should be agreed and followed (see section 4.13).
All monitoring should be undertaken using dedicated **MR CONDITIONAL** or **MR SAFE** monitoring equipment [18, 65, 66, 67]. 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.

Only items recommended by the MR system manufacturer should be used.
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 [18, 65, 66, 67, 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 NRPB

The NRPB advised that when operating in the controlled mode all patients should have simple physiological parameters such as body temperature, blood pressure and heart rate routinely monitored.

4.13.2 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.

4.13.3 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.*

4.13.4 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.
- 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 cannot take place within the scan room.
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 guidelines specific to MR [78]. It is strongly recommended that they be read in conjunction with this document.

4.14.2 Preparation

Patients should be prepared in a side room outside the INNER MR CONTROLLED AREA and no ferromagnetic equipment should be brought into the INNER MR CONTROLLED AREA. Special care is required to prevent needles, oxygen cylinders, laryngoscopes and other anaesthetic equipment being brought into the INNER MR CONTROLLED AREA. 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 INNER MR CONTROLLED AREA must be suitable [67]. 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 A2.2.5). 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 CONTROLLED AREA [88]. 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 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 [79] (NEMA) to aid the distribution and viewing of medical images. Part 3 [80] of the standard contains details of the general and modality modules.

4.15.2 DICOM MR image modality data set

A summary of the MR modality data set is given in Table 3.

Table 3 DICOM MR image module

Samples per pixel	Nominal interval
Bits allocated	Beat Rejection Flag
Scanning sequence	Low R-R value
Sequence variant	High R-R value
Scan options	Intervals acquired
MR acquisition type	Intervals rejected
Repetition time	PVC rejection
Echo time	Skip beats
Echo train length	Heart rate
Inversion time	Cardiac number of images
Trigger time	Trigger window
Sequence name	Reconstruction diameter
Angio flag	Receive coil name
Number of averages	Transmit coil name
Imaging frequency	Acquisition matrix
Imaged nucleus	In-plane phase encoding direction
Echo number	Flip angle
Magnetic field strength	SAR
Spacing between slices	Variable flip angle flag

Number of phase encoding steps	dB/dt
Percent sampling	Temporal position identifier
Percent phase field of view	Number of temporal positions
Pixel bandwidth	Temporal resolution

Other information that should be kept is:

- the approximate time spent in the magnet
- 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, including a signed statement showing confirmation of full explanation given and medical screening conducted.
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 [63].

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 at the request of a registered medical practitioner and at all times 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.

New regulations on prescribing now say that a nurse independent prescriber or pharmacist independent prescriber can prescribe any licensed medicine for any medical condition within his/her competence. Some drugs and contrast agents may be administered by non medical practitioners under a Patient group directive or a patient specific directive. 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 [81].

For units with a remote consultant radiologist, advice is given in RCR/SCoR [32] and RCR guidance [33].

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 [18].

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 [82].

4.16.3 Injection of contrast agents

If injection of contrast agents takes place in the INNER MR CONTROLLED AREA 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 Medicines and Healthcare products Regulatory Agency (MHRA) by use of a Yellow Card, which is available from: MHRA, CHM Freepost, London SW8 5BR or electronically via the MHRA website (http://www.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 AREA 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.
A summary of training requirements is given in Table 4.

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 AREA 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 other staff who are required to enter the MR CONTROLLED AREA when scanning is not taking place, this can include: **dedicated** MRI department porters; persons who may be called upon to deal with an emergency but are not directly involved with the equipment, such as cardiac arrest team members, equipment engineers and hospital engineering staff; staff who need to enter from time to time but are not involved in operating the equipment or with patients and volunteers being scanned, such as hospital maintenance engineers and **dedicated** MRI department cleaners; staff who need to enter the MR CONTROLLED AREA in order to replenish cryogens; MRI department management and administrative staff.
The following identifies specific topics for consideration in the training of various categories of staff that need to enter the MR CONTROLLED 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 a MR CONTROLLED AREA and an INNER MR CONTROLLED AREA 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 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

All other staff who are required to enter the MR CONTROLLED AREA when scanning is not taking place. They must be fully instructed on the potential hazard of ferromagnetic objects and their exclusion from the MR CONTROLLED AREA at all times.

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.

Table 4 Summary of training requirements

	A	B	C
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 understand the safety aspects relating to:			
- The electrical safety of the equipment.	✓	✓	–
- The main static magnetic field and associated equipment.	✓	✓	✓
- Radio-frequency (RF) fields and associated equipment.	✓	✓	–
- Gradient magnetic fields and associated equipment.	✓	✓	
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 MR CONTROLLED AREA and the INNER MR CONTROLLED AREA 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 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.	✓	✓	–

4.18 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:

- 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 ADVISOR(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 AREA and an INNER MR CONTROLLED AREA.
- 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 [83]
- noise concerns.

Special attention must be given to the MR CONTROLLED AREA and INNER MR CONTROLLED AREA 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 (5 Gauss) 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 (5 Gauss) magnetic contour is contained within the confines of the mobile unit.
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 high field units

4.19.1 Introduction

For the purpose of these guidelines, high field units are considered those above the IEC [5] 2 T limit and the NRPB [1] 2.5 T limit. This, therefore, includes the commercially available 3 T scanners.

4.19.2 Hazards

The hazards in MR increase with the increase in field strength. Therefore, MR units working with high field scanners must be extra vigilant.

Static field: There are steeper fringe field gradients involved at high fields. MR units must have a comprehensive field plot in order to understand the projectile risk. These plots can also be used to ensure that staff are not in breach of occupational guidelines for static field exposure (see appendix A2.1.2)

Gradient fields: The noise generated by the switching magnetic field gradients is usually louder at higher field strengths. All patients must be given adequate hearing protection. A risk assessment of noise exposure to staff must be carried out (see appendix A2.2.5). There is also greater potential for patients to experience peripheral nerve stimulation.

RF fields: The risk of patient radiofrequency burns increases as the transmit frequency increases. The transmit frequency used is directly proportional to the field strength. See Table 2 for typical field strength and RF transmit frequencies for MR scanners currently installed in the UK. Databases on adverse incidents show that most burns are reported from systems operating at 1.5 T and above.

4.19.3 Safety of ancillary equipment and implantable medical devices

Sites should take care to ensure that implantable medical devices, monitoring equipment, leads etc. have been tested at the static field strength, gradient field strengths and slew rates for their particular environment. It is essential to re-evaluate all that was **MR CONDITIONAL** at the lower field strength before use with the higher fields. Potential purchasers of high field systems should be aware that very little testing of accessories, monitoring equipment or implantable medical devices has taken place at these field strengths and so a cautionary approach is recommended.

4.19.4 Scanning of patients and volunteers at high field

All patients being scanned will be in either the CONTROLLED MODE of exposure or the RESEARCH / EXPERIMENTAL MODE of exposure. This will depend on the exposure level to the static magnetic field, the radiofrequency field and the time-varying magnetic field gradients. Monitoring will be required.

The local procedure for the management of patients and volunteers being scanned in the CONTROLLED MODE of exposure should be followed (see section 4.13).

When scanning in the RESEARCH / EXPERIMENTAL MODE the requirements of the local ethics committee which approved the procedure should be adhered to.

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

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

4.19.5 Risk assessment exposures to high field systems

The risk assessment must be updated when changing to a high field system.

Static field: The static field exposure near a well-shielded 3 T system can be less than that near a 1.5 T unit. However, this cannot be ascertained without detailed field plots

from the manufacturer. Detailed field plots will identify areas around the magnet where exposure is greatest. Staff should avoid these areas if possible.
RF and gradient fields: Exposure to RF and gradient (dB/dt) fields should be minimal for staff standing outside a tunnel bore system during scanning. Information should be obtained from the manufacturer confirming that staff exposure to RF and gradient (dB/dt) fields are within the relevant occupational exposure limits.
Noise: As previously stated an assessment of noise levels experienced by personnel in the scan room must be undertaken. All who remain in the MR scan room during scanning should wear hearing protection when noise levels exceed 80 dB(A).

4.20 Special issues – management of open systems

4.20.1 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. The advent of high field open systems brings greater need for detailed understanding of projectile and exposure risks. Detailed field plots shall be provided by the manufacturer at the time of tender in order that the extent of magnet shielding can be determined. Areas around the magnet where exposure is greatest shall be Identified, and clearly marked at the time of commissioning. Staff should avoid these areas if at all possible. It is the responsibility of the employer to assess staff exposure levels. Staff monitoring may be required to ensure that they are not exposed to levels greater than the recommendations given in section 3.

4.20.2 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.

4.21 Special issues – management of interventional units

4.21.1 Staff numbers

Greater numbers of personnel and a wider range of equipment will require access to the INNER MR CONTROLLED AREA 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.

4.21.2 Exposure assessment

The MR unit must assess the risk to staff in terms of static field, noise, RF, and gradient (dB/dt) exposure.
Detailed field plots will identify areas around the magnet where exposure is greatest. Staff should avoid these areas if possible. It is the responsibility of the employer to assess staff exposure levels.

4.21.3 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.

4.21.4 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.

4.21.5 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.

4.21.6 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.

4.21.7 Cleaning and decontamination

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

4.22 Special issues – management of radiotherapy planning units

4.22.1 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.

4.22.2 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. (e.g. chemical shift or B_0 distortion), and may differ in different orientations.

4.22.3 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.

4.22.4 Exposure assessment

Sites must assess the risk to staff in terms of static field, noise, RF and gradient (dB/dt) exposure. Field plots from the manufacturer must be obtained along with a statement that the RF and gradient (dB/dt) exposure would not exceed the recommendations presented in section 3.

Detailed field plots will identify areas around the magnet where exposure is greatest. Staff should avoid these areas if possible. It is the responsibility of the employer to assess staff exposure levels. Staff monitoring may be required to ensure that they are not exposed to levels greater than the recommendations given in section 3.

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 ADVISOR
- MR physicist (unless the MR safety advisor 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 Medicines and Healthcare products Regulatory Agency (MHRA) and MagNET: for technical information on the quality and safety aspects of different MR systems.
- 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 Published information for use during MR procurement

At the time of writing, the NHS Purchasing and Supply Agency (PASA) Centre for Evidence-based Purchasing (CEP) funds an evaluation centre, MagNET, at Imperial College. The MagNET team undertakes technical evaluations of commercially available MR systems to assess their quality and safety. The results are published in a series of single product or comparison reports. These may help the purchaser to assess the performance of the scanners they are considering in their tender evaluation. These reports can be obtained by contacting PASA.
MagNET also provides a 'technical questionnaire' that contains a list of technical questions to ask the manufacturer about their MR system. The potential buyer can ask the manufacturer to fill in the questionnaire so that a comprehensive technical specification can be obtained before a purchasing decision is made.

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 [84].
- EN 60601-1-1: Medical electrical equipment – Part 1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems [85].
- EN 60601-1-4: Medical electrical equipment – Part 1-4: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems [86].
- IEC 60601-2-33: Medical electrical equipment – Part 2-33: Particular requirements for safety of magnetic resonance equipment for medical diagnosis [5].

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 [87, 88, 89]. 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' [90] shall be used by healthcare organisations and medical device suppliers responsible for permanent electrical installation of medical devices and associated equipment in diagnostic imaging rooms/suites.

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 [91] 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 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.

5.3 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 [87, 88, 89]. 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 should also include:

- independent electrical safety testing
- independent confirmation of the 0.5 mT (5 Gauss) line
- independent confirmation of noise levels
- confirmation of compliance with MEIGaN [90].

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 ADVISOR and/or MagNET.

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. For more information on MR test objects please contact MagNET.

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 AREA

Irrespective of operating field strength, it is recommended that the MRI equipment is housed in a MR CONTROLLED AREA and, if necessary, an associated INNER MR CONTROLLED AREA with access limited to MR AUTHORISED PERSONNEL or those given temporary authority (which will include all unauthorised staff, patients, volunteers and visitors). Details of the recommendations for the MR CONTROLLED AREA and the INNER MR CONTROLLED AREA are given in section 4.

5.4.2 Number of entrances

The number of entrances should be kept to a strict minimum. Normally, for both the MR CONTROLLED AREA and the INNER MR CONTROLLED AREA, 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 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 INNER MR CONTROLLED AREA should not open directly onto public areas.

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. They should be located outside the MR CONTROLLED AREA.
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 cryogens

In the case of superconducting magnets it will be necessary to duct the cold vapours produced by boil-off out of the INNER MR CONTROLLED AREA (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.

It is possible for helium and nitrogen gas to accumulate within the MR diagnostic equipment unit if there is a fault in the ventilation system. 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.

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 [5]). 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.

Figure 2 MRI door entry sign

5.4.7 Signs

At each entrance to the MR CONTROLLED AREA, 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 IEC 60601-2-33 [5] and BS 5499 [11].

5.4.8 Equalising wave guides

These can be fitted in the wall of the scan room, the scan room door or the ceiling to ensure that the scan room door can be opened in the event of a build-up of pressure due to a venting failure during a quench [5]. 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 A2.1.4.2). For advice on how to operate outside these limits, please refer to the manufacturer for advice as discussed in appendix A2.1.4.2.

5.4.10 Conventional metal detectors

The installation of metal detectors at the entrance to the MR CONTROLLED AREA may be considered appropriate but it has been found in general that they are currently not reliable at detecting relatively small ferromagnetic or metal pieces. The small-coil hand-held metal detectors are more sensitive to small pieces of metal. However, they are highly unlikely to detect intraocular metallic foreign bodies and they do not differentiate between ferromagnetic materials and non-ferromagnetic materials. This would lead to the alarm being set off quite often – even by **MR CONDITIONAL** or **MR SAFE** devices. The resulting number of false alarms is likely to lead to decreased vigilance.

It is very important to ensure that all involved follow appropriate local rules for the removal of ferromagnetic items and that all patients, volunteers and others are adequately screened before being allowed to enter the MR CONTROLLED AREA.

5.4.11 Ferromagnet detectors

A number of ferromagnetic material detectors are now available. The ferromagnetic detection systems have a number of advantages over conventional metal detectors including being totally passive systems and allowing non-ferrous 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 the scan room entryway. In the pre-screening mode the system is typically located in the changing room area and will allow a patient to be scanned for small ferrous items well in advance of entering the scan room.

As well as reducing the likelihood of small projectile incidents, the systems are designed to reduce the likelihood of an MRI scan having to be repeated e.g. due to the presence of an object distorting the MRI scan image. In the MRI entryway protection mode the ferromagnetic detection system would be located at the entrance to the MRI suite. It is placed or mounted either side or the doorway and as such presents no obstruction to entry into the scan room. The detection sensitivity is somewhat lower than a pre-screen mode and the systems are designed to reduce the likelihood of a major ‘projectile effect’ incident.

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.

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 the Medicines and Healthcare products Regulatory Agency 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 the Medicines and Healthcare products Regulatory Agency (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 the first Medical Device Alert of the year [92]. 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 magnets

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).

The MHRA received a report that a patient experienced neurosensory effects during the quench of a 3 T system.

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. Patients should be excluded from the INNER MR CONTROLLED AREA during either of 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 evolution 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 three metre exclusion zone is recommended for the quench vent exhaust [93].

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.


The MHRA recommends annual inspections of all vent piping.

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.

5.5.5 Resistive magnets

The inductance of resistive 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).

Care should be taken to shroud the coils since they become warm. Emergency facilities should be provided in order to arrest the power in an emergency. For example a button similar to those in 5.5.4 above.

5.5.6 Permanent magnets

A permanent magnet **cannot** be turned off, so ferromagnetic objects cannot be released from a permanent magnet structure by arresting the field. If a ferromagnetic object traps someone, the problem of releasing him or her can be formidable. Particular care must be taken to avoid taking such objects into the MR CONTROLLED AREA. The whole structure should be shrouded by a non-ferromagnetic protection of sufficient strength to withstand impact from a 50 kg object accelerating freely from a distance of

1 m. The thickness and strength of the shroud should be such that a force of up to 1 kN can be used, if necessary, to release the ferromagnetic object.

5.5.7 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.

5.5.8 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.

5.5.9 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.

The system must be interlocked to ensure that the peak RF power cannot be delivered continuously, owing to a control system failure, or at an excessive rate either due to operator inattention or to a more subtle system failure. Ideally, the interlocking system should be independent of the main control system, with separate timing and power supplies. It should not be possible to provide radio frequency power unless the interlocks are powered and in all events, the interlocks must fail safely.

There is a need to ensure that there cannot be a flashover between the transmitter coil and the patient. There is also a need to prevent arcing in the transmitted coil system and in the receiver if it is closely coupled to the transmitter. Voltages on transmitter coils can reach 20 kV and insulation of the system needs to be checked regularly by the service provider. At all times, surfaces must be kept clean, and condensation must be avoided.

5.5.10 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.

5.5.11 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.

5.5.12 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.

5.5.13 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 AREA, and the necessary liaison with the appropriate groups both within and outside the establishment. Sections 4.3 and 4.5 cover access to the MR CONTROLLED 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 AREA when an MR AUTHORISED PERSON is not available e.g. 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.

No ferromagnetic material of any kind must enter the INNER MR CONTROLLED AREA. All personnel must be adequately screened for ferromagnetic material being carried on their person – hairgrips, key rings, scissors, knives, etc. – beyond the 0.5 mT (5 gauss) static magnetic field level. There can be only one exception to this rule, which is if the magnet has been de-energised before the entry of unauthorised personnel.

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 INNER MR CONTROLLED AREA as quickly as possible. Resuscitation should then take place outside the INNER MR CONTROLLED AREA by a qualified resuscitation team, as is normal hospital practice. Procedures will need to ensure that a non-ferrous 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 CONTROLLED AREA when the magnet is energised unless it is **MR CONDITIONAL** or **MR SAFE**.

The patient should be taken to the resuscitation area outside the INNER MR CONTROLLED AREA.

The magnetic field of a resistive magnet can usually be switched off without undue complications so that with such equipment it may prove more effective to switch the field off and then bring the resuscitation equipment into the INNER MR CONTROLLED AREA. Users must ensure that the resuscitation equipment and any other non-MR compatible equipment are removed **before** the magnetic field is switched on again.

Exceptions exist. There are circumstances in which resuscitation may take place in the scanner room under carefully controlled conditions – e.g. during combined X-ray and MRI interventional procedures in XMR suites.

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 CONTROLLED AREA unless the magnetic field has been fully quenched or turned off.

Resistive magnet systems: In the event of a fire within a MR diagnostic unit containing a resistive magnet the power should be switched off immediately and the unit evacuated. Once the power is off, the emergency procedures are similar to those of any other large item of electrical equipment. Unauthorised personnel can then enter if necessary.

Permanent magnet systems: The field associated with a permanent magnet cannot be switched off. The fringe field is very low by comparison with other magnets up to distances of about 1 m from the magnet. Nearer than this distance the field will rise rapidly, especially near the bore, giving rise to intense forces on ferromagnetic materials. However, an additional hazard associated with a large-scale fire would be the weight of such a system, especially if it were not sited on the ground floor.
A clear warning should be placed at the entrance to the MR CONTROLLED AREA and on the magnet to the effect that the field is permanently on.

Superconducting magnet systems: In a MR diagnostic equipment unit with a superconducting magnet, the magnet must be quenched if the emergency services wish to enter the INNER MR CONTROLLED AREA 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 INNER MR CONTROLLED AREA.

It is recommended that non-ferrous carbon dioxide extinguishers are used.

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. These could include:

The door is reconfigured to open outwards

The door is replaced with sliding doors that can be opened in a emergency

Emergency escape/ventilation panels are fitted to the door or in a suitable wall.

5.7 Planning for replacement

Advice on equipment management is given in DB2006(05) 'Managing Medical Devices' [94].

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.

6 Example labels

Appendix 1 Cryogens and venting issues

A1.1 Cryogens

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 cryogens

General requirements:

- Training authorised by cryogen suppliers must be undertaken before personnel operate and replenish the cryogens.
- 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 at is practical, use close-fitting overalls without pockets to avoid accumulation of cryogens 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 cryogens, 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 (e.g.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.

A1.2 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 [95, 96] 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 corporate or unincorporate.
The competent person has two 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
- manufacturers 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 of 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 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

General observations regarding the vent system and checks regarding original design:

- the vent system is constructed from a non-ferrous/non-magnetic material such as an austenitic stainless steel
- the vent pipe has been clad with a minimum 25 mm of insulating material, insulation should maintain a surface temperature no less than 0 °C during an actual quench

- all vent joints are either professionally welded by a certified welder or of a bolted flange construction utilising either UH-MW-PE, PTFE (BS EN 13000-1:1998, BS EN 13000-2: 1998 or fiber (ASTM F36, BS 7531, DIN 3754P) gasket if required.
- all vent materials including fixtures and fittings are suitable for applications down to 10K (-263°C)
- the vent system is sized and designed for a minimum pressure capability of up to 0.15 bar or as specified by the MRI manufacturer. On completion, the installation should be pressure and leak tested to achieve a minimum leakage rate of 1 cm^3s^{-1} of helium gas at STP per metre run or as detailed by the MRI manufacturer
- adequate provision for thermal expansion/contraction is to be allowed throughout the quench system by means of lined bellows suitable for the application. As a guide thermal contraction should be based on 3 mm per metre for stainless steel at 10K
- adequate provision for condensate drainage should be provided within the vent system and a minimum vent rise of 5° to the horizontal should be observed to further facilitate the flow of condensation, should it occur.

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.

Appendix 2 Exposure limits

The following section details exposure limits suggested by NRPB, 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 NRPB

The 1991 NRPB report [1] recommended a two level system for routine clinical scanning, outlined below:

- **Uncontrolled level:** exposures below which it is considered safe.
- **Upper level:** exposures which it would be inadvisable to exceed without ethics committee approval.

The data available at the time of publication were insufficient to allow thresholds for adverse effects of acute exposure of humans to magnetic fields to be accurately defined.

The adoption of a two level standard was intended to provide some flexibility and to allow the cautious development of MR diagnostic techniques in which humans may be exposed to magnetic fields greater than those commonly used at the time of publication.

Any exposure of volunteers to MRI requires ethics committee approval. Exposure above the CONTROLLED MODE should be brought specifically to the attention of the ethical committee.

A2.1.1.2 IEC

The IEC standard [5] 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 (i.e. a human studies protocol approved to local requirements).

A2.1.1.3 ICNIRP

ICNIRP also recommends [8] three operating modes for patient scanning (which are identical to the IEC levels):

- **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 local ethics committee approval has been obtained.

A2.1.2 Static magnetic fields (B0)

The NRPB restrictions are expanded on below. The IEC/ICNIRP requires 'medical supervision' of the patient, and the NRPB requires 'clinical supervision' of the patient when working above the normal/uncontrolled level (see section 4.13).

- NORMAL MODE The NRPB states that static magnetic flux density does not exceed 2.5 T to the head and trunk and 4 T to the limbs. The IEC/ICNIRP value is less than 2 T.
- CONTROLLED MODE The NRPB states that the head and trunk may be exposed to a static field of up to 4 T if the patient or volunteer is monitored as appropriate (see section 4.13). The IEC/ICNIRP value is from 2–4 T.
- RESEARCH / EXPERIMENTAL MODE All organisations state that ethics committee approval is needed to work with scanners operating above 4 T.

High B_0 fields. It should be noted that those sites purchasing whole body scanners above 2.5 T would be routinely operating in a controlled mode. See section 4.19 for the management of high field units. Pregnant women should not routinely be exposed above the advised lower levels of restriction i.e. not above 2.5 T.

A2.1.3 Time-varying magnetic field gradients

A2.1.3.1 NRPB restrictions

The NRPB recommendations [1] state the following:

- **Uncontrolled level** For periods of magnetic flux density change exceeding 120 μs, exposures should be restricted to peak rates of change less than 20 Ts^{-1}. For periods of change less than 120 μs the relationship $dB/dt \leq 2.4 \times 10^{-3}/t\ Ts^{-1}$ should be observed where dB/dt is the peak value of the rate of change of magnetic flux density in any part of the body in Ts^{-1} and t is the duration of the change of the magnetic field in seconds.
- **Upper level** If the patient or volunteer is monitored as appropriate (see section 4.13) then for periods of change of less than 3 ms the extent of the rate of change of the field strength can be raised to satisfy the relation $dB/dt < 60 \times 10^{-3}/t\ Ts^{-1}$. This is in order to avoid cardiac muscle stimulation.

The NRPB states that for research/experimental work with ethics committee approval, the derived restrictions on rate of change of magnetic flux density can be exceeded if it can be shown that the basic restriction on induced current density is not exceeded. This is summarised in Table 5.

Table 5 NRPB patient and volunteer exposure limits to time-varying magnetic fields

Duration of field change	Uncontrolled level (Ts^{-1})	Upper level (Ts^{-1})
T < 2.5μs	950* (1 Wkg^{-1})	1300* (2 Wkg^{-1})
2.5μs < t < 45μs	2.4 x 10^{-3}/t	1300* (2 Wkg^{-1})
45μs < t < 120μs	2.4 x 10^{-3}/t	60 x 10^{-3}/t
120 μs < t < 3 ms	20	60 x 10^{-3}/t
t > 3 ms	20	20

*Expressed as peak rates of change of magnetic flux density.

A2.1.3.2 IEC/ICNIRP 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 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 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.

Additionally, IEC has a limit to prevent cardiac stimulation; this is also shown in Table 6.

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

	Normal	First level	Second level
Limits for gradient output: Expressed as a percentage of the median perception threshold, $dB/dt=20(1+0.36 / t_{s,eff})T\ s^{-1}$ (%) *	<80	80–100	>100
To prevent cardiac stimulation. For all modes of operation (Ts^{-1}).	$\frac{dB}{dt} < \frac{20}{\left\{1 - \exp\left(-\frac{t_{s,eff}}{3}\right)\right.}$ *		

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

A2.1.4 Specific absorption rate (SAR) limits

A2.1.4.1 NRPB

The exposure limits from the 1991 NRPB report [1] are given below.

- **Uncontrolled level** For periods of exposure longer than 30 minutes and under moderate environmental conditions (relative humidity (RH)< 50% and ambient temperature < 22°C) restricting the whole-body SAR to an average of 1 Wkg^{-1} will avoid a rise of more than 0.5°C in the whole body temperature of patients. The SAR limit depends on exposure time. Please refer to Table 7.
- **Upper level** If the patient or volunteer is monitored as appropriate (see section 4.13) then the SAR limits can be relaxed according to the body part and exposure times referenced in Table 7.

The NRPB states that for research or experimental work with ethics committee approval, the derived restriction on SAR can be exceeded if it can be shown that the basic restriction on maximum temperature Table 10 and temperature rise Table 9 is not exceeded.

Table 7 NRPB patient and volunteer SAR limits (Wkg^{-1}) for RF field exposure

NRPB level	Uncontrolled	Upper	Uncontrolled Peak SAR		
Body part	Whole*	Whole*	Head/ fetus**	Trunk**	Limbs**
Exposure time t < 15 min	2	4	4	8	12
Exposure time 15 > t < 30 min	30/t	60/t	60/t	120/t	180/t
Exposure time t >30 min	1	2	2	4	6

*Averaged over any 15-minute period. **Averaged over any 6-minute period.

A2.1.4.2 IEC/ICNIRP

IEC/ICNIRP SAR limits are listed in Table 8. IEC also requires scanners to reduce SAR if ambient temperature is above 25°C or if relative humidity is above 60%.
It is recommended that sites make themselves familiar with the SAR limits used by their system from both the IEC standard [5] and the manufacturer's user manual.

Table 8 IEC/ICNIRP patient and volunteer SAR limits (Wkg^{-1}) for RF field exposure

	Whole body	Partial body		Local		
		Head	Not head [a]	Head [b]	Trunk	Extremities
Normal	2	3	2–10	10	10	20
Controlled	4	3	4–10	10	10	20
Restricted	>4	>3	>(4–10)	10	>10	>20

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×r) Wkg^{-1}
– controlled operating mode: SAR = (10-6×r) 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.

NRPB 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 these 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 newer 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 NRPB (1991), IEC (2002) and ICNIRP (2004) all have the same limits with respect to temperature rise (except the fetus in IEC). 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.

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

Mode	Temp °C
Normal	0.5
Controlled	1.0
Research	>1.0

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	38°C	38°C*	39°C	40°C
Controlled	38°C	38°C*	39°C	40°C
Research	>38°C	-	>39°C	>40°C
* only NRPB has a specific limit for the fetus				

A2.1.6 Acoustic noise

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 [5] argues 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 Introduction

In 2004, following a review of the scientific evidence [97], the NRPB recommended [2] that the UK adopt the guidelines of the ICNIRP for occupational and public exposure [7].

A2.2.2 Static magnetic fields

In 2004 the NRPB recommended that 'the ICNIRP exposure guidelines should be used for restricting occupational and general public exposure to static magnetic fields'.
All staff should be subject to the screening set out in section 4 of the guidelines before entering the scan room. The NRPB recommended [2] that staff should not be exposed to a static magnetic field in excess of 2 T to the whole body and 5 T to the hands and limbs. In addition, they should not exceed a time-weighted exposure of more than 0.2 T to the whole body including the hands and limbs. The exposure limits for staff shown in Table 11 are taken from the 2004 NRPB report [2].

Table 11 Basic restrictions for occupational exposure to static magnetic fields

Staff	Upper limit (T)	Max time-weighted average (T)
Body	2.0	0.2
Limbs	5.0	n/a

This advice has been tabulated in Table 12 to show how long staff can stay in high levels of static magnetic fields for a standard 8 hour working day.

The time-averaged exposure restriction is based upon a precautionary approach, as there is a dearth of good data relating to the possible existence of effects from long-term exposures to static magnetic fields.

However, until further published evidence becomes available, the MHRA recommends that sites follow the NRPB guidance.

Table 12 Basic restrictions for whole body occupational exposure to static magnetic fields over time

Exposure time (hours)	Average field strength (T)
8	0.2
4	0.4
2	0.8
1	1.6

Note, irrespective of time interval, 2 T is the limiting factor

Considering the current field strengths of scanners installed in the UK, most sites will be operating well within the above recommendations. To confirm adherence to the guidance given in the above table, sites should have a good understanding of their MR field lines. Currently manufacturers supply field plots up to 200 mT.

A2.2.3 Time-varying magnetic field gradients

The exposure limits for occupational exposure to time-varying magnetic field gradients are taken directly from the ICNIRP 1998 report [7] and are provided to prevent effects on nervous system functions. The exposure levels to the root mean square values of predominantly sinusoidal field variations at various frequencies are given in Table 13.

Table 13 Basic restrictions for occupational exposure to time-varying magnetic fields

Frequency f (Hz)	Current density (mAm^{-2})
Up to 1	40
1 – 4	40/f
4 – 1000	10
1000 – 100,000	f/100

Note: the switching gradient fields are low frequency time varying magnetic fields

Users should be aware that when someone moves through a static field they will experience a time varying magnetic field. The resulting induced current may be at a level above the limits set [6, 42].

A2.2.4 Specific absorption rate

The exposure limits for occupational exposure to radiofrequency magnetic fields are taken directly from ICNIRP 1998 report [7].

Table 14 Basic restrictions for occupational exposure to RF fields

Body part Units	SAR Limit Wkg^{-1}	Tissue mass Grams	Time period Min
Whole body average	0.4	-	6
Localized SAR (head and trunk)	10	10	6
Localized SAR (limbs)	20	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.

A2.2.5 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 15.

Table 15 Occupational noise action values and limits

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

a. 85dB(A) in the previous Noise at Work Regulations 1989
b. 90dB(A) in the previous Noise at Work Regulations 1989

Daily and weekly personal exposure values can be calculated by using the HSE noise calculator [98] or by using the ready reckoner in Table 16. 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 16 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

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 3).

Figure 3 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 [55]. 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

The 1994 ICNIRP report [6] states that the general public should not be exposed to field strengths greater than 40 mT. Overall, this means that no member of the general public should enter the scan room.

Table 17 Basic restrictions for general public exposure to static magnetic fields

General public	Upper limit (mT)
Without pacemakers	40
With pacemakers	0.5

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 18 below.

Table 18 Basic restrictions for general public exposure to time-varying magnetic fields

Frequency	Current density (mAm-2)
Up to 1 Hz	8
1 – 4Hz	8/f (in Hz)
4 Hz – 1 kHz	2
1 kHz– 100 kHz	f (in kHz)/500

Note: Switching gradient fields are low frequency time-varying magnetic fields

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 19 Basic restrictions for general public exposure to RF fields

Body part Units	SAR limit Wkg^{-1}	Tissue mass Grams	Time period Minunte
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.

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Office of Public Sector Information (OPSI)	www.opsi.gov.uk
Institute of Chemical Engineers (IchemE)	www.icheme.org
Institute of Physics and Engineering in Medicine (IPEM)	www.ipem.ac.uk
International Commission on Non-Ionizing Radiation Protection (ICNIRP)	www.icnirp.de
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