Medicines & Healthcare products Regulatory Agency

Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use

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V5.0.1	July 2026	Full review and update.
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1 Introduction

1.1 Use of these Guidelines

This 5th edition of the safety guidelines represents best practice for the safe use and management of magnetic resonance imaging (MRI) equipment in a clinical setting within the UK. The guidelines also have some relevance in academic settings and to users of laboratory and veterinary MR equipment.
Adherence to these guidelines will aid in ensuring that users of MRI equipment comply with relevant legislation, namely:

- The Health and Safety at Work etc Act 1974 [1] and The Health and Safety at Work (Northern Ireland) Order 1978 [2]
- The Management of Health and Safety at Work Regulations 1999 [3] and the Management of Health and Safety at Work Regulations (Northern Ireland) 2000 [4];
- The Control of Electromagnetic Fields at Work Regulations 2016 [5] and the Control of Electromagnetic Fields at Work Regulations (Northern Ireland) 2016 [6];
- The Control of Noise at Work Regulations 2005 [7] and the Control of Noise at Work Regulations (Northern Ireland) 2006 [8].

These guidelines also support compliance with devolved NHS duties by ensuring MRI services are delivered safely and to an appropriate standard:

- England
  - National Health Service Act 2006 [9]
  - The NHS Constitution for England [10]
  - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 [11]
- Scotland
  - National Health Service (Scotland) Act 1978 [12]
  - The Patient Rights (Scotland) Act 2011 [13]
  - Public Services Reform (Scotland) Act 2010 [14]
  - Health and Social Care Standards [15]
- Wales
  - National Health Service (Wales) Act 2006 [16]
  - Health and Social Care (Quality and Engagement) (Wales) Act 2020 [17]
  - National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 and associated implementation framework [18,19]
  - Regulation and Inspection of Social Care (Wales) Act 2016 [20]
- Northern Ireland
  - Health and Social Care (Reform) Act (Northern Ireland) 2009 [21]
  - The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 [22]

This guidance is intended to:

- Bring together different sources of advice, guidelines, legislation etc relevant to MR safety and provide a single source of advice on how that should be applied in the UK context.
- Bring to the attention of those involved with the clinical use of such equipment important matters requiring careful consideration before purchase and after installation of equipment.
- Be an introduction for those who are not familiar with this type of equipment and act as a reminder for those who are.
- Act as a reminder of the legislation and published guidance relating to this equipment.
- Draw the attention of the users to the guidance published by relevant organisations.
- Reflect current risks and hazards.
- Draw on the experience of MHRA and contributing organisations on the safe use of MRI equipment.

1.1.1 Overview of the Health and Safety at Work etc Act

The UK Health and Safety at Work etc Act 1974 [1] and other relevant statutory provisions clearly define 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. Several 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. A guide to the Act is available [23].

1.1.2 Other Regulations and Guidance

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

- Management of Health and Safety at Work Regulations [3,4]
- Medical Device Regulations [24,25]
- Provision and Use of Work Equipment Regulations [26,27]
- Manual Handling Regulations [28,29]
- Workplace (Health, Safety and Welfare) Regulations [30,31]
- Display Screen Equipment Regulations [32,33]
- Personal Protective Equipment (PPE) Regulations [34,35]
- Electricity at Work Regulations [36,37]
- Control of Substances Hazardous to Health Regulations (COSHH) [38,39]
- Pressure Systems Safety Regulations [40]
- The Health and Safety (First Aid) Regulations [41,42]
- Patient Handling Assessments [43]
- Considerations of pregnant workers and new mothers [44]
- Management of stress, violence and lone working in the workplace [45,46,47]

For the current version of each regulation please consult Legislation.gov.uk and the HSE website. The list above is meant as a guide but is not definitive.

1.1.3 Other MRI specific guidance

The Society of Radiographers produce their own MRI guidance, and the American College of Radiology ACR produces a manual on MR Safety.

1.1.4 The Quality Standard for Imaging (QSI)

The Quality Standard for Imaging (QSI) is a UK-based quality framework for diagnostic imaging services, covering all imaging modalities including MRI [48]. QSI allows services to evaluate their performance and develop where needed to continually improve patient experience and outcomes. Key aspects considered are; leadership and management structure, workforce, quality and governance arrangements, clinical processes, patient experience, facilities and safety.

Northern Ireland has achieved the QSI Quality Mark [49]. In 2025, the QSI Quality Mark was also approved for national implementation across NHS Wales.

1.1.5 United Kingdom Accreditation Service (UKAS) accreditation to BS 70000

UKAS accreditation [50] to BS 70000 [51] provides an independent assessment framework for healthcare services, including diagnostic imaging services, focused on clinical and technical competence, service excellence, and continual improvement. The standard enables organisations to evaluate and strengthen the way services are designed, delivered, governed and improved, with the aim of enhancing patient experience, service quality and stakeholder confidence. UKAS accreditation provides confidence that diagnostic imaging services are impartial, technically competent and consistently meeting the requirements of the standard.

Key aspects considered include leadership and organisational culture, service design and delivery, patient and service-user engagement, governance and risk management, workforce capability and competence, innovation and improvement processes, performance measurement, and the achievement of measurable service outcomes.

Diagnostic imaging services accredited by UKAS to BS 70000 [52] demonstrate that they operate within a structured framework for managing and continually improving service quality, whilst maintaining a strong focus on patient-centred care, safety, effectiveness and innovation.

UKAS is appointed by government as the UK's National Accreditation Body. UKAS accreditation provides external assurance to patients, commissioners, regulators and healthcare providers that the service is meeting the requirement of the standard and in doing so is committed to delivering consistent, high-quality care and achieving sustainable improvements in service performance.

1.2 Formatting and Terminology of Recommendations and Warnings

Recommendations that could form part of an audit for best practice are summarised within a green box containing a white tick:

Recommendations (that may form part of a safety audit)

Warnings and cautions are shown in red boxes with a yellow warning symbol:

Warnings and cautions

1.3 Defined Terms and Terminology

Defined terms are in SMALL CAPITALS. The following terms are used in this document:

Defined term	Defined in	Primary source
MR SAFE MR CONDITIONAL MR UNSAFE MR UNLABELLED	Section 1.5	ASTM F2503-26
MR RESPONSIBLE ORGANISATION	Section 4.1.1	ISO 60601
MR RESPONSIBLE PERSON	Section 4.1.2	
MR SAFETY EXPERT	Section 4.1.3	
MR CLINICIAN	Section 4.1.4	
MR SAFETY MEDICAL ADVISER	Section 4.1.5	
MR SAFETY COMMITTEE	Section 4.1.6	
MR REFERRING CLINICIAN	Section 4.1.7	
MR RADIOGRAPHER	Section 4.1.8	
MR CLINICAL SCIENTIST	Section 4.1.9	
MR CONTROLLED ACCESS AREA	Section 4.2.1	
MR ENVIRONMENT	Section 4.2.2	ASTM F2503-26
MR RESPONSIBLE PERSON MR AUTHORISED PERSON (NON-MR ENVIRONMENT) MR AUTHORISED PERSON (MR ENVIRONMENT) MR AUTHORISED PERSON (SUPERVISOR) MR OPERATOR	Section 4.3.1	

Additional terminology	Definition
MR manufacturer	The organisation that is responsible for the manufacturing of the MR system
MRI unit	An MRI unit encompasses any areas that contain MR systems that share the same MR CONTROLLED ACCESS AREA. May also be referred to as the MR suite [53].
MR examination room	The room where MR scanning takes place and the MR system magnet is located
MR technical room	The MR technical room accommodates parts of the MR system that are sited outside of the MR examination room

1.4 Magnetic Resonance Imaging Equipment in Clinical Use

Most MR systems used clinically in the UK are cylindrical closed bore superconducting MR systems typically with static magnetic fields of 1.5 T or 3 T, aligned with the long axis of the cylinder. Ultra-high field strengths have traditionally been used in research, though 7 T systems continue to gain clinical use. MR systems with an open design generate a static magnetic field using either a permanent magnet or electromagnets using either superconducting or resistive coils. Open MR systems tend to use lower magnetic fields than cylindrical closed bore MR systems. There is a returning interest in low magnetic

field systems, for example as small mobile units that could be wheeled to the patient bedside. The safety aspects of these specialist systems are discussed in more detail in section 4.5.

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 ($dB_{(x, y, z)}/dt$)
- radiofrequency (RF) magnetic fields (B_1).

1.5 MR Safety Marking

ASTM International's standard F2503-26 [54] for the marking of devices brought into the MR ENVIRONMENT should be used. An earlier version also been published by the IEC as standard IEC 62570:2025 [55]. The definitions and example colour labels are given in Table 1 (black and white versions are acceptable).

Table 1 Definitions of MR SAFE, MR CONDITIONAL and MR UNSAFE in accordance with ASTM International standard F2503-26.

MR SAFE 3.1.13 MR Safe—posing no known hazards resulting from exposure to any MR environment. 3.1.13.1 Discussion—An item composed entirely of electrically nonconductive, nonmetallic, and nonmagnetic materials may be determined to be MR Safe by providing a scientifically based rationale rather than test data. Examples of MR Safe items are a cotton blanket or a silicone catheter. Under certain circumstances, such items can be visible in MR images or result in an MR image artifact.	 **MR Safe**  **MR Safe**
MR CONDITIONAL 3.1.9 MR Conditional—having demonstrated safety in the MR environment within defined conditions. 3.1.9.1 Discussion—Defined conditions typically include the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.	 **MR Conditional**
MR UNSAFE 3.1.14 MR Unsafe—posing unacceptable risk within the MR environment. 3.1.14.1 Discussion—ISO 14971 "Medical devices— Application of risk management to medical devices" includes a process for the item manufacturer to identify unacceptable risk. MR Unsafe items include items such as a pair of ferromagnetic scissors.	 **MR Unsafe**

Notes:

- ASTM F2503-26 considers the potential for MR image artifacts to be outside the scope of the mandatory portions of the MR safety labelling standard because they do not present a direct safety issue resulting from specific characteristics of the MR examination. This is addressed in ASTM F2119 [56].
- ISO 14971 [57] considers risk-benefit decisions to use a medical device in the context of a particular clinical procedure to be outside the scope of this standard as some of these decisions can be made only by a medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.
- In this document, the term MR UNLABELLED is used to describe an item without an MR SAFE, MR CONDITIONAL or MR UNSAFE label.

2 MRI Hazards

2.1 Introduction

This section describes the hazards associated with each of the magnetic fields produced by MRI equipment. For superconducting MR systems, the static magnetic field is always present (i.e. the magnet is always switched on) and so it presents a constant and immediate hazard. This is also the case for MR systems that use a permanent magnet. The time varying magnetic fields include the imaging gradients and the radiofrequency field. These only present a hazard during image acquisition.

The mechanisms by which each of the three magnetic fields present hazards, including associated biological and acute sensory effects, are detailed in sections 2.2-2.4. The potential interactions of each magnetic field with external medical equipment and implanted medical devices are summarised in section 2.5. Details of risk mitigation through strict and careful management of the MRI unit are set out in Chapters 4 and 5 .

2.2 The Static Magnetic Field (B_0)

Most clinical MR systems in the UK generate the static magnetic field using sufficiently cooled superconducting coils, though permanent and resistive magnets are also available. The static magnetic field of an MR system is denoted by B_0. Although this field does not vary with time, it does change with distance from the centre of the MRI magnet.

The static magnetic field extends beyond the covers of the MR system in all directions and decreases with distance from the system isocentre. This is often referred to as the fringe field of the system. The rate of change of static magnetic field over distance is commonly denoted as dB/d(x,y,z). This is the spatial field gradient, which varies in all three orthogonal directions.

Manufacturers will supply plots detailing the static magnetic field and the spatial field gradient, including the 0.5 mT and 0.9 mT field contours.

2.2.1 Attractive Force

The static magnetic field has major safety implications if any metallic (particularly ferromagnetic) objects are taken into the MR ENVIRONMENT and for individuals with medical implants and devices entering the MR ENVIRONMENT. This section introduces the forces that act on external and implanted objects/devices when exposed to the static magnetic field, and the potential biological and acute sensory effects that can result from this exposure. The spatial field gradient produces an attractive force on ferromagnetic objects causing them to become a projectile when exposed to the static magnetic field of the MR system. The attractive force on an object is:

- Increased for objects with length much longer than diameter (i.e. a long thin cylindrical-shaped object)
- Increased for objects with its longest dimension aligned parallel to the direction of B_0. The internal magnetic field induced by B_0 compensates the least in this orientation; see [58].
- Typically, the maximum static magnetic field strength is just outside the opening of the magnet bore, at both the front and back of the system. This is where the spatial field gradient is near its maximum and the magnetic field is still increasing. The spatial field gradient then falls off towards the imaging volume where the gradient and hence the translational force on the object falls to zero [59]. Check the manufacturer technical manual for system-specific plots of spatial field gradients.

The extent (or steepness) of the spatial field gradient depends on the main magnetic field strength, the design of the magnet (open versus cylindrical closed bore) and the shielding employed (active, cladding, or whole room shielding). Additionally, each installation may differ due to the surrounding structures i.e. large metal objects including lifts and support beams. It is therefore essential that staff at every MRI site have a thorough understanding of the fringe fields relating to each MR system on their site.

The attractive force on an object will often increase sharply on approach to the magnet bore. An item which produces no noticeable pull at the edge of the MR examination room can suddenly become a projectile once taken closer to the MRI scanner. Figure 1 shows example magnetic field lines for a 1.5 T superconducting magnet, where the field strength increases rapidly as you get nearer the magnet.

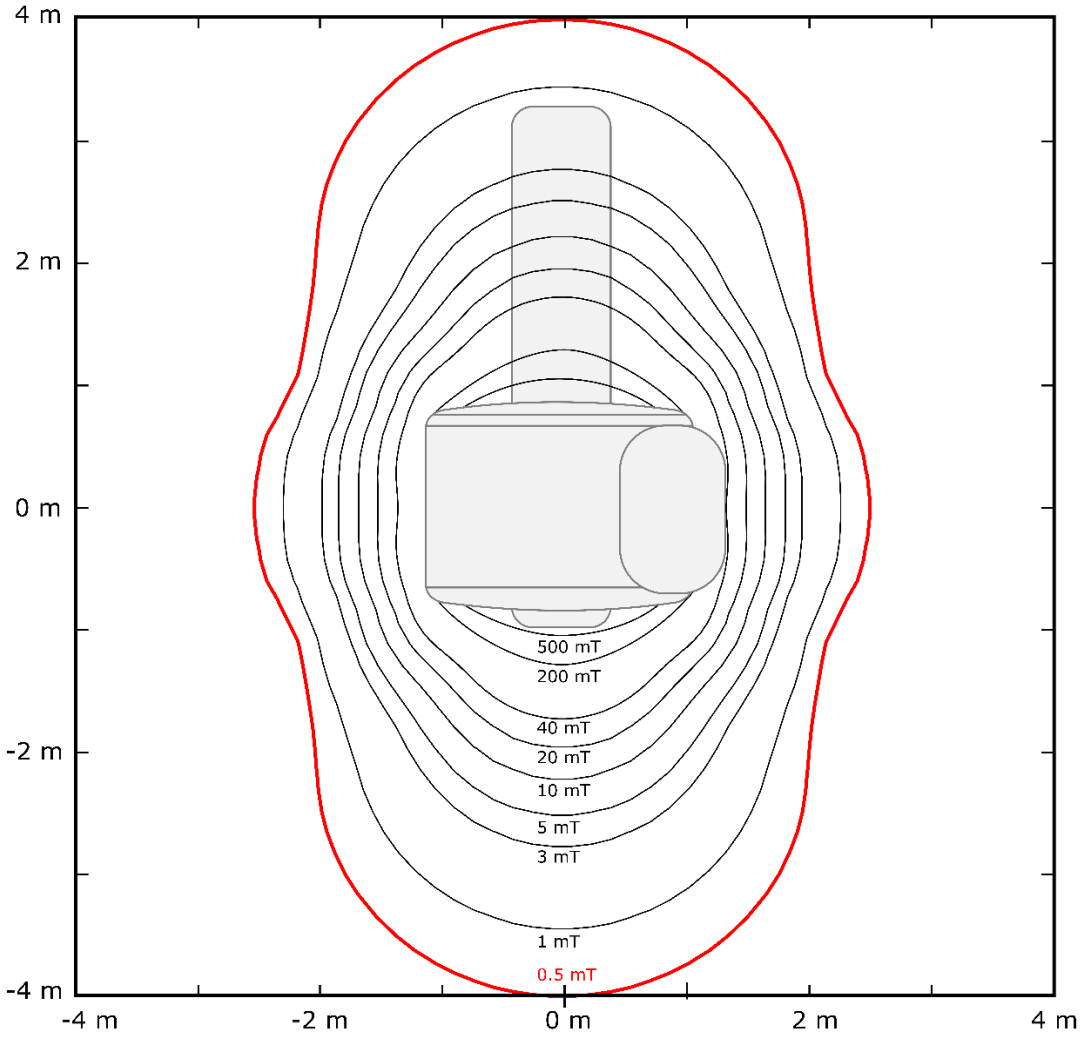


Figure 1 Illustrative magnetic field lines for a 1.5 T superconducting magnet. Drawn with reference to [60]. Note how the field strength increases steeply within 2 m of the magnet bore.

There have been 3 widely reported fatalities relating to the presence of an MR UNSAFE oxygen cylinder in the MR ENVIRONMENT (in 2001 [61], 2018 [62] and 2021 [63]). More recently a fatality was reported following a patient's relative entering the MR ENVIRONMENT without removing a "9 kg weight training chain" that was around their neck [64]. Several serious crushing injuries in the MR ENVIRONMENT requiring surgical treatment have also been reported [65,66,67].

These incidents highlight the requirement for the strict management of all items intended to be used within the MR CONTROLLED ACCESS AREA (see Chapters 4 and 5).

2.2.2 Torque

Ferromagnetic objects will also experience a torque (i.e. a twisting force) when exposed to the static magnetic field (B_0). Torque acts to align the object with the static magnetic field lines. For cylindrical superconducting MR systems, B_0 is aligned with the long dimension of the magnet bore, denoted as the z-direction. The torque on an object in an MR system is:

- Proportional to the square of the static magnetic field strength (B_0^2) for materials below magnetic saturation. Once the saturation field (B_{sat}) is reached, defined as the field strength at which magnetic domains are fully aligned and magnetisation no longer increases with field, the dependence becomes approximately linear with B_0. Ferromagnetic objects may reach magnetic saturation B_{sat} outside the magnet bore.
- Proportional to the volume and dependent on the shape of the object.
- Greater for objects with a length much longer than their diameter (i.e. a long thin object). In comparison, a spherical object experiences minimal torque.

- Dependent on the orientation of the object relative to B_0
- For an elongated ferromagnetic object, maximum torque occurs when the object is at an angle of 45° to B_0.

2.2.3 Lenz Effect

The Lenz effect acts on all conductors, including those made from both ferromagnetic and non-ferromagnetic metals. When a conductor moves through a changing magnetic field such as the spatial field gradient of the MR system, a current is generated within that conductor. This current in turn gives rise to an additional magnetic field within the conductor, which opposes the changing magnetic field that produced it. The result is that the induced magnetic field in the moving conductor resists that movement. The Lenz effect can be substantial on conductors and can make metal behave in an unexpected way within the static magnetic field. This may be of importance in interventional MR settings when using non-ferromagnetic metal tools and in other specialist MR settings.

2.2.4 Biological Effects

The mechanisms through which the static magnetic field interacts with living matter are described in [68]. Magnetic induction is the most widely cited mechanism responsible for reported acute sensory effects in the presence of the static magnetic field. Magnetic induction in biological tissues can occur in the following interactions with the static magnetic field:

- Currents are induced in tissue when moving through the spatial field gradient or from rotational motion in a uniform field or a field gradient. Therefore, currents can be induced in tissue when walking towards an MR system through the spatial field gradient, movement of a patient into or out of the scanner, or from rotation of the head within the static magnetic field. The magnitude of induced currents and resulting electric fields increase with velocity of movement through the spatial field gradient and with the amplitude of the gradient.
- When a current flows in biological tissue in the presence of a magnetic field, a Lorentz force is exerted on the flowing charged particles. For example, when ions in blood vessels move within a static magnetic field, the Lorentz force exerted on the ions induces an electric potential (i.e. a voltage) across the blood vessel. Although there was previously concern that this could reduce blood flow, this has been shown not to be clinically significant up to 8T. However, the electrical potential creates an artefact on an ECG trace acquired when a person is exposed to the static magnetic field of the MR system [69].

2.2.5 Acute Sensory Effects

Acute sensory effects can arise due to exposure to the static magnetic field or the spatial field gradient. Though these effects are transient and will stop after the person has been removed from the field, they may be unpleasant. They do not affect all individuals and so may depend on specific sensitivities. The prevalence of these effects tends to scale with increasing magnetic field.

Effects due to the static magnetic field include metallic taste and magneto-phosphenes (flashing lights), vertigo, nausea and nystagmus (involuntary eye movement).

The acute sensory effects of metallic taste and magneto-phosphenes are thought to arise from the generation of induced currents. In the case of metallic taste this is thought to be due to either direct stimulation of the tongue or from electrolysis of saliva. Magneto-phosphenes are thought to result from the direct stimulation of the retina by induced currents, though these are rarely experienced in the MR ENVIRONMENT.

Vertigo, nausea and nystagmus are related to the interaction of the static magnetic field with the vestibular system [70,71,72]. This system is responsible for coordination of head and eye motion (the vestibular ocular reflex) and compensatory postural changes (the vestibulospinal reflex) [73]. It is thought that discordance between sources of sensory inputs result in the feelings of nausea and vertigo [74]. There is evidence of vertigo sensations occurring in people when moving through the static magnetic field (i.e. experiencing the spatial field gradient) and in those who remain stationary within the static magnetic field [70,72].

To prevent nystagmus and resulting sensations of vertigo, patients and staff should keep their eyes open and focused on a fixed object [58] when exposed to the static magnetic field.

It remains best practice for patients and staff to move slowly within the static magnetic field to minimise the risk of some of these sensory effects. When exposed to the static magnetic field rapid movement and rotation of the head should be avoided.

2.3 Time-Varying Magnetic Field Gradients (dB/dt)

Time varying magnetic field gradients are the switched fields generated during scanning to select the region of diagnostic interest and to spatially encode the MR signal. These are of relatively low frequency (0.5-5 kHz [58,75,76] when compared, for example, to radiofrequency fields and microwaves.

The gradient output of the MR system can be given in terms of electric field (units of V/m) or the rate of change of magnetic field with time (dB/dt in units of T/s). This is the gradient output that is experienced by the patient when they are inside the MR system. It induces electric fields and resultant current densities within the patient's tissues, with potential to produce transient physiological effects. Additionally, time varying magnetic field gradients can cause high levels of acoustic noise (see sections 2.3.1 and 2.3.2) and interaction with implanted medical devices or equipment within/near the bore or aperture of the system (see section 2.5).

At any location, the currents induced will be determined by the rate of change of the magnetic field, the dimensions of the available conductive loop and the local distribution of the body impedance, which is primarily resistive at frequencies below about 1 MHz.

The dB/dt will also vary spatially in all three directions within the bore or scanner aperture. The area of maximum dB/dt along the length of the bore will typically be located about 30 to 50 cm from isocentre.

The performance of an MRI gradient system is typically characterised in terms of its maximum potential amplitude in mT/m and its slew rate. The slew rate is the maximum rate of change of gradient amplitude per unit distance, in units of T/m/s. The maximum dB/dt that an MR system can produce is dependent on the achievable maximum slew rate and the relevant distance from isocentre. For details of the location of maximum gradient output and the variation across the scanner bore for specific MR systems, refer to the manufacturer's technical manual. Further details on appropriate limitations are given in Chapter 3 and Appendix 2.

2.3.1 Biological Effects

Peripheral nerve stimulation (PNS) arises from induced electric fields in tissue caused by rapidly switching gradient fields. This can manifest as painful or uncomfortable tingling, pins-and-needle sensations, or muscle twitching at different locations within the body, depending on the orientation of the applied gradient. Stimulation is described by a strength-duration curve, where the shorter the stimulus duration, the higher the strength of the electric field or dB/dt required to stimulate nerves. Nerves in the periphery are more likely to be stimulated compared to nerves that sit deeper within tissue and compared to those of smaller diameter. A patient would be most likely to experience peripheral nerve stimulation during rapid gradient echo-based MRI pulse sequences, e.g. echo planar imaging.

There is the theoretical potential for time varying magnetic fields to induce cardiac stimulation, defined as the induction of an ectopic beat or other cardiac arrhythmia. This is prevented in all clinical systems by the IEC operating limits [77]. PNS would always occur first so the limits imposed on peripheral nerve stimulation will also prevent cardiac stimulation.

An overview of the biological effects of time-varying magnetic field gradients is given in [76,78].

2.3.2 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 in the presence of the high static magnetic field B_0, forces are exerted on the gradient coils that cause them to vibrate and move like a loudspeaker coil and generate sound waves.

Sound levels are measured in decibels (dB), which is a logarithmic scale. An increase of 3 dB is approximately equivalent to doubling the sound intensity level. Sound level measurements can be A-weighted (dB(A)) to reflect human hearing at low noise levels or C-weighted (dB(C)) when considering very loud noise exposure.

Protection measures against loud noises, such as headphones or earplugs, will have a rating protection value, such as single noise rating (SNR) or noise reduction rating (NRR), indicating the amount of

protection offered. These measures are not interchangeable. Where equipment is intended for use as hearing protection, it must be labelled with a rating protection value or appropriate conformity marking (e.g. BS EN 352 [79]; if this is not present, equipment such as headphones for entertainment should not be expected to additionally provide protection).

MR system manufacturers must characterise the maximum expected noise level in standard clinical use. System manufacturers commonly report either the Maximum Gradient Acoustic Noise (MGAN), which measures the worst-case for the hardware through use of a non-clinical sequence, or the Maximum Clinical Acoustic Noise (MCAN), which characterises the loudest clinical sequence on the system and represents the worst case for clinical use [80]. Most clinical MR systems are loud enough that they are required by IEC to provide guidance on earing protection within their instructions for use [77]. The most recent IEC standard [77] also required manufacturers to indicate the hearing protection value necessary for a specific system. See Steckner [81] for further discussion.

Exposure to elevated noise levels can result in noise-induced hearing loss, primarily through damage to the structures within the cochlea, such as the sensory hair cells. This can range from a mild reduction in hearing to deafness. It may be temporary, particularly for occasional or one-off exposures, but can be permanent following prolonged, repeated, or extremely loud exposure [82,83]. As well as noise-induced hearing loss, high noise levels can lead to temporary or chronic tinnitus (a ringing or hissing sound in the ears) and hypersensitivity [82,84]. Extremely loud noises are painful to experience and can lead to acute hearing loss and acoustic trauma, where mechanical or metabolic damage to the cochlear or other structures in the ear occurs by a single exposure [82,85].

Beyond direct auditory effects, elevated noise levels can negatively impact communication, concentration and stress levels. Long-term exposure is associated with a range non-auditory health effects, such as anxiety and depression, hypertension, and cardiovascular disorders [82,86].

The acoustic noise from the MR system at the location of the patient or volunteer can reach an unacceptable and even dangerous level [81]. Noise levels within the magnet bore can be louder than a pneumatic drill, a fire alarm, or a music concert (> 100 dB). They can approach the loudness of a jet plane taking off nearby (120 - 140 dB) [82]. This is loud enough to cause harm on the timescale of a patient exam.

Similarly, noise levels in positions where staff may operate can be high enough that short or long-term exposure may be hazardous, both inside and outside the MR examination room, requiring management under the Control of Noise at Work Regulations 2005 (the Noise Regulations) [7].

More information on the recommended limitation and protection for staff, patients, and members of the public is available in Chapter 3 and Appendix 2, including guidance on the applicability of personal protective equipment, i.e., ear defenders.

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

Groups of particular concern are paediatric patients and neonates, the foetus, unconscious patients and those with pre-existing aural conditions such as tinnitus, recruitment or hypersensitivity, and those with high sensory sensitivity.

2.4 Radiofrequency Magnetic Fields (B_1)

Radiofrequency (RF) magnetic fields used during MRI (B_1) cause energy deposition within body tissues, producing thermal effects. The principal hazards are heat stress and thermal injury resulting from the absorption of RF power [87]. These fields are only present when the MRI scanner is scanning and are primarily located within the scanner bore or aperture.

At MRI frequencies, oscillating RF fields induce electrical currents in body tissues, producing Joule heating and raising local and whole-body temperatures [87,88].

The RF field is non-uniform, and inhomogeneity increases with field strength and transmit coil geometry, leading to potential local “hot-spots” even when average exposure parameters are within specified limits [77,87].

Tissue heating is normally offset by thermoregulation through blood flow and perspiration. However, this is limited in regions with poor perfusion (e.g. eye lens, testes, cartilage) and in patients with impaired circulation or thermoregulatory control [87,89]. The wavelike properties of the electromagnetic field and differences in tissue parameters, such as permittivity and conductivity, can result in localised tissue hot spots. These do not necessarily correlate with areas of high energy deposition [77,87].

2.4.1 Heat Stress

Heat stress arises when accumulated body heat exceeds the capacity for heat loss. It is of particular concern in patients with impaired thermoregulation, such as those with cardiovascular disease, hypertension, fever, pregnancy, or under sedation or anaesthesia [87,89,90,91,92].

A core temperature rise of up to 1 °C is generally tolerated in healthy adults, while smaller increases (≤ 0.5 °C) are advisable for vulnerable groups [87,88,91,93]. According to international guidance [87,89], adverse effects are unlikely if whole-body temperature increases do not exceed 1 °C (or 0.5 °C in sensitive individuals) and local tissue temperatures remain below approximately 38 °C for the head, 39 °C for the trunk, and 40 °C for the limbs.

Environmental factors such as ambient temperature, airflow, humidity, clothing, and scan duration influence the rate of heat dissipation and should be considered when interpreting RF exposure [88,89].

During MRI examinations, the RF power delivered by the MR system is controlled to limit RF-induced heating and reduce the risk of patient thermal stress. The Specific Absorption Rate (SAR) is the primary system-controlled RF exposure metric used for this purpose. SAR represents the rate at which RF energy is absorbed by the body per unit mass of tissue, expressed in watts per kilogram (W/kg), and incorporates conservative assumptions regarding human thermoregulation and environmental conditions, including MR examination room temperature.

Although SAR does not directly measure tissue temperature rise and is an imperfect surrogate for heating, conservative numerical RF simulations have been used to establish SAR limits that effectively bound RF-induced heating under a wide range of conditions. These limits are intended to prevent excessive temperature increases, thermal stress, and tissue injury during MRI scanning. Further discussion of SAR modelling, limitations, and regulatory exposure limits is provided in Chapter 3 .

2.4.2 Burns

RF burns are the most frequently reported MRI-related adverse incident in the UK. They result from concentrated RF energy deposition at points of conductive contact or coupling, leading to local tissue heating and skin injury [77,94].

Common mechanisms include:

- Contact burns – direct skin contact with metallic objects such as clothing fragments, coils, ECG or oxygen monitor leads, or other conductive materials [95].
- Loop burns – current induction in skin–skin or limb loops (e.g. thighs, arms, fingers) [92,96]. Induced current burns occur when parts of the body are positioned to form a conductive loop pathway, such as when arms or legs touch or cross. These configurations can allow circulating RF currents to concentrate in the loop, producing local heating and skin injury [92,97].
- Proximity burns – near-field coupling to the bore wall or conductive surfaces [97].

Burn severity depends on the local electric field distribution, contact area, and scan duration. These injuries can occur even when heating control parameters remain within approved operating limits, as they arise from local field concentrations rather than global energy absorption [87,97].

Heating depends on the electrical conductivity, permittivity, water content, and thermal properties of the underlying tissue [88,97]. Structures that have higher conductivity or limited perfusion, such as skin, subcutaneous fat, cartilage and the eye lens, can accumulate heat more rapidly and dissipate it less effectively. As a result, these tissues are more likely to experience local temperature rise and thermal injury when exposed to concentrated RF fields [87,93].

The root-mean-square RF magnetic field amplitude (denoted as $B_1{}^+_{RMS}$) is related to SAR and provides a supplemental parameter for controlling RF power deposition in the patient. It is a time-weighted average of the RF magnetic field intensity delivered during MRI scanning. Unlike SAR, $B_1{}^+_{RMS}$ is independent of patient factors and of the static magnetic field B_0. $B_1{}^+_{RMS}$ is most frequently encountered as part of the manufacturer labelling of MR CONDITIONAL medical implants and devices [98]. In the presence of devices with associated leads/electrodes, there is increased potential for localised burns or SAR 'hot spots' to occur. In these circumstances providing limits in terms of $B_1{}^+_{RMS}$ provides direct control over the voltage applied to the RF transmit coil. This is independent of MR system or differences in body habitus allowing greater control over heating of the tissue adjacent to the device and its components.

As actual RF fields are non-uniform and influenced by patient anatomy, positioning, conductive loops, and implants, hazardous local heating can occur even when displayed SAR or $B_1{}^+_{RMS}$ values remain within nominal limits [87,96,97]; see Figure 2 for simulations of heating distribution around a hip implant.

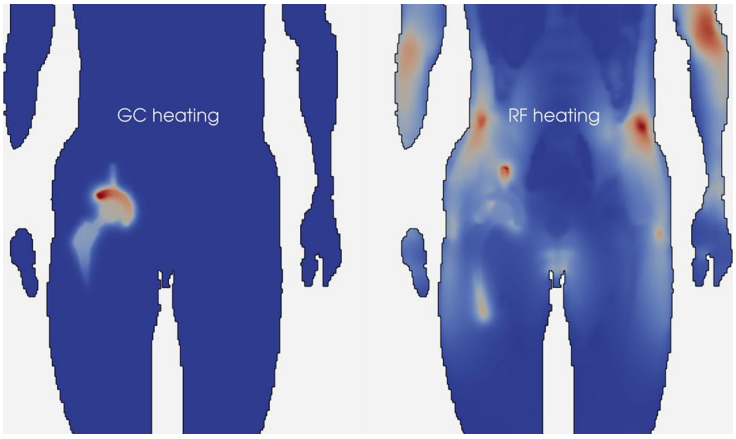


Figure 2. Numerical simulations of heating due to time-varying magnetic field gradients (left) and radiofrequency magnetic fields (right) in the same anatomical model with a hip prothesis. Reproduced under the Creative Commons CC BY licence from [99].

⚠ Burns are the most reported MRI-related adverse incidents recorded by the MHRA.

⚠ 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.

⚠ Burns caused by RF-induced currents are frequently not immediately perceived by patients. As a result, patients may be unable to alert the radiographer to discomfort or pain before clinically significant thermal injury has occurred.

2.5 Interaction with Medical Equipment and Foreign Bodies

Exposure to the strong static magnetic field (B_0), time-varying magnetic field gradients and radiofrequency fields used in MRI can adversely affect medical equipment, including passive and active implantable medical devices, internal foreign bodies, and equipment external to the body. Examples of implanted devices include implantable cardioverter defibrillators, pacemakers and stimulation systems (e.g. for deep brain, sacral nerve or vagus nerve stimulation). Examples of vital equipment external to the patient include infusion pumps, ventilators, anaesthetic machines and monitoring equipment. The relevant device interactions associated with each of the three magnetic fields are summarised in Figure 3. These effects are relevant for any patients or members of staff with implanted medical devices, foreign bodies, or who are reliant on external medical equipment. These effects are covered by ISO 10974:2018 [98].

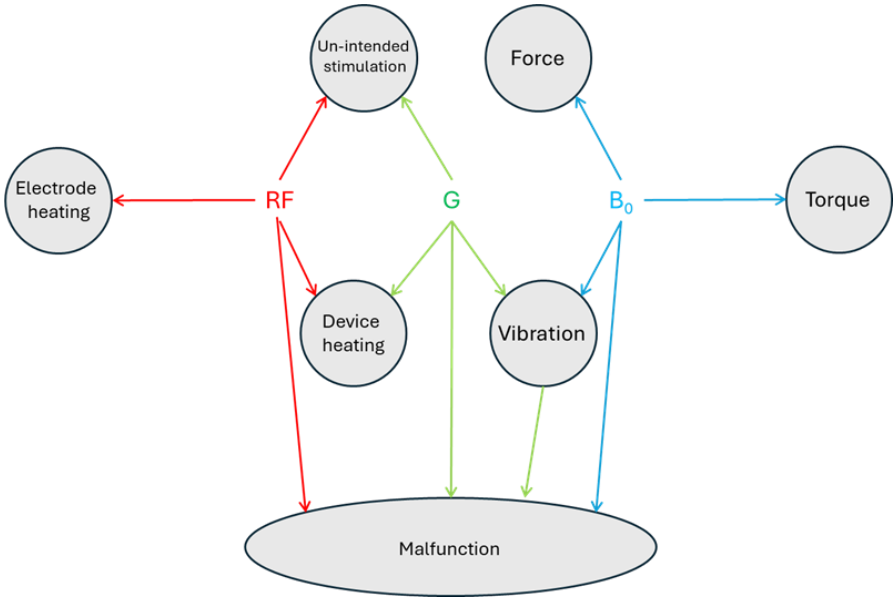


Figure 3 Device interactions from MR systems. Redrawn from [98]. Radio Frequency (RF) Gradient (G), Static Field (B_0)

2.5.1 Device Malfunction

Each of the magnetic fields can cause malfunction of external or implanted medical equipment or devices. This includes the following possibilities: device reset, incorrect measurement, reprogramming, battery drain, permanent damage and magnetic remanence (i.e. retained magnetisation following removal from the external field) [100]. Equipment or device malfunction could have serious consequences for patients who are dependent on devices for treatment or therapy.

2.5.2 Movement

- Ferromagnetic components in any medical equipment or foreign bodies will be subject to an attractive force and torque when exposed to the static magnetic field.
- External medical equipment would be pulled with force towards the system and would rotate to align with the direction of the field lines.
- Implantable medical devices or foreign bodies could move within the body, potentially causing tissue damage and/or device damage.

Table 2 shows the published static magnetic field levels at which certain active implanted medical devices remain unaffected by the field. This table also shows the field limit at which device function will be affected during exposure, but normal function resumes following removal from the field. Devices, especially external equipment, may also quote a maximum spatial field gradient value or maximum distance from the MRI scanner.

Table 2. Static magnetic field immunity levels for Cardiac Implantable Electronic Devices (CIEDs).

Product	Standard	Unaffected up to:	Affected in field but full function returns.
Implantable cardiac pacemakers	EN 45502-2-1:2003 [101]	1 mT	10 mT
Implantable defibrillators	EN 45502-2-2:2008 [102]	1 mT	50 mT

Conductive implants of large cross-sectional area, for example a hip implant, may be subject to additional forces. The time varying magnetic field gradients applied during image acquisition induce an electric field and currents within the implant. As these induced currents are also within the static magnetic field, the implant is subject to the Lorentz force. The time varying magnetic field gradients are switched on and off multiple times during the scan. This makes the induced currents, and the Lorentz

force repeatedly change direction, which can cause substantial vibration of the implant with potential to cause significant patient discomfort.

2.5.3 Heating

Heating of implants and implanted devices can result from the independent action of the time varying magnetic field gradients and the RF magnetic field. A summary of heating mechanisms is given below. Further details can be found in the comprehensive review article by Winters et al. [103].

Time varying magnetic field gradients induce eddy currents within the implants. This can cause direct heating of the implant with resulting diffusion of this thermal energy to adjacent tissue. Conversely, the RF magnetic field does not cause significant heating of the implant. Instead, it is the current-induced secondary (or scattered) electric field that is responsible for RF-related heating of tissue surrounding implants.

Time varying magnetic field gradients induce heating in bulky implants with a large cross-sectional area that is orientated perpendicular to the gradient direction. Heating is increased for an implant positioned in the region of highest dB/dt and is greatest for fast gradient echo-based sequences.

The RF magnetic field can induce significant heating in elongated implants of length much greater than diameter and are equal to about half the RF wavelength in tissue. Heating is increased if the implant is positioned within and parallel to the high electric field. This would typically be found close to the RF transmit body coil, at the periphery of the magnet bore. Conductive components such as wires, leads, stents, plates or coils can couple with the transmitted RF field, allowing currents to form along the device and producing concentrated heating at the tissue interface [76,94,96]. RF related heating can be particularly amplified at the pointed ends of 1-dimensional implants such as wires and leads. These effects can occur even when system reported SAR or $B_1{}^+{}_{RMS}$ values are within limits because the interaction is driven by local field conditions rather than global exposure [87,97].

2.5.4 Unintended Stimulation

Both the time varying imaging gradients and the RF magnetic fields can produce electrical interactions with active implantable devices. Time-varying electric fields may induce voltages in device leads or circuitry which can disrupt normal function [98,104]. Potential responses include inappropriate sensing, pacing inhibition, false arrhythmia detection, unintended stimulation or interference with programmed electronic behaviour. These effects are independent of thermal mechanisms and therefore represent an additional hazard category for active devices.

The likelihood and severity of such interactions depend on the device materials and construction, the presence and configuration of leads, and the RF or dB/dt characteristics of the scan. Factors such as anatomical location, patient position and the distribution of RF fields and time varying magnetic field gradients in the region of the implant all influence the potential for electrical interference.

2.6 Pregnancy and MR Exposure

Due to the risks associated with ionising radiation imaging during pregnancy, MRI is frequently employed for the evaluation of maternal and foetal conditions. Nevertheless, MRI should be performed with caution because of the potential risks associated with exposure to the static magnetic field, time-varying magnetic field gradients, radiofrequency (RF) energy deposition, acoustic noise and the administration of Gadolinium (Gd)-based contrast agents. The current evidence and guidelines pertaining to each of these potential hazards are summarised below.

2.6.1 Static Magnetic Field (B_0)

The 2009 ICNIRP update [68] on pregnancy and exposure to static magnetic fields reiterated that there is limited evidence regarding the effects of fields exceeding 4 T on foetal and infant development. Consequently, the guideline recommends caution when performing MRI examinations above this field strength. Current evidence indicates that maternal exposure to MRI does not produce deleterious effects on foetal development [105,106,107].

2.6.2 Time-varying Magnetic Field Gradients (dB/dt)

Rodegerdts [108] and ICNIRP [69] report that exposure to low-frequency electromagnetic fields (0–100 kHz) shows no consistent evidence of adverse effects on embryonic or foetal development. According to

these sources, there is no clear evidence that exposure to static or low-frequency magnetic fields adversely affects pregnancy outcomes. However, both highlight important limitations in the available research, including the scarcity of human cohort data, interspecies differences, and uncertainties in dosimetry.

2.6.3 Radiofrequency Magnetic Fields (B_1)

Pregnant women and individuals with impaired thermoregulation should be imaged with caution due to uncertainties regarding the effects of increased heat load [89]. Excessive heating is considered a potential teratogen, and because RF dosimetry during pregnancy remains uncertain, exposure duration should be minimised and standard operating levels used [69].

Pregnant women and foetuses are particularly susceptible to increased heat load due to their limited thermoregulatory capacity. Foetal temperature is typically about 0.5°C higher than maternal temperature (Knobel et al 2014 [109]); therefore, limiting maternal core temperature rise is to 0.5°C helps ensure that the foetal temperature increase remains below approximately 1°C. Current regulatory SAR guidelines are primarily based on adult exposure [110]. SAR modelling does not include a dedicated model for pregnancy, as it does not adequately account for limitations in maternal or foetal thermoregulation and may therefore underestimate the impact of RF exposure on core temperature. Because excessive heating is a potential teratogen and precise dosimetry during pregnancy remains uncertain, MRI exposure should be minimised, standard operating limits should be used [69].

Although RF shimming can improve transmit-field uniformity and image quality in MRI, its use during pregnancy is currently discouraged. This is due to the potential for localised hotspots that may increase foetal SAR and heating beyond recommended exposure limits [110,111]. In-silico modelling at 3 T has demonstrated that while RF-shimmed configurations may reduce maternal RF exposure, they can concentrate energy in specific regions, increasing thermal load on the foetus [112]. Circularly polarised (CP) transmit modes provide a more uniform and controlled SAR distribution, reducing the likelihood of local foetal heating. While subject-specific RF shimming may be safe under carefully controlled, vendor-validated protocols, the lack of systematic in vivo data in pregnant women, particularly during early gestation, should be approached with caution. For routine foetal or maternal MRI, standard CP transmit modes remain the safest approach. RF shimming should be avoided unless explicitly supported by safety data and robust electromagnetic modelling.

2.6.4 Acoustic Noise

Since the early 1990s, concerns have been raised regarding the potential effects of excessive noise on foetal health. Reviews by the HSE [113,114] and the American Academy of Pediatrics [115] have remained inconclusive on whether noise exposure affects prematurity or foetal hearing. Reeves et al. [116] specifically investigated foetal exposure to 1.5 T MRI during the second and third trimesters and found no significant increase in the risk of neonatal hearing impairment. Subsequent studies by Strizek et al. [117], Bouyssi-Kobar et al. [118], and Jaimes et al. [119] similarly reported no adverse effects of foetal exposure to 1.5 T or 3 T MRI on neonatal hearing, birth weight, or later functional outcomes, supporting the conclusion that routine prenatal MRI at these field strengths with currently available gradient systems is safe.

The foetus is protected from normal sound transmission by the surrounding amniotic fluid and the fluid within the middle and outer ear [120]. However, mechanical vibrations can still pose an issue, particularly during techniques that introduce additional vibrations, such as magnetic resonance elastography (MRE). Ehman et al. [121] audited in-vivo vibrational amplitudes during human MRE and compared them to EU whole-body vibrations limits, showing that typical MRE vibration exposure are below conservative safety guidelines for adults. Despite these findings, the potential effects on the foetus are not fully established, and caution should be applied when planning sequences that may produce higher vibration levels.

2.6.5 Gadolinium-based Contrast Agents

The administration of gadolinium-based contrast agents (GBCAs) for MRI during pregnancy should generally be avoided and reserved only for situations in which the potential benefits to the patient clearly outweigh the potential risks to the foetus. This recommendation is supported by a large retrospective study by Ray et al. [122], who reported higher rates of rheumatologic, inflammatory, and infiltrative skin conditions up to four years of age among 397 infants exposed to gadolinium at any stage of pregnancy, as well as an increased incidence of stillbirth and neonatal death, compared with unexposed infants.

While the American College of Radiology [123] notes limitations in this study, including sample size and control group issues, the evidence was considered sufficient to warrant restricting GBCA use during pregnancy. Multiple review articles [124,125,126,127] have highlighted these findings, reinforcing the recommendation to avoid GBCA exposure unless clinically essential. Current guidelines [123, 128,129,130] consistently advise that GBCAs should only be used when imaging is expected to meaningfully influence maternal or foetal management.

2.6.6 Recommendations for Patient Exposure During Pregnancy

The 2004 ICNIRP report [69] concluded that there was insufficient knowledge at that time to provide definitive guidance for MRI use in pregnant patients. They recommended that MR procedures should be performed only after a careful risk-benefit assessment, particularly during the first trimester, to address important clinical problems or manage potential complications for the patient or foetus. Similarly, the IEC advise that scanning pregnant patients with the whole-body RF transmit coil should be limited to the normal operating mode with respect to SAR levels [77]. In practice, more conservative imaging is often adopted during early pregnancy, as the embryo may be more susceptible to thermal effects during organogenesis. Multiple studies, including Choi et al. [131], Chartier et al. [105], and Ray et al. [122], have specifically evaluated first-trimester MRI and found no statistically significant increases in adverse pregnancy outcomes, congenital anomalies, or variations in birth weight.

The International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) updated their practice guidelines for fetal MRI in 2023 [132].

Pregnant patients should be scanned in Normal mode whenever possible, with a preference for 1.5 T during the first trimester where both field strengths are available to aid SAR management. RF shimming methods should be avoided but if required, further SAR mitigation should be considered. Reduced-noise scanning techniques should be employed whenever possible. The use of Gadolinium-based contrast agents should be avoided unless clinically essential.

Where scanning in First Level Controlled mode or where Gadolinium administration is clinically necessary, the decision should be made collaboratively by the referring clinician, MR CLINICIAN, patient, and where necessary the MR SAFETY EXPERT weighing potential risks against clinical benefit.

2.6.7 Recommendations for Staff Exposure During Pregnancy

It is generally accepted that MR staff may continue their normal duties during pregnancy, including patient positioning, system operation, administration of contrast agents, and entry into the MR examination room [58]. While current evidence does not demonstrate any adverse effects on the foetus resulting from occupational exposure to the MR ENVIRONMENT, it is considered prudent that pregnant staff do not remain within the MR examination room during image acquisition.

Under the Management of Health and Safety at Work Regulations, employers are required to undertake a specific risk assessment for expectant mothers, addressing hazards associated with physical agents, including electromagnetic and acoustic exposures.

In general, exposure levels to time-varying magnetic fields are low except when near the magnet bore during image acquisition. This is of greater concern during interventional MRI procedures. The level of static magnetic field exposure is determined by the magnet's field strength and the effectiveness of its shielding. To date, there are no available data regarding human pregnancy exposures at 7 T or higher field strengths [53].

Pregnant staff should avoid remaining in the MR examination room while scanning is in progress due to concerns regarding foetal acoustic noise exposure.

2.7 Other Hazards

2.7.1 Cryogens (where applicable)

MR systems using superconducting electromagnets to produce the static magnetic field routinely use low temperature liquefied gases to maintain superconductivity, such as helium.
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.

In many systems, the quantity of helium used is large enough that the volume of gas produced by normal or explosive boil-off cannot be contained and recondensed within the system and must be vented to the outside. However, some systems use sufficiently low amounts of helium that there is no appreciable risk of over-pressurisation, allowing them to be completely sealed.

There should be no hazards from cryogens provided adequate attention has been paid to the management of all potential sources of helium and nitrogen following normal boil-off or in the event of a pressure release valve bursting, such as provision of venting directly to the outside of the building.

Chapter 6 and Appendix 1 contain information on the requirements for safe site management and working practices for cryogens.

2.7.2 Phantom Fluids

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

Sites should prepare procedures for dealing with phantom fluid spills, clean-up and disposal as per COSHH [38]. System vendors should provide information on any COSHH-relevant materials used in the system phantoms provided with the system in the accompanying documentation.

Sites should have procedures and equipment for the safe clean-up and disposal of phantom materials following a spill.

3 Exposure Management

3.1 Introduction

This section summarises the MHRA's recommendations on exposure limits to the following groups:

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

Recommendations are made with reference to relevant ICNIRP publications [68,72,75,76,87], the IEC 60601-2-33 2022 standard [77], The Control of Electromagnetic Fields at Work Regulations 2016 (CEMFAW) [5] and The Control of Noise at Work Regulations 2005 (CNAW) [7] as appropriate. The purpose of ICNIRP and IEC recommended exposure limits are described in Appendix 2.

3.2 Modes of Operation

ICNIRP and the IEC define three modes of operations of the MR system. While preventing unacceptable harm in exposed individuals, each mode applies different levels of restriction over the induction of adverse health effects and transient sensory changes. The modes of operation can be applied to each of the magnetic fields produced by the MR system. The hazards associated with these are described in Chapter 2 .

IEC and ICNIRP each use slightly different terms for each mode. The MHRA recommend that the following terminology is used to describe these modes of operations

NORMAL MODE - This is the default mode of operation where exposure carries only minimal risk of ill effect to the patient.

FIRST LEVEL CONTROLLED OPERATING MODE - Exposure in this mode is higher than in normal mode. Some people may experience some effects at this level, such as sensory disturbance or transient discomfort due to heating or PNS. To enter this mode of operation requires deliberate action by the MR OPERATOR. Before doing so the MR OPERATOR must ensure that this will be of benefit to the patient (e.g. improved image quality). The MR OPERATOR must also determine the most appropriate form of patient monitoring equipment (see section 5.3.10).

SECOND LEVEL CONTROLLED OPERATING MODE - Exposure is only restricted to prevent harmful effects. Scanning in this mode is only permitted following approval of a research ethics committee. As part of that approval, appropriate patient/volunteer monitoring is required (see section 5.3.10).

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

It is important to recognise that the modes of operation do **not** in isolation consider the risk of effects due to the presence of patient implants or implanted medical devices. In the presence of MR CONDITIONAL implants, the exposure risks are minimised by adhering to implant/device manufacturer's instructions.

3.3 Management of Exposure in Patients, Volunteers and Carers

Table 3 provides a summary of each mode of operation as it applies to the static magnetic field, the time varying magnetic field gradients and the radiofrequency magnetic field. Full details can be found in Appendix 2.

All the following exposure recommendations are subject to the conditions for entry of individuals to the CONTROLLED ACCESS AREA (see Chapter 4)

Table 3. Summary of the modes of operation as they apply to the static magnetic field, the time varying magnetic field gradients and the radiofrequency magnetic field.

Mode of Operation	Static Magnetic Field (B_0)	Time-Varying Magnetic Field Gradients (dB/dt)	Radiofrequency Magnetic Field (B_1)
	Restriction of transient sensory effects e.g. vertigo and nausea	Restriction of PNS and prevention of cardiac muscle stimulation	Restriction of whole-body temperature rise and restriction of tissue damage by limiting SAR
Normal Mode	Some patient may experience these effects at B_0 less than 3 T.	Patients may experience PNS, but it is prevented from being uncomfortable for most patients.	Whole-body temperature increase is limited to a maximum of 0.5 °C. Maximum whole-body SAR of 2 W/kg
First Level Controlled Operating Mode	Patient may experience these effects at B_0 greater than 3 T. Exposure up to 8 T is permitted.	Some patients may experience uncomfortable PNS.	Whole-body temperature increase is limited to a maximum of 1 °C. Maximum whole-body SAR of 4 W/kg.
Second Level Controlled Operating Mode	Exposure is unrestricted, i.e., exposure greater than 8 T is permitted.	There is increased potential for uncomfortable or painful PNS. Exposure is restricted to prevent cardiac muscle stimulation.	Exposure is restricted to avoid tissue damage. Maximum whole-body SAR greater than 4 W/kg.

3.3.1 Static Magnetic Field (B_0)

The purpose of restricting the static magnetic field is to prevent individuals experiencing acute but transient sensory effects such as nausea, vertigo and metallic taste in the mouth, described in section 2.2.5. These effects are unlikely to be experienced in a magnetic field of less than 3 T. The Controlled Mode permits exposure to a static magnetic field of 8 T, and the Research/Experimental Mode does not impose a restriction but would require ethical approvals to be in place.

3.3.2 Time-varying Magnetic Field Gradients (dB/dt)

For time varying magnetic field gradients, the focus is on restriction of an individual experiencing PNS. Therefore, exposure limits are based on volunteer studies that measure the mean perception threshold at which PNS occurs. Whereas Normal Mode restricts the gradient output to 80% of this measured median PNS perception threshold, the first and second level Controlled Modes permit a gradient output of 100% and 120% respectively [77]. This restriction ensures that most individuals are prevented from experiencing extreme discomfort due to PNS. For all modes of operation, MR system manufacturers are required to ensure that the system prevents the unacceptable risk of cardiac muscle stimulation [77].

3.3.3 Radiofrequency Magnetic Fields (B_1)

When the radiofrequency magnetic field is delivered from the integrated whole-body volume RF transmit coil, exposure is controlled by limiting the rise in core body temperature or the temperature rise of the exposed patient tissue. In practice this is controlled by limiting the whole-body SAR (over the total patient mass) and head SAR in combination with either the partial body SAR or local SAR. Whereas the partial body SAR represents the RF exposed patient mass, local SAR is averaged over 10 grams of tissue.

When a local volume RF transmit coil is used (e.g. transmit-receive knee coil), SAR limits are controlled using local and whole-body SAR estimates.

SAR is averaged over 6-minute periods and 10 second periods. The 10 second average SAR must not exceed double the 6-minute SAR limit, all the while ensuring that the 6-minute SAR limit is met.

Full details of exposure limits for whole-body, partial and local SAR can be found in Appendix 2.

The radiofrequency magnetic field (B_1) column of Table 3 summarises the core temperature increase and associated whole-body SAR for each mode. The different modes reflect that some individuals may

be at greater risk of heat stress (see section 2.4.1). In Normal Mode the whole-body SAR limit is 2 W/kg which limits core temperature rise to a maximum of 0.5 °C [87]. This is expected to be tolerated by most individuals as 2 W/kg corresponds to the average metabolic rate during moderate physical activity for individuals weighing 100 kg [133]. In Controlled Mode the whole-body SAR limit is 4 W/kg which restricts core temperature increase to 1 °C. ICNIRP [87] use this as a conservative limit for core body temperature increase and is easily tolerated by healthy adults with normal thermoregulation. Operation of the MR system that could result in a core body temperature increase of greater than 1°C would require ethical approval.

The whole-body SAR limits in Table 3 are only valid at ambient temperatures up to 25 °C. If the MR examination room temperature exceeds 25 °C, the IEC stipulates that the MR system reverts to Normal Mode or that SAR is reduced by 0.25 W/kg per degree above 25 °C until Normal Mode limit is reached.

Another parameter that is also of interest in preventing patient temperature rise is the Specific Absorption (SA), previously known as the Specific Energy Dose (SED) or the Specific Absorbed Energy (SAE). This is a measure of the total energy that the patient receives over a whole MRI exam. It has particular importance for prolonged MRI scans lasting up to or over an hour. Previous versions of IEC 60601-2-33 had included limits on SA [134]. However, the current version [77] states that the MR equipment shall provide an *indication* to the MR OPERATOR when SA exceeds a value of 120 W min/kg (equal to 7.2 kJ/kg). This indication shall not interrupt scanning. The decision to continue scanning beyond this indication rests with the MR OPERATOR and shall depend on factors such as patient thermoregulation, the expected SAR of the remaining sequences in the protocol and the total time of the protocol. Previous versions of IEC 60601-2-33 defined a SA limit of 240 W min/kg (14.4 kJ/kg). Therefore the 'indication' given to the MR OPERATOR reports when half this previous SA limit is reached.

3.3.4 MR Equipment Output Conditioning (MROC)

In 2022 the IEC [77] defined MR Equipment Output Conditioning (MROC). This is additional functionality allowing the MR OPERATOR to specify conditions to limit outputs during an MR examination. The IEC mandates that MROC must be implemented on new superconducting cylindrical 1.5 T and 3 T MR systems intended for use with patients with MR CONDITIONAL implants. The intended use of this software is to assist the MR OPERATOR in adhering to the limits set out in medical implant/device MR CONDITIONAL labelling. MROC is **not** an additional operating mode. The MR OPERATOR must additionally ensure that other conditions not controlled by MROC are adhered to (e.g. restrictions on patient position and landmark and on the duration of the MR exam. When MROC is enabled, the maximum $B_1^+{}_{PEAK}$ values are limited to less than or equal to 30 µT at 1.5 T and to less than or equal to 24 µT at 3 T (see A2.1.2). The MR OPERATOR can control the RF transmit type (e.g., integrated body coil or detachable head coil), the RF polarisation (e.g. circularly polarised), the maximum $B_1^+{}_{RMS}$ (in units of µT) and the maximum gradient slew rate per axis (in units of T/m/s).

The MR OPERATOR should refer to their MR system user manual for details of how to enable and use MROC functionality. This may not be available on older MR systems.

3.3.5 Acoustic Noise

Short-term/peak exposure is characterised in $L_{C,\,peak}$ (peak sound pressure level in dB(C)) and long-term exposure in $L_{Aeq,\,t}$ (average sound pressure level in dB(A), averaged over an exposure time, t). For patients and volunteers, exposure limits assume an hour-long exposure per week, $L_{Aeq,\,1h}$. Exam times longer than an hour should consider a longer time base.

Hearing protection shall always be made available to anyone in the MR examination room during imaging unless it can be demonstrated that noise levels will **not exceed** 80 dB(A).

Hearing protection should always be worn for MR procedures with noise levels **exceeding** 85 dB(A).

Unless local measurement of expected noise levels within the bore have taken place for the specific sequence used, the sound level should be assumed to breach the 85 dB(A) limit.

The instructions for use should be consulted for the manufacturer's recommendations on required protection and how to apply it. For high noise sequences, ear plugs and ear defenders/muffs can be used in combination, however the protection provided is less than the sum of the two; additional protection should be assumed to offer no more than an additional 5-6 dB(A) of protection on the primary means [7,77].

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

3.4 Management of Occupational Exposure in MR

Occupational exposure to electromagnetic fields is managed under relevant legislation described below.

3.4.1 Management of Health and Safety at Work Regulation 1999

Many aspects of occupational exposure to electromagnetic fields (EMFs) are largely managed within the framework of the Management of Health and Safety at Work Regulations [3]. Some examples of how this legislation applies to MR safety are given below.

Identifying risks associated with the MR ENVIRONMENT and completing formal risk assessments, including details of preventative measures that have been put in place. There is a particular requirement to carry out a risk assessment for pregnant staff members including both exposure-related and more general risks such as manual handling (see section 2.6.7 and guidance from HSE [44]. The British Institute of Radiology (BIR) have provided example risk assessments detailing a variety of risks associated with the MR ENVIRONMENT [135].

Define an MR CONTROLLED ACCESS AREA and "restrict access on grounds of health and safety unless the employee concerned has received adequate health and safety instruction".

Establishing procedures (e.g. Local Rules and standard operating procedures) to be followed to mitigate risks associated with working in the MR CONTROLLED ACCESS AREA in emergency situations. "*Ensure that any necessary contacts with external services are arranged, particularly as regards first-aid, emergency medical care and rescue work*".

"*Every employer shall appoint one or more competent persons to assist … in undertaking the measures … needs to take to comply with the requirements…*". In the context of MRI this relates to the requirement for sufficiently safe staffing levels of MRI departments, including the appointment of a sufficient number of individuals acting as MR RESPONSIBLE PERSON and MR SAFETY EXPERT.

"*Every employer shall provide … employees with comprehensible and relevant information on risks to their health and safety*".

"*Every employer shall ensure that … employees are provided with adequate health and safety training*".

Employees having received MR safety training must bring to the attention of their employer any work situation that they "*consider represented a serious and immediate danger to health and safety*" and of any matter that they consider "*represented a shortcoming in the employer's protection arrangements for health and safety*". Training must "*be repeated periodically where appropriate*".

"*Every employer shall ensure that … employees are provided with such health surveillance as is appropriate*". As required for all individuals before entering the MR CONTROLLED ACCESS AREA, staff members must have completed MR safety screening. See also section 3.4.2 regarding requirements to minimise staff exposure to electromagnetic fields and to reduce the potential for staff members to experience sensory or health effects due to such exposure.

The Health and Safety Executive (HSE) may inspect MRI departments. Such inspections are undertaken to assess compliance with relevant health and safety legislation; see section 1.1 for details.

Each employer/organisation must refer to the full details of the legislation and be assured that they are in full adherence. Adherence to these MHRA guidelines will assist the employer/organisation in ensuring that they are compliant with the legislation.

3.4.2 The Control of Electromagnetic Fields at Work (CEMFAW) Regulations 2016

CEMFAW came into force in the UK on the 1st July 2016 [5]. This is the UK implementation of EU Directive 2013/35/EU [136] which describes the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents, in this case electromagnetic fields. CEMFAW includes an exemption relating to MRI where an employee is permitted to be exposed to electromagnetic field levels greater than the Exposure Limit Values (ELVs):

> "*For any activity in respect of which a suitable and sufficient exposure limitation system is in place, where that activity is carried out"* in relation to the *"development, testing, installation, use and maintenance of, or research related to, magnetic resonance imaging equipment for patients in the health sector where -*
> *i. the exposure of employees to electromagnetic fields is as low as is reasonably practicable; and*
> ii. *employees are protected against any health effects and safety risks related to that exposure*."

The use of MRI other than for patients in the health sector, such as veterinary medicine, is covered by a separate and time-limited exemption certificate [137]. See the HSE website for the activities covered on the current certificate; employers are responsible for confirming that their activity is exempted. More details in section 4.5.10.

The HSE advise that despite this exemption for the use of MRI in the health sector, it is necessary to comply with all other requirements of the CEMFAW regulations, except the requirement to develop an action plan [138]. Employers must be assured that they meet their obligations under the CEMFAW regulations. Adherence to the practices set out in these guidelines in concert with professional body recommendations [139] will assist employers in meeting these requirements. These include the following:

- Providing information and training to ensure that staff can adhere to safe working practices including the use of methods to limit:
  - their exposure to the electromagnetic fields where practical, particularly for time-varying gradient fields and RF
  - the health effects associated with the magnetic fields of the MR system (e.g. PNS, heating)
  - the potential for transient sensory effects (e.g. nausea, vertigo, metallic taste in mouth)
- The demarcation of an MR CONTROLLED ACCESS AREA with access restricted to those who have completed such MR safety training
- The implementation of standard operating procedures for staff working in the MR ENVIRONMENT
- The implementation of risk assessments detailing risks and corresponding mitigations associated with:
  - sensory effects or health effects in the MR ENVIRONMENT
  - indirect effects, i.e., safety or health hazards resulting from the presence of an object or a substance in an electromagnetic field
- Providing a route for staff members to report any sensory or health effects that they experience within the MR ENVIRONMENT and a procedure to review how these effects could have been avoided
- Special consideration of employees at particular risk, such as those with active or passive implanted, or body-worn, medical devices, or those who are pregnant. These employees must have a risk assessment in place, with mitigations as required to reduce the risk to as low as reasonably practicable. In particular:
  - employers should consider the action level for indirect effects of 0.5 mT when fulfilling the requirement for risk assessment for employees with implanted or body-worn medical devices – however, they may choose to use 0.9 mT in practice, in line with the IEC [77], following suitable risk assessment such as that provided by the BIR [135]; see section 3.4.1 and [140] for further information
  - employers may wish to limit pregnant staff to exposure limits for members of the general public (see Appendix A2.3.1). See section 2.6.7 for more detail on staff exposure during pregnancy.

Appendix A2.2 provides a summary of the exposure limits required under CEMFAW and detail on the information provided by manufacturers on expected exposure. For full details please refer to the complete statutory instrument [5] and associated guidance [138,139,141].

3.4.3 The Control of Noise at Work (CNAW) Regulations 2005

The hazards associated with acoustic noise produced by the MR system were described in sections 2.3.2 and 2.6.4.

CNAW [7] require employers to consider both the daily or weekly personal noise exposure level ($L_{Aeq,t}$ with t = 8 or 40 hours respectively, with the choice depending on level of variation in daily exposure) and the peak sound pressure level ($L_{C,\,peak}$) to which employees may be exposed. Depending on the level of noise exposure, employers are required to:

- Assess the risks to employees from noise at work.
- Take action to reduce the noise exposure that produces those risks.
- Provide employees with hearing protection if the noise exposure cannot be reduced enough by using other methods.
- Make sure the legal limits on noise exposure are not exceeded.
- Provide employees with information, instruction and training.
- Carry out health surveillance where there is a risk to health.

CNAW defines action levels and exposure limits for average and peak sound levels. If employee exposure is likely to be above the action levels, employers must take action to ensure the exposure limits are not breached.

Staff must be made aware of how to obtain and use hearing protection. Additional protection should be assumed to offer no more than an additional 5-6 dB(A) of protection on the primary means [7].

IEC and ICNIRP both advise that staff exposure follows the same rules as recommended for patient exposure [69,77]. See Appendix A2.2.4 for a summary of the occupational exposure limits and recommendations from CNAW, ICNIRP and IEC. For full details of CNAW requirements, please refer to the complete statutory instrument [7] and the associated guidance [142].

3.4.4 Other Relevant Staff Exposure

Under the Control of Substances Hazardous to Health (COSHH) 2002 [38] the employer has the responsibility to "*ensure that the exposure of … employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled*". This requires a risk assessment to identify such hazards and to set out methods for prevention or limitation of exposure. Staff must be provided with information, instruction and training regarding the risks and the procedures required to mitigate risks. A step-by-step guide to COSHH assessment is provided by the HSE [143].

The employer must identify risks relating to employee exposure to hazardous substances. Staff must be given instruction in the practices they should follow to prevent or mitigate exposure. Personal protective equipment must be available and used as directed.

An example in the context of MRI units concerns the use of MRI test objects that are filled with hazardous solutions. Normally the test objects are sealed and present no hazard but if damaged the solution can be expelled. Typical chemical solutions found in MRI test objects include nickel sulphate, copper sulphate, nickel chloride and manganese chloride. These present a health hazard if absorbed (e.g. through contact with the skin or eyes), ingested or inhaled. MRI units must ensure that they complete a COSHH assessment covering all hazardous materials that staff could be exposed to. The assessment should identify control measures that staff should use to ensure their safety, for example when cleaning leaks or spillages. Personal protective equipment (PPE) must be available and used (e.g. gloves or protective glasses). Appropriate disposal routes of phantom solutions must also be identified.

3.5 Management of exposure to the general public

The Health and Safety at Work etc Act 1974 [1] states that every employer has a duty to ensure that work is carried out in such a way to ensure that "*persons not in … employment who may be affected are not exposed to risks to their health or safety*". As part of this, the Management of Health and Safety

Regulations 1999 [3] requires that the employer assess "*the risks to the health and safety of persons not in … employment*" that arise due to their work

The recommended practices set out in section 4.2 of these guidelines ensures that access to the MR ENVIRONMENT is restricted. Therefore, it is not expected that members of the general public would 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 MRI Units

4.1 Governance

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.

4.1.1 The Employer and the MR RESPONSIBLE ORGANISATION

As per UK legislation (The Health and Safety at Work etc Act 1974 [1], the employer has an overall responsibility in terms of safety (see sections 3.4 and 3.5). For example, the employer:

- Is responsible for ensuring that individuals/bodies with MR safety responsibilities are trained and appointed.
- Is responsible for ensuring maintenance of competency and having training records available for inspection when required by the enforcement agencies.
- Is ultimately responsible for the implementation and maintenance of procedures to ensure the health and safety of all individuals.
- Must be satisfied that organisational arrangements exist for the safe installation and use of MRI equipment within its authority.

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

Adapted from the international standard IEC 60601 [144], the term MR RESPONSIBLE ORGANISATION can be defined as the organisation responsible for the use and maintenance of the MR system, e.g. hospital.

In the majority of cases, the employer and the MR RESPONSIBLE ORGANISATION will be the same entity, however, there might be scenarios where this might not be the case, e.g. where MRI services (equipment or staff) are provided on site by a third party (section 4.5.1). In these cases, both parties should consider all aspects of these guidelines and formally agree the extent of their separate and mutual responsibilities.

4.1.2 MR RESPONSIBLE PERSON

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

If more than one diagnostic MR system is available for clinical use in the same MR CONTROLLED ACCESS AREA, then the appointment of more than one MR RESPONSIBLE PERSON may be appropriate, especially if the MR systems belong to distinct departments with different management and remit (e.g. radiology and cardiology). Clear, written instructions detailing the extent of the delegation and the ensuing managerial responsibilities of each MR RESPONSIBLE PERSON and the relationship between these responsibilities should be brought to the attention of all staff involved at any time with such equipment and its location. This includes all relevant staff categories of staff, including emergency staff and any contractors.

To cover all the necessary aspects of safety, each MR RESPONSIBLE PERSON should be in full consultation with an MR SAFETY EXPERT. The MR RESPONSIBLE PERSON should not take on the role of MR SAFETY EXPERT.

The MR RESPONSIBLE PERSON should retain close contact with other relevant groups or committees responsible for onsite safety and welfare, such as research ethics committees, local radiation safety committee or the MR SAFETY COMMITTEE (see section 4.1.6). Links should be established with any

local, regional and/or professional bodies. Training options and potential qualifications for MR RESPONSIBLE PERSON(s) to consider are discussed in Appendix 3.

4.1.3 MR SAFETY EXPERT

The MR SAFETY EXPERT is an individual who provides scientific advice on all aspects of MR safety. The expert should be a designated professional with adequate training, knowledge and experience of MRI equipment, its uses and associated requirements. Typically, they will be an MR CLINICAL SCIENTIST. IPEM has a position statement defining typical roles and responsibilities [145].

MRI units should appoint an MR SAFETY EXPERT to provide scientific advice on all aspects of MR safety. They should act according to recognised standards, i.e., for clinical units they should normally have Health and Care Professional Council (HCPC) registration or General Medical Council (GMC) specialist registration.

The MR SAFETY EXPERT should be certified by a scheme that assesses both knowledge and experience. IPEM administers a scheme that fulfils these requirements [146].

Some organisations will not be in a position to incorporate general scientific support to MRI within their clinical service and will not have direct access to an MR SAFETY EXPERT. These units should seek to establish support from an MR SAFETY EXPERT to provide appropriate MR safety advice by other means, e.g., via a service level agreement with a third party.

4.1.4 MR CLINICIAN

Any clinician responsible for reviewing the appropriateness of referrals, protocolling and/or reporting the MRI scan of a patient. For most sites this will be a radiologist, but it may vary dependent on scan indication and setting, for example, a cardiologist for a cardiology-led MRI service or a radiographer (working at enhanced, advanced or consultant level dependent on role and scope).

The MR CLINICIAN is overall responsible for the clinical oversight and safety of a patient in the MRI unit (e.g. reviewing the appropriateness of referral, protocolling and/or reporting the MRI scan of a patient).

The MR CLINICIAN is also responsible for individual risk-benefit decisions on a patient with potential MRI contraindications, e.g. unknown implants (section 5.5.3), contrast agents in pregnancy (section 2.6.5).

4.1.5 MR SAFETY MEDICAL ADVISER

It is recommended that a radiologist or another medical professional fills the role of MR SAFETY MEDICAL ADVISER.

The MR SAFETY MEDICAL ADVISER will attend the MR SAFETY COMMITTEE and will be required to provide medical input where required into MRI implant safety policies and procedures and lead on ensuring medical colleagues complete any relevant MR safety training. They will also play a role in communicating pertinent MR safety issues to referrers and other medical colleagues. It is not the role of the MR SAFETY MEDICAL ADVISER to routinely deal with individual patient safety queries.

4.1.6 MR SAFETY COMMITTEE

It is recommended that each MRI unit reports to an MR SAFETY COMMITTEE with representation from key persons. This should include the MR RESPONSIBLE PERSON, MR SAFETY EXPERT, MR SAFETY MEDICAL ADVISER and any relevant management representatives. Multiple MRI units may report to a single MR SAFETY COMMITTEE.

Additional membership of this group may be necessary depending on local services and staff group representation. The MR SAFETY COMMITTEE will be required to assist the MR RESPONSIBLE PERSON to develop and deploy all aspects of local MR safety governance, policies, procedures and training. It is expected that this group will include review processes for near misses and adverse events.

The MR SAFETY COMMITTEE should be incorporated into the wider governance structure of the organisation.

4.1.7 MR REFERRING CLINICIAN

Referrers are the first line of defence in a multistep process to ensure the safety of patients undergoing MRI. As such, referrers are required to provide enough information in regard to patient implants or other potential MRI contraindications (e.g. the presence of medical devices) such that the MRI unit receiving the referral can determine the MR safety status of each patient in advance of their appointment. This is key to minimise delays, slot cancellations and to increase the efficiency and robustness of the screening process.

Organisations should ensure that MR safety training forms part of the process by which MR REFERRING CLINICIANs are authorised to request MRI examinations. Training recommendations for referrers are discussed in Appendix 3.

4.1.8 MR RADIOGRAPHER

The MR RADIOGRAPHER is responsible for the entire episode of care. If the operator is not a registered radiographer, responsibility for the episode of care must be delivered within a supervisory framework overseen by a registered radiographer or other appropriate medical professional.
The training framework for the radiographic workforce is discussed in Appendix 3.

4.1.9 MR CLINICAL SCIENTIST

MR CLINICAL SCIENTISTs have core responsibilities in MRI safety, protocol development and quality assurance [147]. Clinical Scientists are regulated by HCPC and must practice according to recognised standards [148]. When carrying out duties within the scope of practice of an MR SAFETY EXPERT, the responsibility should be within a supervisory framework from an MR SAFETY EXPERT. Similarly, for MR physicists carrying out activities within the scope of practice of an MR CLINICAL SCIENTIST, especially where those activities will contribute to clinical safety, the responsibility should be within a supervisory framework from an MR CLINICAL SCIENTIST or other registered healthcare professional. The training framework for MR CLINICAL SCIENTISTs is discussed in Appendix 3.

4.1.10 Local Rules

The MR RESPONSIBLE PERSON needs to ensure that adequate written safety procedures, work instructions, emergency procedures and operating instructions, are issued to all concerned after full consultation with the MR SAFETY EXPERT and representatives of all MR AUTHORISED PERSON(s) who have access to the equipment (see section 4.3).

The MR RESPONSIBLE PERSON must ensure that Local Rules are in place for every MRI unit.

The Local Rules should be reviewed and updated at regular intervals in consultation with an MR SAFETY EXPERT and after any significant changes to equipment or working practices.

4.1.11 Safety Audit and Risk Assessments

The MR RESPONSIBLE PERSON must ensure that risk assessments are undertaken annually for every MRI unit, and these should be reviewed and updated after any significant changes to equipment or working practices in consultation with an MR SAFETY EXPERT as part of a safety audit programme.

Regular site safety audits should be regularly performed against compliance with national legislation, MHRA guidance, local policies, and manufacturer safety requirements. The audit should be conducted at least annually or whenever significant changes occur to the MRI unit.

Safety audits could be performed against the recommendations in the green boxes throughout these guidelines including for example: checking signage, documentation, training records, labelling of equipment, quench pipes, oxygen and humidity monitors, door seals and handles, suitable access to the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT. The British Institute of Radiology (BIR) has published examples of MRI risk assessments [135].

Safety audits should be signed off by the MR RESPONSIBLE PERSON and the MR SAFETY EXPERT.

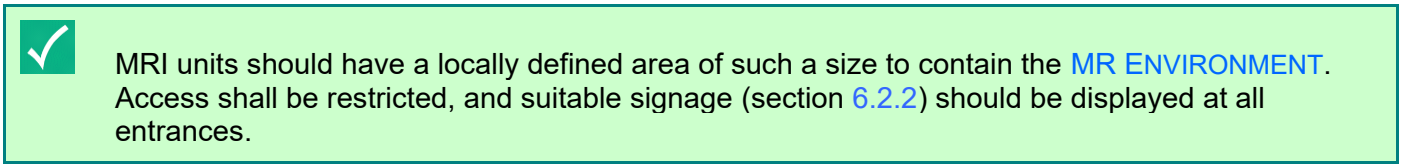
4.1.12 Specialist MRI Units

These are special cases in terms of responsibility and location, with a wide range of possible variations (see section 4.5). Careful consideration must be given to all aspects of responsibility to ensure full conformity with these guidelines and how these responsibilities will be shared.

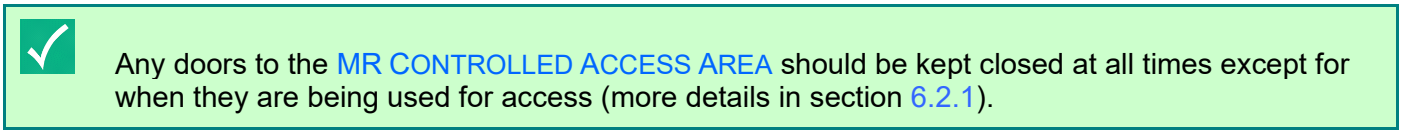
4.2 Controlled Access

Each MRI unit should define two areas of controlled access, for both people and equipment: the MR CONTROLLED ACCESS AREA and the MR ENVIRONMENT. Sites may also find it useful to identify additional regions or zones, for example relating to specific items of equipment and their permitted proximity to the system. Such zones should be determined locally.

4.2.1 MR CONTROLLED ACCESS AREA



MRI units should have a locally defined area of such a size to contain the MR ENVIRONMENT. Access shall be restricted, and suitable signage (section 6.2.2) should be displayed at all entrances.



Any doors to the MR CONTROLLED ACCESS AREA should be kept closed at all times except for when they are being used for access (more details in section 6.2.1).

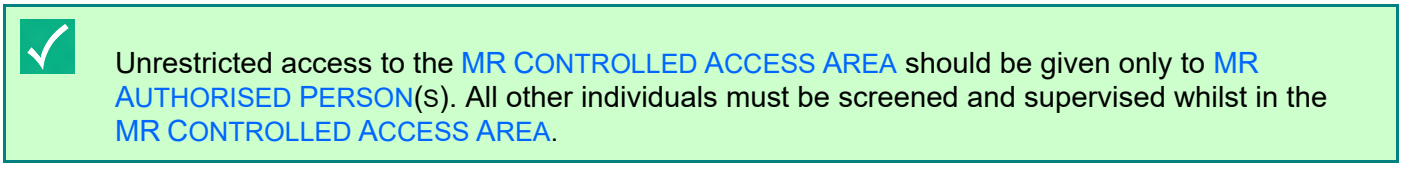
Its purpose is to provide a ‘buffer zone’ between the MR ENVIRONMENT and the outside world, as an extra layer of safety for access control. Generally, it is best practice to ensure that the MR CONTROLLED ACCESS AREA footprint is limited in size and only contains spaces immediately required as part of the MRI exam. An example of this may be an area to accommodate a general anaesthetic MRI service.

Further information on general space requirements, general design recommendations and room specifics can be found in the Guidance for Planning and Acceptance of New MRI Installations [149].

An example of a basic MRI suite layout showing the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT is shown in Figure 4.

It is vital to control access of people and equipment to the MR CONTROLLED ACCESS AREA and entrances should be kept to a minimum (see also section 6.2.)

Suitable access control methods are critically important (e.g. RFID-based ID badge access control) and unrestricted access should only be made available to MR AUTHORISED PERSON(s). Combination-based locks are generally discouraged as codes tend to become more widely distributed than originally intended [149]



Unrestricted access to the MR CONTROLLED ACCESS AREA should be given only to MR AUTHORISED PERSON(S). All other individuals must be screened and supervised whilst in the MR CONTROLLED ACCESS AREA.

✓ All individuals must be screened before being permitted entry into the MR CONTROLLED ACCESS AREA.

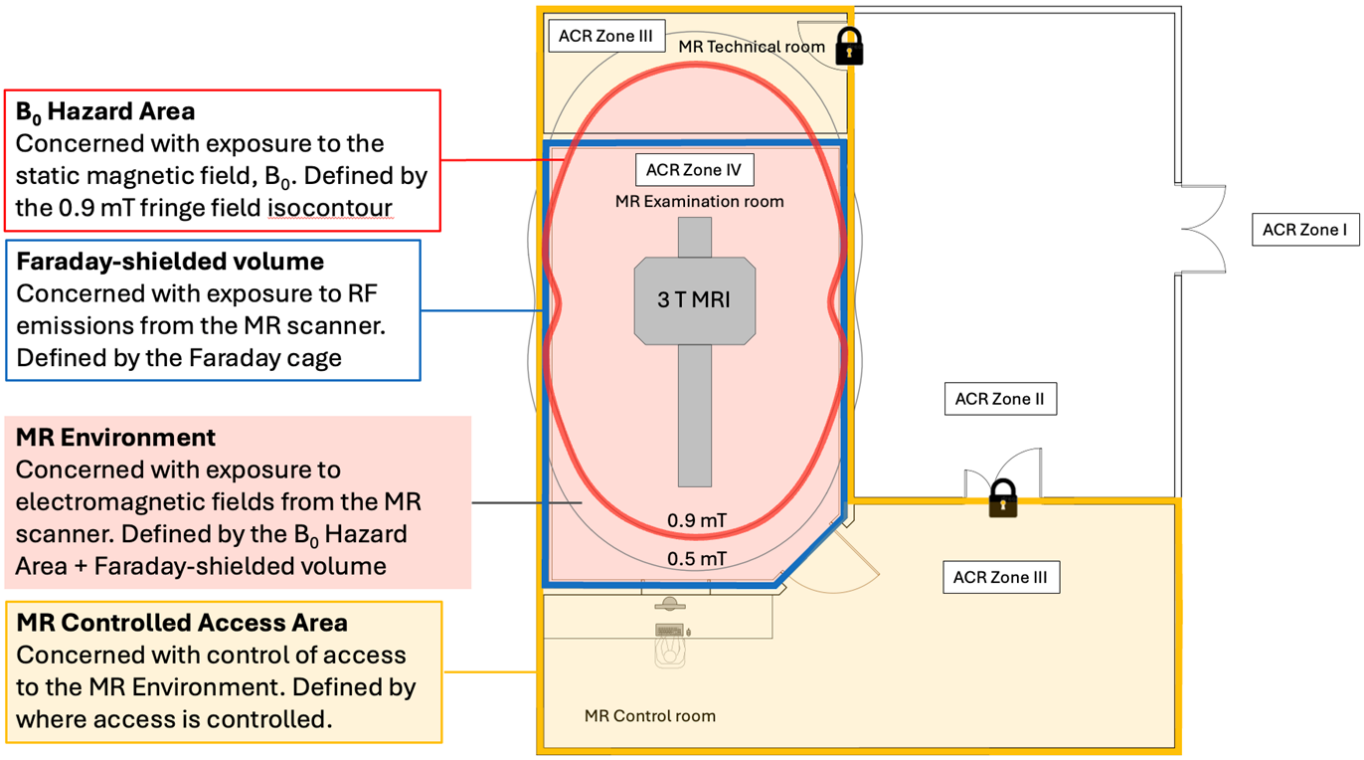


Figure 4 Illustrative floor plan showing the MR ENVIRONMENT (red shaded area) and the MR CONTROLLED ACCESS AREA (yellow shaded area). The grey contour indicates the 0.5 mT (5 G) static magnetic field contour. The bold red contour indicates the 0.9 mT (9 G) static magnetic field isocontour known as the B_0 Hazard Zone/Area. The Faraday-shielded volume (blue outline) shows the extent of the RF cabin. The four MR safety zones described by the ACR manual on MR safety [53] are also represented for reference.

4.2.2 MR ENVIRONMENT

The MR ENVIRONMENT is "*three-dimensional volume surrounding the MR magnet that contains both the Special Environment (Faraday shielded volume) and the B_0 Hazard Area (space around the MR equipment where the static magnetic field can cause harm). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories, and for which access control is part of the risk mitigation.*" [56,54].

The B_0 Hazard Area is defined as the region where the static magnetic field exceeds a particular value. Historically, this threshold was 0.5 mT, however, the 2022 update (2024 in the UK) to the IEC 60601-2-33 standard increased this value to 0.9 mT [150].

An action limit of 0.5 mT, as defined in current UK legislation [5], based on Directive 2013/35/EU of the European Parliament and of the Council [136] (Table B4), still must be considered when risk assessing indirect exposure effects and formulating training requirements. This value is derived from ICNIRP guidance.

✓ Suitable warning signage should be displayed at all entrances to rooms containing the MR ENVIRONMENT (6.2.2).

An easily removable physical barrier across the entrance to the MR examination room, e.g. a retractable belt stating, "AUTHORISED ACCESS ONLY", may also provide an additional layer of protection.

Anyone seeking to enter the MR ENVIRONMENT must be fully screened (see section 5.3.4 for patients and section 4.3.2 for staff) and should be warned of:

- the possible hazards of the magnetic field, in particular to the operation or malfunction of active implantable devices, including pacemakers (see section 5.5).
- the potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field (see section 2.2).

Before entering the MR examination room, everyone must take the following precautions:

- they must remove watches, phones, credit cards, other magnetic recording media and ferromagnetic objects. These should be placed in a suitable locker (section 6.2.8). They must remove from their clothing all ferromagnetic objects such as coins, pins, scissors, keys, tools, hair grips, certain spectacles that have ferromagnetic parts, etc.
- ferromagnetic objects such as tools, gas cylinders, trolleys, life support systems etc must not be allowed into the MR ENVIRONMENT except under a strict local procedure (see details below). It is not always obvious that an object is ferromagnetic. A hand-held ferromagnetic material detector may be used to check items in order to determine an object's ferromagnetic status.

Bringing Equipment into the MR ENVIRONMENT

Equipment that needs to be brought into the MR CONTROLLED ACCESS AREA should be kept to a minimum and should be clearly labelled. Normally, no equipment is to be taken into the MR ENVIRONMENT unless it has been labelled MR SAFE or MR CONDITIONAL and all conditions can be met.

On the rare occasion that there is a requirement to take items into the MR ENVIRONMENT established as MR SAFE or MR CONDITIONAL where all conditions cannot be met (e.g. ferromagnetic objects), sites should have local procedures in place. At a minimum, these procedures should consider projectile and equipment malfunction risks, and consider the mitigations required to minimise them such as e.g. tethering equipment appropriately, plus ensuring that records of staff MR safety training are current. The MR SAFETY EXPERT and the MR RESPONSIBLE PERSON should be involved in developing the local procedure.

Consideration should be given to whether additional regions should be marked within the MR examination room to highlight to users where specific items of equipment can be safely operated [149]. (e.g. to demarcate a specific static magnetic field strength around the MR system or to enforce the intended location of a specific piece of equipment). Figure 1 shows how small changes in position can correspond to a sudden increase in static magnetic field strength, such that a piece of MR CONDITIONAL equipment used in a slightly different location may suddenly become a hazard.

Equipment Policy and Responsibility

The MR RESPONSIBLE PERSON should ensure that there is a clear policy for the purchasing, servicing and return to use, testing and labelling of all equipment that will be taken into the MR ENVIRONMENT. Control of equipment entering the MR ENVIRONMENT on a day-to-day basis is the responsibility of the MR OPERATOR responsible for the examination at the time/episode of care.

The MR RESPONSIBLE PERSON should keep an inventory of all equipment that is in use in the MR ENVIRONMENT, including their labelling and conditions.

Labelling of Equipment

When labelling equipment as MR CONDITIONAL the MR conditions must be included on the label (see examples in Appendix 5). 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 devices should typically show information such as the maximum magnetic field in which the device was tested, the magnitude and location of the maximum spatial gradient, the maximum rate of change of the gradient field, and radio-frequency fields tolerated in terms

of RF interference, RF heating and type of transmit mode. Input should be requested from an MR SAFETY EXPERT to assist with labelling items correctly, especially in terms of their RF interference and heating and the transmit mode required.

MRI units may need to re-examine each device's safety status after service, repair or refill (e.g. of auxiliary equipment), or whenever changes are made to the MR ENVIRONMENT such as when changing to a new MR system or upgrading an existing system.

All equipment taken away for maintenance or servicing should also be re-examined once returned to the MRI unit. This does not apply for MR CONDITIONAL equipment serviced by its manufacturer.

Many items, such as consumables and other items such as phantoms, patient slides cannot be reasonably labelled.

All equipment in the MRI unit should be clearly labelled using safety markings in line with the latest version of ASTM International standard F2503 (see section 1.5) and any MR conditions should be included on the label (see examples in Appendix 5).

The safety labelling of MRI equipment should be checked on a regular basis to ensure the correct labels are in place and remain legible.

The conditions for safe use that accompany MR CONDITIONAL devices should be consulted before allowing them into the MR ENVIRONMENT.

Items which are not labelled (MR UNLABELLED) should be considered MR **UNSAFE** until determined to be otherwise (see section 5.5.3)

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 [151]. Devices which are not labelled are considered MR UNLABELLED.

Hand-held Test Magnet

Sites may choose to use a strong hand-held magnet (for example, with a field strength of approximately 0.1 T) to assess the ferromagnetic properties of superficial metallic foreign bodies in patients and equipment that may need to be brought into the MR ENVIRONMENT. The MR SAFETY EXPERT and the MR RESPONSIBLE PERSON should be involved in developing the local policy and procedure governing the use of such magnets.

When using such a magnet, the risk of harm to the patient should be carefully considered, assessing the properties of the hand-held test magnet and the depth, geometry, and proximity of the object to sensitive anatomical structures. The translational force acting on a superficial ferromagnetic object may be greater with a strong hand-held magnet than with the MR system. Conversely, for elongated ferromagnetic objects, the torque experienced within the MR system may be substantially greater than that produced by a hand-held test magnet.

It is recommended that MRI units have access to a strong ~ 0.1T hand-held magnet, together with associated policies and procedures for its use, when assessing superficial metallic foreign bodies in patients and for testing items of equipment that may need to be taken into the MR ENVIRONMENT [5453].

4.3 MR AUTHORISED PERSON(s)

4.3.1 Definitions

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

The MR RESPONSIBLE PERSON should formally approve designation of MR AUTHORISED PERSON(s), only when they have satisfactorily completed the requirements of screening as well as training in their responsibilities and MR safety training (Appendix 3).

Sites may choose to subdivide access, supervision and screening rights of the MR AUTHORISED PERSON to better reflect working practice as follows, and the number of roles should be kept to those necessary to minimise confusion over routes of responsibility:

MR AUTHORISED PERSON (NON-MR ENVIRONMENT)

- An MR AUTHORISED PERSON authorised to have unrestricted access to the MR CONTROLLED ACCESS AREA but not the MR ENVIRONMENT. They do not have permission to enter the MR ENVIRONMENT without an MR AUTHORISED PERSON (SUPERVISOR). Within the MR CONTROLLED ACCESS AREA they have responsibility only for their own safety but cannot supervise others.

MR AUTHORISED PERSON (MR ENVIRONMENT)

- An MR AUTHORISED PERSON authorised to have unrestricted access to the MR CONTROLLED ACCESS AREA including the MR ENVIRONMENT. They are not permitted to supervise others within the MR ENVIRONMENT but can take responsibility for their own safety there. They are permitted to supervise others in the other areas of the MR CONTROLLED ACCESS AREA.

MR AUTHORISED PERSON (SUPERVISOR)

- An MR AUTHORISED PERSON who is authorised to have unrestricted access to the MR CONTROLLED ACCESS AREA including the MR ENVIRONMENT, supervise others in there and perform safety screening of other people for access to the MR ENVIRONMENT.

MR OPERATOR

- An MR OPERATOR is an MR AUTHORISED PERSON who is also entitled to operate the MRI equipment. MR OPERATOR(s) are normally radiographers but may include radiologists, cardiologists, MR CLINICAL SCIENTISTs, maintenance and research staff.
- Sites may designate two types of MR OPERATOR: clinical and technical/non-clinical, where the latter may only scan test objects/phantoms.

Non-MR Authorised staff with occasional MR CONTROLLED ACCESS AREA duties

- Any staff members who are not MR AUTHORISED PERSON(s) but have occasional work duties in the MR CONTROLLED ACCESS AREA (e.g. porters, estates, cleaners) must receive suitable basic MR safety training (see Appendix 3) and they need to be supervised at all times in there by a relevant MR AUTHORISED PERSON. Alternatively, access to the MR ENVIRONMENT must be locked to prevent entry (e.g. for cleaning purposes out of hours).

- Any members of staff with regular duties in the MRI unit must be MR AUTHORISED PERSON(s).

- All MR AUTHORISED PERSON(s) must be suitably trained in MR safety. Training recommendations are in Appendix 3.

Table 4. Access, supervision and screening rights of MR AUTHORISED PERSON(s)

		MR CONTROLLED ACCESS AREA ONLY	MR ENVIRONMENT
MR AUTHORISED PERSON (NON-MR ENVIRONMENT)	Unrestricted entry	Yes	No
	Responsibility for own safety	Yes	No
	Responsibility for safety of others	No	No
	Can screen themselves	No	
	Can screen others	No	
MR AUTHORISED PERSON (MR ENVIRONMENT)	Unrestricted entry	Yes	Yes
	Responsibility for own safety	Yes	Yes
	Responsibility for safety of others	Yes	No
	Can screen themselves	Yes	
	Can screen others	No*	
MR AUTHORISED PERSON (SUPERVISOR)	Unrestricted entry	Yes	Yes
	Responsibility for own safety	Yes	Yes
	Responsibility for safety of others	Yes	Yes †
	Can screen themselves	Yes	
	Can screen others	Yes †	

*Sites may choose to have MR AUTHORISED PERSON (MR ENVIRONMENT) assist with screening duties, but an MR AUTHORISED PERSON (SUPERVISOR) should always ratify the screening form.

† Sites may further subdivide the MR AUTHORISED PERSON (SUPERVISOR) category for operational reasons, e.g. scanning patients vs. scanning healthy volunteers or phantoms.

The MR RESPONSIBLE PERSON should maintain a list of all MR AUTHORISED PERSON(s) together with full details of their training.

All members of staff must be made aware that there are specific risks and hazards related to working in the MRI unit and that there are training requirements to enable working safely in this area.

4.3.2 Screening

Written procedures must be in place for screening of all members of staff and visitors seeking access to the MR ENVIRONMENT. If staff members/visitors cannot satisfactorily complete the requirements of screening, they should be restricted from exposure as appropriate.

- Staff with known contraindications to MRI may enter the MR ENVIRONMENT only when the associated risk has been evaluated and deemed acceptable for that specific device or condition. Staff with higher-risk contraindications must not enter unless a formal risk assessment has taken place.
- All MR AUTHORISED PERSONMR RESPONSIBLE PERSON(s) must have satisfactorily passed screening for the required level of access.

Written procedures must be in place for screening of all members of staff and visitors seeking access to the MR ENVIRONMENT.

Repeat screening of MR AUTHORISED PERSON(s) must take place at least annually and records should be maintained by the MR RESPONSIBLE PERSON.

If the screening information relates to staff, and is relevant to their professional duties, then it should be regarded as part of their Human Resources (HR) record and should be kept in line with local policy on HR records. Where personal staff information is held at the unit it should be held securely and treated in accordance with the UK General Data Protection Regulation (GDPR) [152].

All MR AUTHORISED PERSON(s) should immediately tell the MR RESPONSIBLE PERSON if something changes in their medical or personal status that might prevent them from being permitted into the MR ENVIRONMENT and screening should be repeated to record any changes.

4.3.3 Responsibilities

- On entering the MR CONTROLLED ACCESS AREA, all MR AUTHORISED PERSON(s) must comply with the safety recommendations given in section 4.2.
- All other persons, which may include visitors, patients and unauthorised staff, should have access only if accompanied by a relevant MR AUTHORISED PERSON.
- All MR AUTHORISED PERSON(s) who act as volunteers for scanning must conform to the requirements referred to in section 5.2.

4.3.4 Lone Working

Staffing levels and configurations will vary to meet local circumstances and service delivery models [153]. However, staffing levels should consider both patient and staff safety [1], particularly the safety issues associated with the MR ENVIRONMENT and its hazards.

Issues around equitable service provision in terms of quality and safety throughout the day, for example in out-of-hours/on-call situations should also be considered [153154].

Staff should not work alone in the MR ENVIRONMENT (that is, without anyone in the control room or immediately available in the MR CONTROLLED ACCESS AREA). Where staff are required to work alone within the MR CONTROLLED ACCESS AREA only, their local Lone Working Policy applies.

Unless the MR examination room is locked and not in use, MHRA recommends that two MR AUTHORISED PERSON(s) work in the MR CONTROLLED ACCESS AREA as a minimum at any given time. This is to fulfil minimum competency levels to ensure the safety of patients and staff both during standard clinical duties and in an emergency.

To ensure compliance and minimise delays in urgent out-of-hours examinations, it is recommended that any training is delivered to staff before they have occasion to attend the MRI unit.

4.4 Emergency Procedures

4.4.1 General

An emergency can relate to the well-being of patients, volunteers or staff members, or to an environmental emergency such as a fire or a loss of electrical power.

Careful consideration must be given to setting up the correct form of training for the variety of staff involved in any form of emergency which requires entry into the MR CONTROLLED ACCESS AREA, (particularly any staff members who are not MR AUTHORISED PERSON(s)) and the necessary liaison with the appropriate groups both within and outside the organisation. Section 4.2 covers access to the MR CONTROLLED ACCESS AREA and training recommendations are in Appendix 3.

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:

- Evacuation of a patient from the system (e.g. medical emergency)
- Fire
- Loss of electrical power/lighting
- Projectile incident
- Quench in the MRI unit or decreased oxygen level
- MR examination room door failure

✓ These procedures must be reviewed and audited at regular periods by the MR RESPONSIBLE PERSON in consultation with the MR SAFETY EXPERT. Procedures should be known and understood by all MR AUTHORISED PERSON(s) and practised regularly.

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

4.4.2 Medical Emergency (e.g. Cardiac Arrest)

In the event of a cardiac arrest, immediate resuscitation should be initiated, including airway management and cardiopulmonary resuscitation. Simultaneously, assistance from the hospital resuscitation team should be requested.

The patient should be removed from the MR ENVIRONMENT as quickly as possible. Resuscitation should then take place/continue in a previously identified area outside MR ENVIRONMENT by a qualified resuscitation/crash team, according to local policy/procedure. The MR ENVIRONMENT should be secured after the patient has been evacuated to avoid unauthorised entry. Local procedures will need to ensure that a non-ferromagnetic trolley is available at all times if the couch is not able to undock and be used to transport the patient.

Be aware that there might be safety implications of using an electronic defibrillator on a patient lying on a dockable system table. Alternatives, such as non-ferromagnetic trolleys to transfer patients onto, should be considered in local emergency procedures.

Physiological patient monitoring recommendations are described in detail in section 5.3.10.

✓ It is recommended that the MR RESPONSIBLE PERSON conducts an evacuation / resuscitation drill at least annually.

✓ Local emergency procedure for medical emergency should be on display in the MRI unit.

Resuscitation equipment should never be taken to the patient in the MR ENVIRONMENT when the magnet is energised, unless it is either MR SAFE or MR CONDITIONAL and the conditions are met.

4.4.3 Fire

For superconducting magnet systems: the magnet must be quenched if the emergency services need to enter the MR ENVIRONMENT with ferromagnetic equipment. Warning notices must be displayed. Only MR AUTHORISED PERSON(s) should enter the MR ENVIRONMENT unless the magnetic field has been fully quenched or turned off.

It is recommended that only MR CONDITIONAL fire extinguishers are provided within the MR CONTROLLED ACCESS AREA.

It is recommended that the MR RESPONSIBLE PERSON invites the local fire and rescue service, via the hospital fire officer, to visit the MRI unit to familiarise themselves with the local situation.

A fire box/fire action card should be placed at an agreed location providing comprehensive but succinct information regarding the MRI risks and hazards for attending fire teams, including:

- Fire emergency procedures (including out of hours procedures and contact details).
- Phantom chemical record.
- Map of the MRI unit, including location of the MR examination room and a warning about risks and hazards.
- Location and designation of quench and emergency power off buttons.
- Location of MR CONDITIONAL fire extinguishers.

4.4.4 Loss of Electrical Power

If there is a mains electricity power failure and a patient is being scanned, they should be removed from the system using the manual table emergency release procedure. As the table may be stuck at height, MR CONDITIONAL or MR SAFE portable steps should be available for ambulant patients. A plan of action for removing patients who are under general anaesthesia or unable to move off the table themselves should also be formulated.

There should be local procedures in place in case of a power outage to restart both the chiller(s), the cryo-compressor and the MR system. Estates, IT and the vendor (e.g. remote monitoring system and alerts) might all be involved.

Some MRI units might have secondary or tertiary power supply support in place (e.g. for the MR system or other related critical equipment) in the event of a failure of the primary electrical supply [14].

4.4.5 Projectile Incident

If a ferromagnetic object becomes attached to the system, scanning should cease immediately.

For non-permanent magnets, a prompt assessment must be made on whether the static magnetic field should be removed (de-energised or quenched depending on system type). This will depend on whether the projectile event presents an immediate danger to life or limb. If it does, then the emergency magnet off (quench) button should be activated. Action must also be taken to prevent further injury occurring as the released ferromagnetic object moves position and falls to the ground following removal of the static magnetic field. If the lodged ferromagnetic object does not present an immediate threat to life or limb, then all persons should be immediately evacuated from the MR ENVIRONMENT. The MR RESPONSIBLE PERSON should be informed, and the MR manufacturer should be contacted to organise a controlled ramp down to allow removal of the object.

If a ferromagnetic object enters the MR ENVIRONMENT but has not yet become a projectile, prior to attempting removal of this free object, an assessment must first be made to determine the safest method of removal. It is best practice to have a procedure in place for such an eventuality.

For non-permanent magnets, if there is an immediate danger to life or limb, e.g., a person is trapped against the magnet by a ferromagnetic object, the emergency magnet off (quench) button should be activated. Action must be taken to prevent further injury following removal of the static magnetic field.

4.4.6 Superconducting Magnet Quench and/or MR Examination Room Oxygen Warning

Cryogens, such as liquid helium and nitrogen, are used in MR systems to cool the superconducting magnets and maintain their low temperatures. The main hazards associated with cryogens in MR systems are detailed in Appendix 1.

Systems with Quench Pipes

A quench will produce a rapid boiling of the cryogens and a large increase in internal pressure. This over-pressure causes the magnet's burst disk to rupture, with the gaseous helium normally routed through the quench pipe and vented safely to the outside environment. A quench will therefore in general be accompanied by a loud bang and the emission of large quantities of cold gas as a visible cloud. The visible white cloud or fog is produced by condensation of atmospheric moisture as a result of contact with the extremely cold helium gas and does not represent smoke or fire.

If there is inadequate venting, e.g. faults within the magnet system or quench pipe (6.2.4), helium may spread through the MR examination room. It will form a white fog that eventually clings to the ceiling. As the released helium displaces atmospheric oxygen, an oxygen deficiency monitor alarm (6.2.5) should be automatically activated. If the oxygen alarm sounds, or a quench is otherwise suspected, it should be confirmed that any emergency exhaust or extract system has been activated, either automatically or manually, keeping in mind that these are usually not enough on their own to fully mitigate the cryogen hazard [149].

The MR examination room and surrounding area must be evacuated at once. Those in the MR examination room should keep low to the ground when evacuating, as the helium gas will displace the air in the room very quickly. There have also been reports that the rapid increase in room pressure associated with helium release can impede the opening of inward MR examination room doors and one instance of an outwards opening door being blown open. The door to the MR examination room should therefore be propped open to let the gas escape until the MR examination room is evacuated.

After a quench, the static magnetic field and helium level should be assessed by a suitably qualified person or manufacturer representative to confirm the static field has fallen before re-entry and before bringing any ferromagnetic objects into the MR ENVIRONMENT.

In the event of a quench and/or oxygen alarm, stop the scan and, if it is safe to do so, evacuate anyone from the MR examination room as quickly and safely as possible.

It is recommended that the MR RESPONSIBLE PERSON conducts regular quench simulation/evacuation drills.

Systems without Quench Pipes

The main hazards associated with cryogens are not present (see section 4.5.7).

4.4.7 MR Examination Room Door Failure

There are a multitude of potential causes of MR examination room door failure, which can prevent MR staff from accessing the patient [155]. MR examination room doors require regular maintenance (see section 6.6.8) and backup/mitigation options should be considered [149].

A local policy should be available that describes the procedure for forcing open the MR examination room door or gaining entry by alternative methods, for example involving Estates or similar, or potentially the local fire and rescue service.

Any tools used to gain access in the case of MRI examination door failure must not enter the MR ENVIRONMENT unless they are either MR SAFE or MR CONDITIONAL and the conditions are met.

4.5 Management of Specialist Units

4.5.1 Mobile/Relocatable MRI

For the purposes of this document, 'mobile' includes relocatable and modular MR systems. These systems might be managed by the host organisation or more likely, they will constitute a third party managed mobile MRI service.

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 any associated staff (the third party).
- The hospital or clinical institution responsible for the patients and volunteers who are being examined in the mobile equipment (the host organisation). They might sometimes also provide the staff.

A wide range of variations can be envisaged. Two extremes are:

- The host organisation hires the equipment and is responsible for its location, operation and all staff.
- 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.

In both these situations and any others in between, both parties should consider all aspects of these guidelines and formally agree the extent of their separate and mutual responsibilities.

The safety procedures and policies between the mobile unit and any other MR systems on site may differ. The host organisation (via the MR SAFETY COMMITTEE) should satisfy themselves that the third-party mobile provider adheres to the safety guidelines outlined in this document and agreements should be in place to ensure patients are managed appropriately. This may include ensuring inappropriate patients are not sent to the mobile unit (e.g. patients with particular implants) and governance is in place should there be the need for clinical sign off on particularly complex patients (e.g. pregnant patients). The arrangements should be decided and agreed via the governance process prior to commencement of scanning.

Additional Issues of Particular Concern

Attention must be paid to:

- The need to appoint one or more MR RESPONSIBLE PERSON(s), an MR SAFETY EXPERT and suitably trained MR AUTHORISED PERSON(s).
- The need to give clear written instructions detailing the extent of any delegation and the ensuing responsibilities to all staff involved at any time with the equipment and its location.
- The location of the mobile equipment during operation, e.g. manufacturer recommendations regarding minimum distances from nearby equipment or large moving ferromagnetic objects. More details on this can be found in the Guidance for Planning and Acceptance of New MRI Installations [149].
- The location of the mobile equipment regarding patient flow. Mobile MRI units are outside hospital buildings and at times are in areas which were not designed for patient access and may have limited facilities, e.g., toilets may need to be accessed. As such, only appropriate patient groups should be considered who can safely attend the MRI unit.
- For systems with quench pipes, the quench pipe should not be obstructed and access to the outlet should be appropriately controlled, i.e., the mobile unit should not be parked under an overhang or positioned close to regions where a person may have access within 3 m (or within the manufacturer's exclusion zone).
- The need to control access to the MRI equipment, e.g. the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT must be adequately partitioned or fenced off in such a way that

members of the public do not have unrestricted access. MR AUTHORISED PERSON(s) must carefully control access to such units.

- Emergency procedures, particularly the unique aspects associated with a mobile unit. This may include issues with the resuscitation team attending the unit in the case of medical emergency, having a contactable MR AUTHORISED PERSON to attend in the case of an out-of- hours fire and access for emergency vehicles.
- The safety of the equipment during transit. 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. The requirements of The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations [156] must be met.

4.5.2 Interventional MRI

Staff Numbers

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

Exposure Assessment

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

Geometric Accuracy

Geometric accuracy is particularly important for those MRI 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. MRI 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.

Suitability 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 considered during the planning process.

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 SAFE or MR CONDITIONAL. The availability of these devices will need to be confirmed.

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.

Cleaning and Decontamination

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

4.5.3 Radiotherapy Planning

The IPEM topical report titled guidance on the use of MRI for external beam radiotherapy treatment planning [157] provides recommendations on implementation of MRI for radiotherapy planning including those related to training and a quality assurance programme.

MR Safety and Staffing Considerations

Radiotherapy planning scans may be performed on MR systems that are either physically or organisationally separate from the Radiology department. Furthermore, MRI scans for radiotherapy planning may be undertaken by a team including therapeutic radiographers and diagnostic radiographers, distinct staffing groups with regards to experience working with MR systems and relevant training and designation of staff is required to ensure safe working practices.

Geometric Accuracy

Radiotherapy relies on geometric accuracy. Some magnet designs can often have relatively high static magnetic field and/or gradient field distortion levels. MRI 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.

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.

4.5.4 Ultra-high Field

Ultra-high field (UHF) MR systems, typically defined as operating at field strengths of ≥ 7 T, introduce additional safety considerations beyond those encountered at conventional clinical field strengths [158]. These considerations arise from the increased static magnetic field strength, higher RF frequencies, and the use of multi-channel RF transmission systems (parallel transmit, pTx).

The stronger static magnetic field (B_0) increases magnetically induced forces and torques on ferromagnetic objects, thereby elevating projectile risk and further constraining the safe use of implants and devices. Spatial field gradients are also greater (118), increasing the likelihood of sensory effects such as vertigo, nausea, and magnetophosphenes during movement within the fringe field [59]. Accordingly, enhanced screening procedures and more conservative approaches to implant conditionality are typically required.

At field strengths of 7 T and above, higher RF frequencies result in shorter RF wavelengths in tissue, leading to increased B_1^+ field inhomogeneity and the potential for highly localised RF heating. Local SAR hotspots may arise even when global SAR limits are within accepted thresholds, and this effect is more pronounced than at lower field strengths such as 3 T. Consequently, local SAR modelling is often a key limiting factor in the design and conduct of UHF MRI examinations.

The lack of a history of safe usage from scans under exigent circumstances means that the evidence base for implant safety is much more limited at ultra-high field, with many devices that are MR CONDITIONAL at 1.5 T or 3 T not approved (often not assessed) for use at 7 T. This requires cautious risk assessment that may lead to exclusion of subjects with implanted devices. Now that 7 T MRI can be approved as a diagnostic clinical imaging modality, it is important to implement institutional governance procedures that balance the potential benefits vs risks of a scan. Note that ultra-high field MRI is not necessarily more dangerous than high field MRI. Rather the assessment must be made based on the specific geometry of the implanted device.

4.5.5 Low Field and Open

The category of low field MRI typically includes MR systems which are < 1.5 T in field strength but are permanently sited and cannot be taken to the patient point of care. These systems often have field lines which differ from a superconducting magnet field distribution, e.g. fields that point in a direction transverse to the body generated from an open MR system architecture. However, both legacy and modern superconducting systems with standard z-direction field orientation are available at fields lower than 1.5 T too.

Considerations for Projectile Incidents

Projectile forces acting on a ferromagnetic object depend on both field strength and spatial gradient and although the field strength is lower, the spatial gradient can be higher for open systems and projectile forces might be greater than anticipated given the low field. Furthermore, low field open MR systems typically use permanent magnets which have the additional concern that they cannot be switched off (quenched) in the case of an emergency. As such, all procedures and controls outlined in this document should be in place to ensure safe operation, in particular precautions to protect against MR **UNSAFE** ferromagnetic objects being taken into the MR ENVIRONMENT.

Considerations for Implanted Medical Devices

Although heating, gradient effects, projectile and torque forces are typically reduced for lower field systems they can still be dangerous. Furthermore, many implant manufacturers have only tested their devices at 1.5 T and/or 3 T and therefore, often will not comment regarding MR safety at lower field strengths or for open systems where the field is oriented differently to the system on which the device was tested (typically closed bore superconducting systems). This means that many devices are MR UNLABELLED at lower fields strengths and scanning these devices will need to be done following an off-label process (see section 5.5.3) or under a generic implant safety procedure (GISP) (see section 5.5.2). The work of Shellock et al. provides guidance on managing implants at fields below 1.5 T [159]. Active implants can be of particular concern given the additional consideration of unintended stimulation or device malfunction.

Acoustic Noise Considerations

Acoustic noise levels are typically reduced for lower field systems and in some cases hearing protection may not be required. The acoustic output levels of the system should be carefully considered and if there is potential for exposure to levels above those outlined in section 3.3.5 hearing protection should be provided. If the acoustic levels are below those outlined in section 3.3.5, hearing protection may be offered for those who might be particularly hearing sensitive.

4.5.6 Point of Care MRI

Point-of-care MRI (POC-MRI) systems present a different set of risks compared with a conventional MR system and require a robust, yet proportionate, safety framework. In some cases, the safety framework may need specific variations from some aspects of these guidelines.

Equipment Location

POC-MR systems are likely to be used outside Radiology departments, and the MR ENVIRONMENT is unlikely to be contained within an MR CONTROLLED ACCESS AREA. Sites will need to identify locations where the equipment can be stored securely and take measures to ensure the safety of staff, patients and the public when the equipment is in use or being transported.
The MR ENVIRONMENT (simply the relevant field contour in the absence of a Faraday shielded volume) for POC-MRI equipment must be clearly visible and access must be restricted within this volume. Field maps must be obtained for the POC-MR system and included in the Local Rules, including noting the location and strength of the maximum field strength of the system.

Safety

The projectile risk is greatly reduced for ultra-low field strength (<0.1T) POC-MR systems compared with conventional superconducting 1.5 T and 3 T magnets. However, individual sites must determine what equipment is permitted to enter the MR ENVIRONMENT.

Screening must be performed by an MR AUTHORISED PERSON trained to perform safety screening before entry is permitted into the POC-MR system MR ENVIRONMENT. Many implants have not undergone MR safety testing on POC-MR systems and so sites will need to develop local implant safety procedures for POC-MRI.

There is no cryogen risk as POC-MR systems use permanent magnets.

The POC-MRI manufacturer must provide information on the maximum acoustic noise levels to allow the site to determine if hearing protection is required for the patient/volunteer and anyone around the POC-MR system during operation.

Acceptance testing, maintenance and regular quality assurance should not be overlooked for POC-MR systems.

POC-MRI sites must have a system to report and follow up on incidents and near misses, ideally using the same system as the conventional high-field MR systems. With the POC-MRI potentially moving between departments, it should be agreed who takes on the ultimate responsibility for all aspects of safety.

Staff Training

It is recommended that sites appoint an MR RESPONSIBLE PERSON with MR experience and an MR SAFETY EXPERT to provide support in the safe use of a POC-MR system.

POC-MR systems are relatively straight-forward to operate compared with conventional MR systems. For example, unless users have a research agreement, the protocols may not be adjusted by the MR OPERATOR, and the scan is planned automatically. Whilst MR OPERATOR(s) are typically radiographers, sites may decide to provide training to other staff groups with less MR experience to operate POC-MR systems. All MR OPERATOR(s) of POC-MR systems must receive training covering the relevant aspects from Table 4/A3.1 plus training on moving and handling of patients. Additional guidance and Standard Operating Procedures (SOPs) may be required to support MR OPERATOR(s) with limited prior MRI experience.

There is a 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.

4.5.7 Low cryogen/Sealed Superconducting MR Systems

Low-cryogen superconducting MR systems represent a significant evolution in magnet design, aimed at reducing reliance on liquid helium while preserving the performance advantages of conventional superconducting MRI [160]. Traditional MRI magnets typically contain 1,000–2,000 litres of liquid helium to maintain the magnet at superconducting temperatures. In contrast, low-cryogen systems operate with dramatically smaller helium volumes, from < 1 litre to a few tens of litres, contained within a sealed cryostat.

This reduction is achieved through the use of modern cryocoolers that continuously recondense helium gas back into the liquid phase, resulting in near zero boil-off during normal operation. As a result, routine helium refills are no longer required, and the system becomes largely independent of the global helium supply chain. These sealed, “helium-light” designs are therefore more resilient to helium shortages and rising costs, while also offering environmental benefits through reduced helium loss.

From an installation and operational perspective, low-cryogen systems offer increased flexibility. The greatly reduced helium inventory means that quench behaviour differs from that of conventional magnets, and in many designs the need for a quench pipe is eliminated, subject to the manufacturer’s safety case. This can simplify siting, particularly in constrained clinical environments or retrofit installations. Emergency procedures must be adapted to reflect the specific quench and cryogenic behaviour of sealed-magnet systems (see section 4.4.6). Low-helium/ sealed superconducting magnets are equipped with an emergency magnet-off button, designed to rapidly reduce the magnetic field to zero in the event of an emergency.

There are, however, considerations that accompany the reduced cryogen approach. Low-cryogen systems are more dependent on continuous cryocooler operation, making reliability, redundancy and service response times important factors in procurement decisions. In addition, while the term “helium-free” is sometimes used in marketing, these systems still contain helium; the distinction lies in the greatly reduced volume and sealed operation rather than complete elimination.

4.5.8 Hybrid Positron Emission Tomography-MRI (PET/MR)

PET-MR systems are used in both clinical and research settings and often involve staff not used to working within the MR ENVIRONMENT. This requires collaborative management by individuals fulfilling statutory ionising radiation roles (e.g. Radiation Protection Advisor and Medical Physics Expert) and the MR SAFETY EXPERT. It may be appropriate to put in place combined MRI and PET procedures for working within the MR CONTROLLED ACCESS AREA. A suitable safety training programme must be implemented for different staff groups to ensure adherence to MR safety and ionising radiation safety practices.

Patient MR safety screening must take place prior to injection of the required radiopharmaceutical. If a later contraindication to MRI is discovered, then the scan would not be able to proceed, and the patient would have received a dose of ionising radiation without the intended diagnostic benefit. This should be reported and assessed in accordance with local protocol and in adherence to the Ionising Radiation (Medical Exposures) Regulations 2017 [161]and the Ionising Radiation Regulations 2017 [162].

Careful consideration must also be given to the planning of PET/MR departments to ensure that the physical environment meets all safety requirements. For example, ionising radiation shielding may additionally be required within the MR CONTROLLED ACCESS AREA. Provision must also be made for staff members to monitor their hands for radioactive contamination within the MR CONTROLLED ACCESS AREA. A designated handwashing sink must also be available.

The following activities would ideally take place outside the MR CONTROLLED ACCESS AREA but remain within an ionising radiation Controlled Area:

- Receiving, checking and preparing radiopharmaceuticals for patient injection.
- Preparation of PET phantoms.
- Legally compliant routes for disposal of all radioactive waste e.g. shielded and secure storage areas in addition to patient lavatories.
- Patient changing and storage of personal items.
- An “uptake” room, where the patient would typically rest for an optimum time post-injection before proceeding with scanning.
- Secure storage for all MR **UNSAFE** items that must not enter the PET-MRI MR CONTROLLED ACCESS AREA. In all areas that form part of the PET-MRI patient pathway, the MR safety of all easily moveable equipment must be assessed, and it must be appropriately labelled.
- Final patient MR safety check prior to transit into the MR CONTROLLED ACCESS AREA.

Some radiopharmaceuticals with very short half-lives may require injection when the patient is on the PET-MR system (e.g. O^{15} with half-life of just over two minutes). This would necessitate consideration of MR CONDITIONAL syringes and syringe shields. Staff should be aware that the syringe shield may behave in an unexpected way when being moved through the static magnetic field due to the Lenz effect.

Within nuclear medicine and PET departments, radiation monitors are routinely used to assess whether radioactive contamination is present. Such measurements are typically carried out daily but would also be necessary in the event of a witnessed or suspected contamination incident e.g. radioactive patient excreta or a radioactive spill from a syringe, vial or a phantom being transported into the PET-MRI unit. Only MR CONDITIONAL radiation monitors must be used within the MR CONTROLLED ACCESS AREA.

4.5.9 Hybrid MRI-Linear Accelerator (MR-Linac)

A hybrid MRI-Linac comprises an MR system and a radiotherapy linear accelerator in a single device to deliver simultaneous imaging and treatment capabilities. The principles in section 4.5.3 on management of radiotherapy planning units apply to hybrid MRI-Linac systems. For MRI-Linac systems there is the presence of both the MRI-related hazards and ionising radiation hazards.

To accommodate the radiotherapy treatment beam, the design of the magnet, gradient coils and the RF transmit and receive coils on the MRI-Linac differ from a diagnostic system. The MR images acquired may be used to inform real time adjustments to radiotherapy delivery. As a result, specialist quality assurance of the MR system performance is recommended [163].

MR Safety Considerations

MRI-Linac staff members should have significant knowledge of the safety considerations unique to both modalities. Non-MR specialist radiographers, physicists and engineers who join MRI-Linac departments should receive sufficient MR safety training to be designated MR AUTHORISED PERSON(s).

The MRI-Linac bunker is different to the layout of diagnostic MR departments, which will inform novel emergency procedures. Specific systems of work may be needed for ferromagnetic equipment required to service the Linac part of the device to be brought through the MR ENVIRONMENT. All radiotherapy test objects should be MR SAFE or MR CONDITIONAL if used in the MR ENVIRONMENT.

Certain patient populations may be contraindicated due to the high levels of radiation during treatment delivery, for example patients who need supporting staff to be in the room during their MRI scan. Patients who visit for many fractions of treatment should have MR safety screening on every visit.

4.5.10 Veterinary

Whilst it is recognised that this guidance is primarily for usage of MRI in human patients and volunteers, MRI is widely used within the veterinary sector. This section covers extra considerations for usage of MRI in a veterinary setting.

Staff

Staff within veterinary MRI units may include but are not limited to veterinary radiographers, registered veterinary nurses, veterinary surgeons, domestic and clerical staff. Compared to usage of MRI in a human setting, greater numbers of personnel and a wider range of equipment (e.g. specialist anaesthetic equipment) will require regular access to the MR ENVIRONMENT. Roles and responsibilities of staff must be clearly identified within the Local Rules, for example, who is responsible for anaesthetic monitoring of the patient (generally the registered veterinary nurse).

Control of Electromagnetic Fields at Work Regulations (CEMFAW) Exception

The use of MRI in veterinary practice is exempt from the exposure limits in CEMFAW by virtue of an exemption identified certificate issued by the health and safety executive (HSE) under the category: "*the use of magnetic resonance imaging equipment other than for patients in the health sector*" [164]. The certificate is valid for a limited period of time, and although there is no expectation that the certificate will not continue to be renewed the onus is on employers to check that it is still in place. Users will need to comply with all other requirements of the CEMFAW Regulations, except the requirement to develop an action plan.

Screening of Veterinary Patients

Screening of veterinary patients for MR safety should be undertaken in accordance with local procedures to identify the presence of any passive or active implanted medical devices. Compared to human scanning where extensive testing of both passive and active implanted devices has been undertaken by manufacturers, there is little evidence of similar testing in animals. Therefore, scanning of the majority of implants in veterinary MRI will be classed as off label.

Active implants such as radiofrequency microchip identification tags often implanted in veterinary patients have been shown safe to scan up to 3 T in two studies, although they have been shown to produce signal void artefacts [165,166], due to their widespread use these are not routinely screened for in veterinary MRI. Whilst rare, it is important to note that other active implants such as pacemakers are in use in the veterinary sector, often these devices are donated after death from humans and therefore MRI conditions could be established for these devices. Passive implants such as orthopaedic metal work may also be present. Veterinary patients with passive or active implants should undergo a risk benefit analysis before proceeding with MRI.

Anaesthetic Requirements

Veterinary patients are highly likely to be anaesthetised during the MRI, as such they will require close monitoring and management. Section 5.6 covers general guidance on safe use of anaesthesia in MRI, principles outlined in 5.6 are also applicable in veterinary practice.

Radiofrequency Exposure

Weight and height of veterinary patients vary significantly within and between species. Therefore, care should be paid in the management of radiofrequency exposure during MRI. For veterinary patients, no safety limits have been established for SAR and modelling of SAR is based on human patients. Care should be taken to ensure that SAR is as low as reasonably possible whilst maintaining the required image quality. Consideration should also be paid to the positioning of the patient, to avoid formation of conductive loops which have been shown to contribute to burns in veterinary patients undergoing MRI [167]. The system manufacturer should be consulted if there are difficulties ensuring radiofrequency exposure is kept to an acceptable level.

4.5.11 Remote Scanning

Remote MR scanning encompasses a range of models, including remote protocol planning and optimisation, real-time training of on-site radiographers, hub-and-spoke command centre support for multiple systems, and full remote console control in which a remote MR RADIOGRAPHER performs the scan while on-site staff maintain direct patient care. These models do not change the underlying MRI

hazards; instead, they redistribute who controls the risks and how safety-critical information is communicated. The standard of safety for patients and staff must be at least equivalent to conventional on-site scanning.

Safe implementation requires clearly defined governance including:

- Defined roles and responsibilities with clear designation of who holds final decision-making authority in real time
- Robust local policies and standard operating procedures (SOPs) for remote scanning
- Documented training and competency requirements for both remote and on-site staff aligned with existing MR safety frameworks
- Clear emergency procedures, including roles and actions for both remote and on-site staff

Services should ensure reliable two-way audio-visual communication between remote and on-site staff, safety time-outs, checklists and escalation pathways, and defined minimum technical and cybersecurity requirements (authentication, data protection, connection resilience and fail-safe procedures for loss of communication or control). The remote MR RADIOGRAPHER should also be able to view the patient in the bore.

The remote MR RADIOGRAPHER must be trained to the level of an MR AUTHORISED PERSON (SUPERVISOR) and MR OPERATOR. On-site there should be a minimum of two people (see section 4.3.4) per MR system and at least one person must be trained to the levels of an MR AUTHORISED PERSON (SUPERVISOR) and MR OPERATOR.

Patient selection criteria should ensure that higher-risk or complex cases are managed under conventional on-site workflows. Adverse incidents, near misses and technical interruptions should be captured within existing clinical governance and audit systems to demonstrate that remote MRI services remain at least as safe and effective as traditional on-site scanning.

The Society of Radiographers (SoR) has published a position statement [168] and guiding principles for implementation [169].

5 Management of Patients and Volunteers

5.1 MRI Patient Referrals

MRI referrals for diagnostic studies 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. Training recommendations for referrers are discussed in Appendix 3.

The referral process must ask specific MRI questions to find patients with possible contraindications. Examples of suitable questions can be found in the Royal College of Radiologists publication on implementing order communications [170]. Referrers should provide accurate information and identify any implanted medical devices for the patient they are referring. This allows the MRI unit to identify potential contraindications to MRI and to determine the MR safety status of any devices before the patient attends for their appointment.

The MR CLINICIAN should be fully informed regarding the patient's state of health and relevant medical history when accepting requests for scans and takes overall responsibility for patient safety.

Patients should be exposed only with the approval of a registered practitioner who should be satisfied that the exposure is likely to contribute to the treatment of the patient. For exposures as part of research the registered practitioner should be satisfied that this has been approved by a research ethics committee.

Referrals should be made in a form that allows provision of MRI screening questions. Audit of the referral process can ensure questions are appropriately completed.

Referrers should receive sufficient MR safety training to be able to fulfil their role in the screening process (training recommendations are in Appendix 3).

Patients should be exposed only with the approval of a registered practitioner who should be satisfied that the exposure is likely to contribute to the treatment of the patient.

5.2 Volunteer Scanning

All volunteers, including staff participating in experimental trials of MRI diagnostic equipment, in-house testing of sequences, quality assurance and protocol validation, should have relevant MR safety screening before exposure (see section 5.3.4). Volunteers should be consented and fully informed [171].

Volunteers engaged for in-house testing of sequences, quality assurance, protocol development and validation should be managed through established local clinical governance procedures including for the reporting of incidental imaging findings [172,173].

Volunteers taking part in trials over a period of time with repeated exposures should be re-screened for safety.

Local policies should clearly state which people should be excluded as volunteers, for example women who are or may be pregnant and persons under 18 years of age (unless the trial is specific to pregnancy or paediatric imaging).

For research, a favourable opinion should be obtained from the relevant research ethics committee; this should normally be a committee recognised by the UK Health Departments under the Governance Arrangements for Research Ethics Committees (GAfREC) [174,175], but may be a delegated committee from such, or an institutional (university or other) convened ethics committee.

Following advice from the National Research Ethics Service (NRES), it should be noted that under the Research Governance Framework for Health and Social Care, experimental procedures require ethical review where they are to be carried out in the formal research setting and managed as research.

If undertaken outside the research setting (e.g. in house validation, QA), ethical review and research and development approval would not be required, although many NHS organisations have clinical ethics committees that would be a suitable source of advice. For those not scanned under ethics, an appropriate policy should be in place and approved through local governance arrangements.

The ethical issues arising from incidental findings during imaging research were discussed at a meeting initiated and organised by the RCR and the SINAPSE Collaboration held at the Wellcome Trust in 2010. This is a complex area, and researchers should review the report 'Management of Incidental Findings Detected During Research Imaging' [173]. The principles in this report should also apply to volunteers for quality assurance and clinical protocol development.

It is recommended that MRI units establish a policy for volunteer scanning, including the circumstances in which formal reporting of images is required for incidental abnormalities or findings, how these are communicated to the volunteer and how onward referral to an appropriate specialist for advice is handled when necessary.

5.3 Scan Preparation

5.3.1 Patient Identification

There must 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/Welsh is not their first language. Further guidance is available from the Society of Radiographers [176].

Sites must have a robust policy to ensure that the correct patient is identified.

5.3.2 Patient Measurement

MR systems typically require patient height and/or weight to be input for SAR calculations. Facilities should be available to allow these to be routinely measured in the department. It is important that current measurements are used at the time of scanning for the MRI equipment to accurately predict the SAR levels to which the patient will be exposed, and these should be recorded as part of the patient record.

MRI units should have facilities to measure the patient weight and height if required for system SAR predictions.

5.3.3 Availability of Previous Examinations

It is advisable that there is a process in place whereby images and reports of any relevant previous imaging examinations undertaken at the local institute are available before the MRI examination. This can aid with investigating the safety of implants. For some patients their medical records or notes will also be required.

5.3.4 Screening Prior to Examination

Where possible, it is recommended that a four-stage screening process is adopted for patients, as shown in Figure 5.

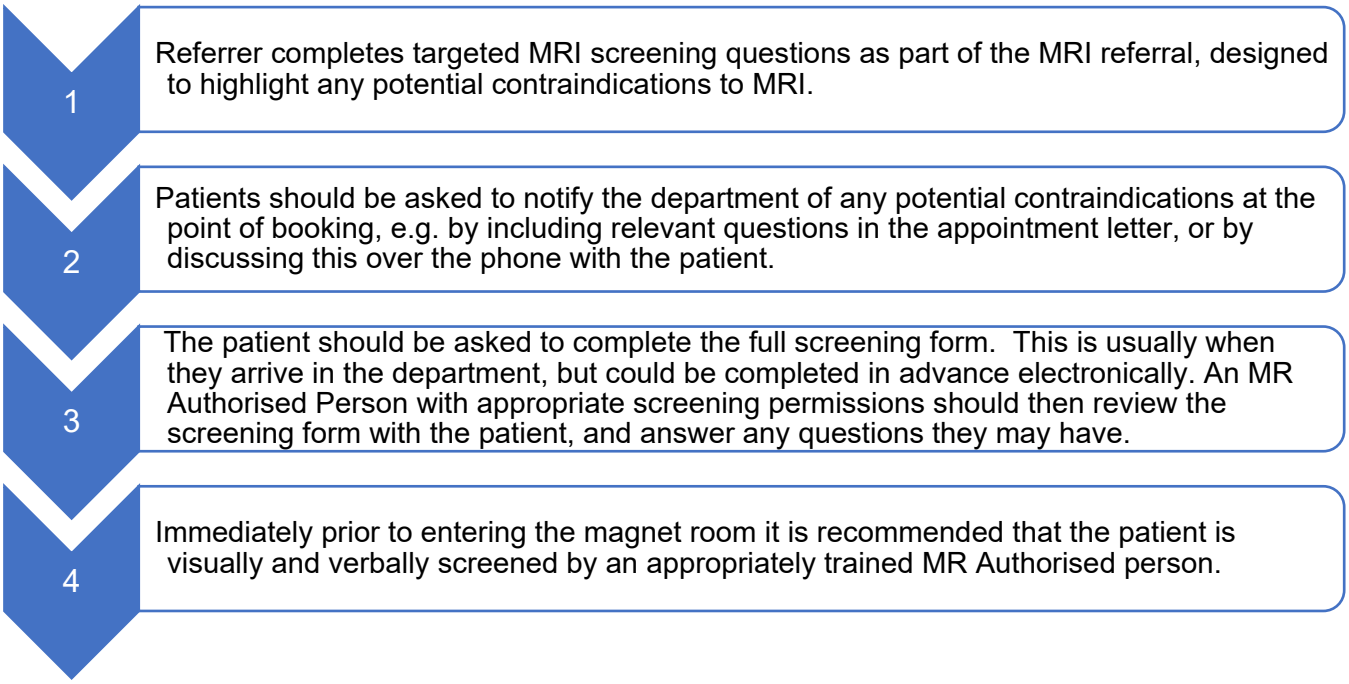


Figure 5. Example workflow for MR safety screening

All patients and family members/carers must undergo MR safety screening prior to entering the MR CONTROLLED ACCESS AREA, regardless of whether they plan to enter the MR ENVIRONMENT itself.

Screening must be performed by an MR AUTHORISED PERSON (SUPERVISOR). Section 4.3.1. provides additional information on the screening rights of authorised persons, and Appendix 3 details the training required. Any questions or doubts about the suitability of the patient for MRI should be referred to the MR RESPONSIBLE PERSON in the first instance and further assistance may be provided by the MR SAFETY EXPERT. The outcome of this discussion must be documented.

The screening form should be signed by the patient, verified, and then countersigned by an MR AUTHORISED PERSON (SUPERVISOR) before entry to the MR ENVIRONMENT is permitted. This process should be subject to regular audit, to ensure that screening is being undertaken correctly. Examples of screening forms are available from the BAMRR [177]and MR safety websites [178].

✓ MRI units should regularly audit their screening process and form(s).

Screening must take place every time the patient attends the MRI unit, even if the patient has already had a previous MRI examination either locally or at another facility.

The importance of providing accurate and complete information during screening should be highlighted to the patient. This is particularly important for patients who may not wish to declare concealed items which could then pose a safety risk to both patient and staff, e.g. prisoners.

If a patient is to undergo sedation or anaesthesia for the scan, all required safety screening should be completed prior to its administration.

The MR RADIOGRAPHER will remain responsible for the health and safety of the patient throughout the exposure. Only personnel that have been trained and are competent in the use of the MRI equipment should scan patients. Further information on staff training is provided in Appendix 3.

In cases where a different radiology staff member may have undertaken the written screening, the scanning radiographer should be aware of the outcome and should satisfy themselves that there are no contraindications and of any potential issues prior to the patient entering the MR ENVIRONMENT.

Screening Patients Unable to Complete the Screening Form

A procedure should be in place for scanning patients who are unable to complete the safety screening form, either because they are unconscious, have a mental health condition, learning disability, unable to

communicate or otherwise lacking the capacity. A number of approaches should be considered to ensure reliable safety information is obtained. These can include:

- Having a family member or guardian provide a medical history and complete the MR screening form on the patient's behalf. If no family member with sufficient knowledge of the patient's medical history is contactable and the scan is not immediately urgent, the scan should be rebooked for a time when a family member will be available to complete the screening form.
- Identifying the medical history and any implants from the patient's medical records where available. If the scan is not urgent, then the patient's GP records can also be a useful record of past medical history.
- A review of previous imaging to identify implants [179].
- Obtaining x-ray images to rule out the presence of high-risk implants and foreign bodies.
- Checking the patient for scars which may indicate the presence of an implant.

The referring clinician should be responsible for obtaining the necessary additional information regarding potential implants which may contraindicate the scan. It may be useful to have a specific screening form for this.

Any cases where the patient history remains unclear should be discussed with a consultant MR CLINICIAN and a risk benefit analysis, in consultation with the MR SAFETY EXPERT where required, should be undertaken before proceeding with the MR examination.

Screening of patients communicating in other languages

A policy should be in place that describes the process to follow for the screening of patients communicating in other languages. This should include consideration of those requiring accessible or alternative communication formats. The screening form may be completed with a relative or friend of the patient, a departmental approved translator, a translator/language phoneline service or a member of staff as translator, depending on local policy. It is essential that the MR AUTHORISED PERSON (SUPERVISOR) is confident that true patient consent has been received and that the questions have been interpreted correctly, e.g. the translator must demonstrate understanding of MRI and terms like pacemaker and aneurysm clips. If necessary, the scan should be rebooked for a time when a suitable translator is available.

Welsh patients have a statutory right to receive healthcare services in their preferred language (Welsh Language Standards [180]. For example, any patient documentation in Wales (e.g. screening forms, patient information sheets, patient consent forms) should be readily available in both English and Welsh.

Sites should have a robust safety screening process, with multiple opportunities for contraindications to be identified prior to the patient entering the MR ENVIRONMENT. This procedure should include patients who are unable to complete the screening form.

5.3.5 Patient Clothing

Scanning patients wearing fabrics containing conductive fibres or anti-microbial treatments has resulted in image artefacts, and patient burns [181]. Consideration should be given to ensuring that clothing does not inhibit heat loss or conceal a metallic item that could heat up or become a projectile. Sites should develop a local policy to ensure that patient clothing is safe. This may include changing the patient into suitable clothing provided by the MRI unit.

Patients should be scanned in appropriate MR SAFE clothing. Ideally, patients should be changed into clothing provided by the MRI unit to minimise the risk of burns.

5.3.6 Patient Comfort and Reassurance

Information on what the MRI procedure entails should be made available to all patients in advance of the scan whenever possible.

A suitable MR AUTHORISED PERSON (SUPERVISOR) MR RESPONSIBLE 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 duration of the examination.

Steps should be taken to ensure that the patient is positioned comfortably, e.g. using pillows and leg support. Time taken to ensure that the patient is comfortable will lead to greater patient compliance with the scan.

A two-way intercom between operator and patient is required. The system may additionally allow recorded music or narrative of the patient's choice via a suitable audio system interface.

A staff call button, often referred to as a squeeze ball should be given to the patients so that they can attract the attention of staff when they are in the magnet. The device should be given to patients with an explanation of its intended use and tested before each examination starts.

Adequate lighting and ventilation inside the magnet 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 able to see any signs of discomfort or concern exhibited by the patient.

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.

An accompanying relative or attendant, screened, checked and authorised, may be allowed to remain in the MR examination room in verbal and, if necessary, physical contact with the patient.

The MR OPERATOR must be able to maintain visual and audio contact with the patient throughout the scan. If the MR OPERATOR needs to leave the control room whilst the patient is on the table, another MR OPERATOR, must be identified to take over for as long as required.

The MR OPERATOR should maintain regular communication with the patient, wherever possible. A two-way intercom between operator and patient is required and should be tested before the exam starts to reassure the patient that they can hear the operator and that the operator can hear them.

5.3.7 Patient Burns

Patient burns are commonly reported to the MHRA and can be caused by implanted devices, metal in clothing, medicinal patches, and contact with the magnet bore, cables, leads and sensors. Burns may not be painful immediately, because tissue damage can begin at temperatures as low as 43°C [182]. It is normal for patients to experience mild general heating during an MRI scan. However, patients should be instructed to inform staff immediately if they feel any focal warming or tingling on their skin.

Any patient burns must be reported via local incident reporting systems, and also to the MHRA. All sites should have a locally developed procedure for managing patients with burns or potential burns. BAMRR guidance may be a useful resource but should be used in conjunction with local expertise [183]. Departments should also consider providing patients with an after-care leaflet as it is possible that a burn may develop after the patient has left the department.

To avoid burns caused by RF heating [184]:

- Ensure that the patient's skin does not touch the bore of the magnet.
- Ensure that sufficient padding is placed between the patient and the magnet bore or receive coil cable if contact cannot be avoided. Use padding such as the thick insulating pads provided by the MR vendor if necessary.
- Do not loop conductive cables/wires or allow them to cross one another.
- Do not pass cables or wires diagonally across the patient.
- Ensure that no conductive loops form with any parts of the patient's body, i.e. avoid skin-to-skin contact. Manufacturer advised thick insulating pads should be used to avoid this, e.g. between the thighs, arms, legs, etc to avoid the formation of any conductive loops.

- Ensure that regular checks for damage are made on all coils, cables and leads and do not use if damage is seen.
- Ensure that operators are familiar with and follow the system manufacturer's instructions at all times.
- Ensure only MR CONDITIONAL monitoring equipment, ECG electrodes, leads and accessories are used, and that conditions for use are followed.

✓ Thick insulating pads should be used to protect the patient from cables, transmitting RF elements, the bore and between limbs. The manufacturer will advise the minimum thickness required for these. The use of clothing or blankets as a form of insulation is often not sufficient.

✓ All sites should have a procedure in place for assessing and treating burns, or potential burns.

5.3.8 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.

Patients with certain medical disorders or under medication may be at some risk when scanning above normal operating mode. In particular, patients with compromised thermoregulatory function may be particularly susceptible to RF heating.

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

The prevailing ambient conditions surrounding the patient and volunteer such as temperature, humidity and airflow will affect the rate of cooling of the individual and should also be considered

5.3.9 Acoustic Noise

Patients should be clearly warned that they may be exposed to high levels of noise. In certain patient groups, such as infants and those with an increased sensitivity to noise, steps should be taken to reduce the audible noise to a minimum.

Anyone remaining in the MR examination room during scanning, such as staff and accompanying visitors, must also wear suitable hearing protection (see section 3.3.5) [185].

Staff should be trained in the selection and fitting of hearing protection.

Manufacturers should specify the noise level for normal operation of the equipment, but sites must carry out their own risk assessments related to acoustic noise exposure [185].

Sites should have procedures in place to advise patients on appropriate follow up if hearing impairment is reported after the scan. Any such incidents should be reported via the local incident reporting system, and also to the MHRA.

✓ All patients and volunteers being scanned should wear suitable hearing protection. The fit and function of hearing protection should always be verified before commencing scans. Ear plugs with sufficient single number rating (SNR) or noise reduction rating (NRR) to meet manufacturer's requirements should be used for all patients/volunteers and alternative hearing protection methods should be in place for neonates, e.g. MiniMuffs. The headphones provided by the system manufacturer often do not provide sufficient protection and therefore may not be relied on as the only hearing protection method.

✓ All sites should have a procedure in place for appropriate follow up of patients who may have experienced hearing impairment.

5.3.10 Physiological Patient Monitoring

For patients who are at clinical risk, e.g. unstable, anaesthetised, or sedated, monitoring is required. Monitoring may also be required when scanning patients with specific implants, e.g., cardiac implantable electronic devices [186], and for scans which require cardiac gating.

All monitoring should be undertaken using dedicated MR SAFE or MR CONDITIONAL equipment, e.g., the use of high impedance leads. Care must be taken with the placement of all leads, electrodes and sensors (see section 5.3.7). There have been adverse incidents reported where devices have become hot enough to cause severe burns due to the heating effect of the radiofrequency (B_1) field.

During ECG monitoring in MRI, movement of blood, which is a conducting fluid, through the static magnetic field induces an additional voltage superimposed on the ECG at the time of the T-wave (ventricular repolarisation). This change in ECG trace represents an electrical artefact and is not a direct indication of a change in cardiac health or function. However, it does mean that subtle ECG changes, e.g. ST-segment variations, may not be detectable. It is therefore not possible to obtain a physiologically accurate ECG from within an MR system.

Most MR systems also provide the option to monitor the patient's heart rate and to trigger MRI acquisitions using photoplethysmography (PPG). This device simply measures the change in blood volume in an extremity and is not a replacement for an MR SAFE or MR CONDITIONAL pulse oximeter which measures blood oxygen saturation level (SpO2) as well as heart rate.

Patients who are being monitored must be advised to inform staff immediately if warming or discomfort is felt at the sensor site. Unconscious or sedated patients must be carefully checked to ensure that they do not have any MR **UNSAFE** electrodes, leads or devices about their person prior to entering the MR ENVIRONMENT.

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

✓ Sites should ensure that MR SAFE or MR CONDITIONAL monitoring equipment is available for use in patients who require it.

5.3.11 Final Pause and Check

It is good practice to introduce a final pause and check before taking the patient into the MR ENVIRONMENT to ensure all necessary screening and safety checks have been completed [187]. This is particularly important for complex patients, such as those that are anaesthetised. For these patients a dedicated checklist should be considered.

✓ A final pause and check should be performed before entering the MR ENVIRONMENT. For anaesthetised patients a dedicated checklist is recommended before taking the patient into the MR ENVIRONMENT.

5.4 Records and Image Archiving

Relevant imaging records must be stored electronically. This should include a copy of the patient/volunteer screening form. Images should be stored appropriately, with essential imaging parameters forming part of the DICOM image header. Details of any exogenous contrast administered should also be recorded (see section 5.7).

This information will form part of the patient notes and should be held securely for a period that ensures compliance with the current guidance from the Department of Health and Social Care [188].

Where personal information is held at the unit it should be held securely and treated in accordance with the UK General Data Protection Regulations (UK GDPR) [152].

✓ Records of screening and imaging performed must be stored for each patient or volunteer in accordance with the UK GDPR.

5.5 Implanted Medical Devices and Other Potential Contraindications to Scanning

5.5.1 Implanted Medical Devices

Implantable medical devices fall into two main categories:

- **Active implantable medical devices (AIMDs) and active body-worn medical devices.** These have a functionality which is dependent upon an energy source such as electrical, mechanical, magnetic or pneumatic power. For example: cardiac implantable electrical devices (CIEDs), deep brain stimulators (DBS), spinal cord stimulators (SCS) and other stimulators, cochlear implants, intracranial pressure (ICP) monitors, drug infusion pumps and continuous glucose monitors.
- **Non-active/passive implantable medical devices.** These require no power source for their function. For example: hip/knee joint replacements, heart valves, aneurysm clips, shunts, coronary stents and breast implants.

The hazards associated with MRI scans in patients with implanted medical devices have already been discussed in Chapter 2.5. Several serious incidents highlight the importance of establishing implant safety prior to MRI scanning [189,190,191].

Surgeons and other medical practitioners should provide patients with accurate documentation and information about the medical devices implanted into them, for example, providing them with an implant card and patient information provided by the implant manufacturer.

The make and model of all implanted devices should also be documented clearly in electronic operation notes that will be accessible to those involved in MRI screening.

Information pertaining to implantable medical devices should be available before the patient attends their examination to allow time to confirm the MR safety status of the device.

5.5.2 Managing Patients with Implants

Sites must establish a procedure for managing patients with implants. An example safety procedure is shown in Figure 6.

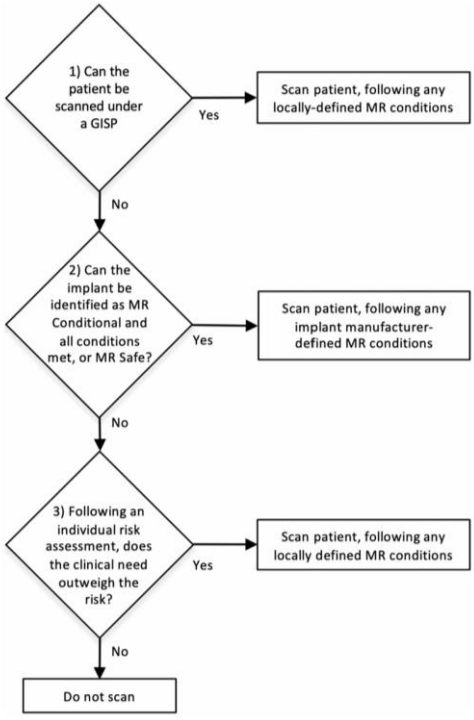


Figure 6. Example workflow for clinical MRI patients highlighting how implants should be managed, including how generic implant safety procedures (GISPs) fit into the safety process. From [192].

It is recommended that sites establish local generic implant safety procedures (GISPs) to allow scanning of low-risk implants without needing to establish the make and model. It is essential that any local GISPs are formally approved and managed within the local institution's governance framework. Further guidance on establishing local GISPs is provided in [192]. The Institute of Physics and Engineering in Medicine (IPEM) hosts information on UK GISPs [193]. The information contained in these can be useful to support the implementation of local GISPs.

Where a local GISP does not exist, sites should have a process for identifying the make and model of the implant. Guidance can then be sought from the manufacturer as to the safety status of the implant, and any conditions that should be followed to allow safe scanning. If this cannot be determined or there is an urgent requirement for the MRI, then an off-label procedure may be followed.

Specific implant safety information is not provided here, as this can be a rapidly changing field. Instead, it is recommended that sites refer to the latest professional body guidance, where this is available, for example:

- Joint British Society consensus recommendations for MRI for patients with cardiac implantable devices [186].
- British Cochlear Implant Group [194].

Sites should establish a procedure for managing patients with implants and other metallic devices and objects. This should include the identification, documentation, imaging and provision of any necessary aftercare for patients with implantable medical devices undergoing an MRI examination.

It is recommended that sites establish local generic implant safety procedures (GISPs) to allow scanning of low-risk implants without needing to establish the make and model. These should be developed and managed under local governance processes.

Caution is advised regarding use of MR safety advice obtained using generative artificial intelligence

5.5.3 Managing Patients with Devices of Unknown MR Safety Status and Off-Label Scenarios

There may be a need to perform an MRI examination in the following scenarios:

- the patient has an MR CONDITIONAL device, but one or more MR Conditions cannot be met
- the patient is implanted with a device labelled as MR **UNSAFE**
- the patient has a device whose MR safety status is unknown, e.g., because the make and model of the device is unknown.
- the patient has an MR UNLABELLED implanted device.

If the benefit to the patient of this off-label procedure outweighs the potential risk, then scanning can be undertaken. Sites should develop local processes for scanning in these situations [195]. The following should be documented and available before the scan:

A multidisciplinary team (MDT) should undertake a risk assessment. As a minimum this should involve an MR RADIOGRAPHER, an MR SAFETY EXPERT and the MR CLINICIAN. It may be appropriate to also include a relevant specialist clinician (e.g. a cardiologist for advice regarding a CIED). The referring clinician is required to provide sufficient information to allow the MDT to perform the risk assessment. The following should be considered:

- Whether the scan has the potential to change patient management.
- Alternative imaging modalities/other diagnostic tests.
- The risks regarding onwards clinical management if a decision is made not to perform the MRI.

        - Scanning on an MR system with lower static and/or gradient fields, which may require referral to other centres if not available locally.
        - Advice from the implant manufacturer.
        - Available Professional Body recommendations.
        - Published evidence of scanning the device.
        - Assessment of possible artefacts, and the impact they will have on diagnostic performance.
    - Identification and implementation of precautions to minimise the risk. The following should be considered:
        - Appropriate programming of the device.
        - Suitable monitoring (e.g. SAR/$B_1{}^+_{RMS}$ levels, physiological signals) during the scan. Physiological monitoring may require additional suitably trained personnel to operate and/or interpret the results.
        - SAR/$B_1{}^+_{RMS}$ exposure including consideration of methods to reduce it, e.g. reduced flip angles, longer TRs, use of transmit/receive coils.
        - Patient positioning in the system.
        - The need to move the patient slowly into the bore of the magnet. This allows the patient to communicate whether they can feel any pain or discomfort.
    - Provision of procedures to ensure that a suitable clinician is available and in the department at the time of the scan, e.g. for CIEDs, a cardiologist or cardiac physiologist.
    - Post scan evaluation of the patient and where relevant, evaluation of the implanted device.

The MR CLINICIAN ultimately takes responsibility for the decision of whether to proceed with the scan. Consideration should be given to what level of patient consent should be obtained for the procedure, and who is the most suitable person to consent the patient.

MRI unit staff should not feel pressured into adopting the above procedure if they do not have the skills, experience, staff and support available to them, e.g. mobile units. It may be appropriate for such units to refer a particular patient to another MRI unit with experience in either scanning the device/implant or in the general application of the above procedure. Sites that do not currently have expertise in scanning patients with complex implants are encouraged to work with an MR SAFETY EXPERT to develop local procedures to allow patients to access MRI.

Sites should develop local processes for scanning off-label and where the MR safety status of an implant is unknown. This should include a multidisciplinary team (MR RADIOGRAPHER, MR SAFETY EXPERT and MR CLINICIAN) risk assessment, risk minimisation strategies, support from relevant clinicians and post scan evaluation of the patient.

5.5.4 Other Potential Contraindications to MRI

Other potential contraindications to MRI include skin patches, tattoos, makeup, piercings, hair extensions and jewellery. Sites must establish a local procedure for managing these patients. These procedures must be reviewed and audited at regular periods by the MR RESPONSIBLE PERSON in consultation with the MR SAFETY EXPERT.

It is recommended that anything that is removable should be removed prior to entering the MR ENVIRONMENT where it is safe to do so. A single metallic item that is less than 2 cm in size in all dimensions is not expected to be a heating concern, unless it is within 3 cm of another metallic item [196]. Consideration should be given to what level of patient consent should be obtained for the procedure, and who is the most suitable person to consent the patient.

Transdermal Patches

Burns due to the presence of metallic components in medicinal patches have been reported to the MHRA. For example, patches containing fentanyl may result in a serious overdose if exposed to heat [197]. Sites should have a documented process for the removal and reapplication/disposal of patches.

Tattoos

Patients with tattoos should be advised to immediately report any warming or tingling around the tattoo during scanning. Particular attention should be paid to tattoos within the field of view for scanning.

Makeup

Permanent and semi-permanent make-up (such as micro-bladed eyebrows) may cause local artefacts and potentially heating. Patients should be advised to notify the MR OPERATOR in case of any discomfort or tingling near to these during the scan.

Piercings

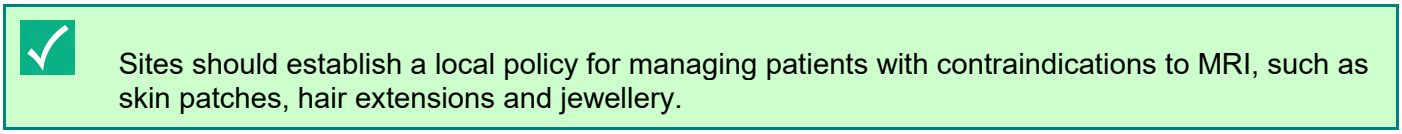
If a patient cannot remove a piercing, it should be tested with a handheld magnet to ensure that it is not ferromagnetic before entering the MR ENVIRONMENT. Single piercings less than 2 cm in all dimensions, are not considered to present a risk of RF heating, unless they are within 3 cm of another metallic object [196]. If a patient has larger piercings or several piercings close together in the field of view, there is a risk of heating, and steps should be taken to mitigate these.

Hair Extensions

Some hair extensions contain metal and therefore should be tested with a hand-held test magnet to ensure that they are not ferromagnetic, before entering the MR ENVIRONMENT. Consideration should also be given to the risk of heating.

Jewellery

All jewellery should be removed, where possible. If jewellery cannot be removed, then a risk assessment should be completed.



Sites should establish a local policy for managing patients with contraindications to MRI, such as skin patches, hair extensions and jewellery.

5.5.5 Metallic Foreign Bodies

The presence of metallic objects such as bullets, pellets, shrapnel and broken needles can be a hazard in MRI. This is also of relevance to patients who are or have been involved in metalworking. Depending on the size and material, any retained metallic foreign bodies may move or become dislodged if exposed to the spatial gradient of the static magnetic field. 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.

Any embedded metal fragments of less than 2 cm in size in all dimensions are not considered to present a risk of RF heating, unless they are within 3 cm of another metallic object [196].

One of the most vulnerable parts of the body is the eye. The adequate screening of patients and others with suspected intra-ocular ferromagnetic foreign bodies (IOFBs) is particularly important before they are allowed to enter the MR ENVIRONMENT [198].

For foreign bodies, an X-ray or low dose CT may be required to confirm the presence, location and size of any metal fragments. Sites should develop local policies for identifying and managing individuals at risk. This may include the use of hand-held test magnets to test superficial foreign bodies (see section 4.2.2), and the role that radiologists play in identifying sensitive structures near to the foreign body. An example flowchart for the identification of IOFBs is given by the Society of Radiographers [199].

Sites should establish a local policy for managing patients with metallic foreign bodies.

5.5.6 Unexpected Metal Artefact on MRI

Despite completing rigorous safety screening, it may be possible that an unexpected metal artefact is observed during scanning. The source of this could, for example, be an external metallic object, implanted medical device or foreign body, or something within the patient's clothing.

If this happens, the scan should be paused whilst the cause of the artefact is investigated. Sites should have local policies in place to advise next steps. This may include consultation with an MR SAFETY EXPERT, alongside consideration of:

- Confirmation of whether any patient harm has already occurred, and the need for urgent medical attention.

- Identification of the source of the artefact, e.g., from speaking to the patient or through identification from previous imaging
- Consideration of the ferromagnetic (or non-ferromagnetic) nature of the artefact.
- Removal of any external metallic objects, remembering that if these are ferromagnetic, they could pose a projectile risk when moved in proximity to the magnet.
- Establishing the safety status of any undeclared implanted medical devices.
- Whether it is safe to proceed with the scan, or whether the scan should be terminated.
- Careful removal of the patient from the MR ENVIRONMENT. The approach must minimise the risk of injury from dislodgement/movement of the metallic object as the patient transits through the spatial field gradient (i.e. ensure the patient remains in the same position and does not sit up until they have been fully removed from the bore of the magnet).
- Incident documentation and reporting.
- Clinical follow-up of the patient.

5.6 Anaesthesia

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

A nominated consultant anaesthetist should lead and be responsible for anaesthesia services in MRI units. During anaesthetic sessions in the MR ENVIRONMENT, decisions regarding the MR safety of patient implants/devices and accompanying equipment must continue to be made by an MR AUTHORISED PERSON (SUPERVISOR). A consultant anaesthetist should be involved in the design and planning of new MRI units. This should include necessary air changes and supply of anaesthetic gases.

Adequate space should be made available for the provision of anaesthesia services. The anaesthetic preparation and recovery area should be the minimum practicable distance from the MR examination room, and its location should be agreed with anaesthetics considering the potential need for emergency evacuation to that area from the MR examination room in the event of an emergency. Resuscitation should not normally take place within the MR examination room. However, there are circumstances in which resuscitation can be undertaken in the MR ENVIRONMENT under carefully controlled conditions, e.g., during combined X-ray and MRI interventional procedures in XMR suites.

A remote monitoring facility should be available to allow the anaesthetic team to remain outside the MR examination 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 (usually the radiographer responsible for the session).

The Association of Anaesthetists and the Neuro Anaesthesia and Critical Care Society of Great Britain and Ireland have published guidelines specific to MR [200]. It is recommended that they be read in conjunction with this document and referred to in planning.

5.6.1 Patient Preparation

Patients should be prepared in a side room outside the MR ENVIRONMENT and items can only be brought into the MR ENVIRONMENT if they are labelled as MR SAFE or MR CONDITIONAL and conditions can be met. 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 physiological monitoring are essential.

5.6.2 Equipment

All anaesthetic equipment required to enter the MR ENVIRONMENT must be MR SAFE or MR CONDITIONAL The hazards associated with using the wrong equipment include the projectile effect, burns and equipment malfunction. Funding for dedicated MR SAFE or MR CONDITIONAL equipment should be sought during the planning phase.

The need for acoustic protection during MR imaging might make audible alarms unsuitable. Clear visible alarms should be provided on all monitors when the anaesthetist is in the MR examination room with the patient. Anaesthetists remaining in the control room should ideally have an unobstructed view of the

remote monitor, anaesthetic machine and patient throughout the scan, although if a remote monitor fully replicates the information on the anaesthetic machine, then this is acceptable.

5.6.3 The Supply of Gases

Piped oxygen and suction will be required in the anaesthetic room, the MR examination room and the recovery area. Only MR SAFE or MR CONDITIONAL cylinders can be taken into the MR ENVIRONMENT, and any backup oxygen cylinder on the anaesthetic machine must also be MR SAFE or MR CONDITIONAL. A process should be in place to manage oxygen cylinders which are regularly changed ensuring the risk of hazardous cylinders being taken into the MR ENVIRONMENT is minimised.

Where users are unsure of the safety of gas cylinders, they should be checked with a hand-held test magnet or ferromagnetic detector before being allowed into the MR CONTROLLED ACCESS AREA. This should include all associated valves, regulators and keys.

5.6.4 Appropriate Training

An anaesthetist trained and experienced in administration of anaesthesia for MRI and 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. Screening and training should be formalised and documented for all anaesthetic team members who are required to enter the MR ENVIRONMENT as part of their clinical duties. It is not acceptable for inexperienced staff, unfamiliar with the MR ENVIRONMENT and safety issues including cardiac arrest procedures, to manage a patient in this environment, particularly out-of-hours. Other support staff who are required during an anaesthetic procedure, e.g. operating department practitioners (ODPs), should also be adequately trained and aware of the safety risks associated with MRI. This does not negate the requirement for supervision by an MR AUTHORISED PERSON (SUPERVISOR).

MR safety incidents are more likely to involve staff who do not routinely work in the MRI department as they are less familiar with the strict vigilance required to maintain MR safety. Heightened vigilance by the MR AUTHORISED PERSON (SUPERVISOR) is essential.

5.7 Contrast Agents and Other Drugs (Anti-Spasmodics, Vasodilators etc.)

5.7.1 Supervision

The administration of contrast agents and other drugs to patients undergoing MRI must be under either a prescription, a Patient Specific Direction (PSD) or a Patient Group Direction (PGD) [201,202].

Current regulations allow that some drugs and most contrast agents may be administered by non-medical practitioners under a PGD or PSD. PGDs can only be used by certain registered and regulated health care professionals. Support staff can use PSDs but not PGDs.

For units operating with a remote radiologist, advice is given in RCR/SoR guidance [203].

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

5.7.2 Contraindications and Cautions to Administration of Contrast Agents and Other Drugs

Prior to administration, care should be taken to ensure that there are no contraindications relating to administration of the contrast agent or other drug to the patient. MRI units should have local policies relating to those patients who are at higher risk including:

- Anyone that has previously had a relevant allergic reaction
- Anyone with relevant cardiac conditions
- Anyone with renal impairment
- Anyone who is or may be pregnant
- Children and neonates

Further guidance is available from The Royal College of Radiologists [204].

Breastfeeding can usually continue after contrast administration, with further guidance available from the Society of Radiographers, Royal College of Radiologists and the Breastfeeding Network [204,205,206].

The MRI unit must have readily available drugs and equipment to deal with all possible reactions including anaphylactic shock and MRI unit personnel should be trained and regularly updated in resuscitation procedures [204].

Trace amounts of gadolinium containing contrast agents (GBCAs) have been shown to be retained in the body for all patients in whom they are administered, regardless of kidney function. There is no evidence of adverse consequences to this in the populations exposed [204,207]. Nevertheless, under the precautionary principle the minimum dose required for a diagnostic examination should always be used based upon patient size and image protocol. This is particularly important in younger patients and other groups where multiple examinations requiring contrast are likely to be required over time.

5.7.3 Injection of Contrast Agents

If injection of contrast agents takes place in the MR ENVIRONMENT attention must be paid to the use of only dedicated MR SAFE or MR CONDITIONAL devices. Funding for appropriate power injectors should be considered during the planning phase.

Records of Administration

Full details of the contrast agent administered must be recorded in the patient record, including:

- Name of the administrator
- Name of the contrast agent
- Manufacturer
- Batch number
- Quantity administered
- Method and site of administration

This data should be in a form from which full details of cumulative dose can be retrieved if required in the future.

Adverse Events

Suspected adverse drug reactions should be reported to the MHRA online at Yellow Card.

5.8 Incidents, Near Misses and National Reporting Taxonomy

An appropriate electronic system (for example, Datix or Radar) should be in place to support the reporting, management, and follow-up of incidents and near misses. Incidents should be reviewed at the MR SAFETY COMMITTEE to support structured analysis, identification of root causes, and dissemination of lessons learned. Together, these processes underpin a robust and transparent approach to incident investigation.

Such an approach supports the development and maintenance of a strong organisational safety culture in MRI. Incidents and near misses should be recorded, reviewed, and analysed in a systematic manner to identify contributory factors and underlying causes. The sharing of findings within and across services supports organisational learning and contributes to the continuous improvement of MR safety.

When completing incident reports, the national taxonomy for incident learning in clinical imaging, MRI and nuclear medicine should be used [208]. The taxonomy provides a consistent framework for categorising events, enabling both local and national trend analysis, and supporting the identification of system-level risks.

Services are encouraged to participate in the national incident learning system. This voluntary system enables the submission of coded incident and near miss data using the national taxonomy. Participation contributes to the development of a national overview of MR safety events, supports benchmarking of local trends, and informs the development of evidence-based improvements across the sector. Participation does not replace existing statutory or regulatory reporting requirements. Further information is available via the Medical Exposures Group webpage.

Equipment incident reports

Incidents that result in, or have the potential to result in, direct or indirect harm to patients or users should also be reported to the MHRA via the Yellow Card scheme. This may include relevant near misses. Guidance on reportable incidents is provided in Appendix 4.

Where incidents involve implants or equipment, consideration should also be given to reporting to the relevant manufacturer or supplier (see section 6.5.2).

All sites must have an appropriate electronic incident reporting and management software, and all incidents and near misses should be reported and investigated, ideally using the national taxonomy. Incidents and near misses should be reviewed at the MR SAFETY COMMITTEE.

6 Equipment Lifecycle

The MRI equipment lifecycle includes operational business case, site selection, design of the MRI suite, procurement of MR system and ancillary equipment, installation, acceptance and commissioning, maintenance, decommissioning and replacement. In this chapter we'll describe the safety considerations related to the above processes. General advice on equipment management is given in MHRA's 'Managing Medical Devices' [209].

6.1 Procurement

6.1.1 Project Team

The purchasing of MRI equipment and site design should be undertaken using a consultation team including representatives from a range of relevant staff groups. Consultation of those mentioned below facilitates good purchasing decisions, a smooth installation and the establishment of a relevant clinical service. A typical multidisciplinary team is shown in Table 5.

Table 5. Typical multidisciplinary team for an MRI procurement project

Core team (internal/external)	Internal advisors	External advisors
MR RADIOGRAPHER(s)	Clinical specialities using the MRI service (e.g. surgeons, oncologists, anaesthetist, nursing)	MR system manufacturer/vendor representative
MR CLINICIAN(s)	Fire officer	Architects
MR SAFETY EXPERT	Estates and or/facilities staff	RF shielding experts
Clinical scientist (MRI physics)	Clinical specialist advisors e.g. manual handling, occupational therapy	Magnetic shielding experts
Clinical engineering	Infection, prevention and control	Structural engineers
Capital project manager	PACS manager	Patient & public involvement and engagement representative
Radiology manager	IT manager	
Purchasing and supplies / finance department		

An MR SAFETY EXPERT should be included in the project team.

6.1.2 Safety of UKCA, UKNI and CE Marked Medical Devices

In the United Kingdom, medical devices are regulated under the Medical Devices Regulations 2002 [24] in Great Britain, while Northern Ireland adheres to the EU Medical Device Regulation 2017 [25]. The MHRA acts as the regulatory authority for both cases.

Regulations stipulate that the manufacturer of a medical device (both hardware and software) is responsible for establishing that the device is safe and that it is suitable for its intended purpose. To establish this, manufacturers implement 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, correct labelling, the preparation of instructions for use and, if necessary, specific training schemes.

Manufacturers are required to register their devices with the MHRA and establish a means of post market surveillance. From such activities, manufacturers are able to verify that risks have been and can continue to be eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

Not following 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 [210].

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

MR imaging equipment that is UKCA, CE UKNI or 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. If the intended use at procurement stage is off-label, similar risk assessments and processes should be in place as in section 3.4. The risks and benefits to the patient must be balanced, considering the following recommendations:

- Carry out a risk assessment and document it
- Consider the ethical and legal implications
- Implement suitable precautions to minimize the risk
- Review the risk assessment at suitable periods
- Consider getting approval from the MHRA for exceptional use of non-complying devices

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

When modifying an existing device or using a non-medical device for a medical purpose, the organisation undertaking the modification is effectively acting as manufacturer and will need to adhere to the legislative requirements for 'In-House Manufacture'. Whilst both EU and UK regulations make provision for 'In-House Manufacture', the EU regulations (Article 5(5)) for in-house exemption are considered best practice and include the following conditions:

- The institution must justify that no suitable CE-marked device exists to meet patient needs.
- Devices must meet the General Safety and Performance Requirements (Annex I of MDR).
- The institution must operate an appropriate Quality Management System (QMS) for device manufacture.
- Full records of design, manufacture, and performance must be maintained.
- Systems must be in place to monitor device performance and report incidents.
- Documentation must be provided to competent authorities upon request.
- Devices must not be transferred to other legal entities or sold commercially.

If considering in-house manufacturing, please refer to the guidelines from MHRA [211], IPEM [212] and the Medical Device Coordination Group (MDCG) [213]. Be aware that the same rules for In-House Exemption also apply to software as a medical device.

6.1.3 Equipment Conformity

The equipment should comply with the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020 (Consolidated). Medical electrical equipment - Part 1: General requirements for basic safety and essential performance [144].
- BS EN IEC 60601-2-33:2024. Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis [150].

6.2 MRI Unit Design and Recommendations

Please refer to Chapter 4 and particularly the Guidance for Planning and Acceptance of New MRI Installations, where the key points in this section are covered in some detail [149].

MR CONTROLLED ACCESS AREA

The MR system must be located in an MR CONTROLLED ACCESS AREA with access limited to MR AUTHORISED PERSON (SUPERVISOR)(s) or those under supervision.

6.2.1 Entrances and Doors

The number of entrances should be kept to a minimum. Normally, there should be a single door large enough for patient access on a trolley, wheelchair or bed, equipment replacement and cryogenic storage dewars in the case of superconducting magnets. All doors to the MR CONTROLLED ACCESS AREA should be self-closing and locking with security locks that can be operated by MR AUTHORISED PERSON (SUPERVISOR)(s) only from the outside but freely opening from the inside in case of emergency.

Entrance doors to the MR examination room should be lockable, should not open directly onto public areas and should be visible from the operator's console at all times. The direction of opening of the MRI MR examination room door should be discussed with the MR vendor and MR SAFETY EXPERT. Risks should be considered for either outward or inward door opening. The need for pressure release mechanism should be independent of door direction.

If ferromagnetic metal detectors are installed by the door to the MR examination room, they must not replace robust screening processes mentioned in Chapter 5 .

The number of entrances to the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT should be kept to a minimum.

6.2.2 Signs

At each entrance to the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT, adequate, clearly visible warnings must be displayed. IPEM has produced a comprehensive set of MR safety notices for free download [214].

Visible warnings signs must be displayed at each entrance to the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT.

6.2.3 Venting Cryogens

In the case of conventional superconducting magnets (with quench pipes), it will be necessary to duct the cold vapours produced by boil-off out of the MR ENVIRONMENT to the outside of the building. Cryogenic storage dewars and ducting must be made from non-ferromagnetic material.

Refill operations should only be undertaken by an appropriately qualified MR equipment vendor. Prior to any refill, the operator must verify that the system's essential protective measures are functioning correctly. This includes the dedicated cryogen vent (quench vent), the active exhaust fan, and a passive over-pressure relief that is independent of the RF door.

Access to the MR ENVIRONMENT will be necessary to bring dewars to the point of filling. Adequate ventilation must be provided during the filling process, which could include manually activating the automatic air extract system.

6.2.4 Quench Pipe Safety

Where a quench pipe is needed, before installation of new MRI equipment, the site should check with suppliers and their local estates department 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.
- The external quench pipe terminal is positioned such that in the event of a quench, no risk will be posed to any person. Care must be taken to ensure that the vent outlet is positioned a safe distance from any openable window, walkway or escape routes (3 m, or according to manufacturer's exclusion zone). Access to the area surrounding the external quench pipe terminal should be restricted.
- A warning sign must be sited at the vent outlet, (see Appendix 5 for an example).
- The quench pipe is manufactured and installed in accordance with the material and installation specifications and guidance of the manufacturer.

- 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 MR system. The quench pipe must be sized based on the MRI manufacturers' recommendations and design calculations.

MRI vendors are not usually responsible for the maintenance of quench pipes and do not routinely check them during planned preventive maintenance. The external quench pipe should be visually checked annually as part of the MR safety audit. The internal parts of the quench pipe could be inspected to ensure there is no blockage or cracks.

The external quench pipe outlet terminal must be positioned to minimise risks of cryogenic exposure.

Visible warning signs must be displayed next to the quench pipe outlet terminal.

6.2.5 Emergency Magnet Off (Quench) and Power Off Buttons

Emergency magnet off (quench) and power off buttons should be located in the MR examination room and in the control room. Such buttons should be easily depressed in the case of an emergency and be provided with a protective cover or box fitted over them. They should also be labelled and the emergency magnet off (quench) button needs to differentiate between conventional and low helium (sealed) systems, which have different associated risks. 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, e.g., 20 mT, following activation of the switch. This time varies between systems and must be provided by the manufacturer (Appendix 5 for examples).

Emergency magnet off (quench) and power off buttons must be provided and labelled.

6.2.6 Oxygen Monitors

There is a risk of asphyxiation from the leaking of helium gas, displacing oxygen in the room for conventional superconducting systems. Oxygen monitors must be installed in a location where they can be seen and heard at all times if the oxygen concentration goes below a specified level (19.5% would be a suitable level [215]). They should be labelled and checked regularly as part of a planned preventative maintenance programme. At the sound of the alarm, the MR examination room must be evacuated immediately in line with local written and approved policy and as outlined in section 4.4.6.

In conventional superconducting systems (with a quench pipe), oxygen levels must be monitored and displayed in a location where they can be always seen and heard.

Oxygen monitors should be labelled and checked annually.

6.2.7 Temperature and Humidity Monitoring

It is essential that temperature and humidity of the MR examination room are monitored and displayed. Maintaining manufacturer recommended levels is a factor in the protection of the patient from heat stress and burns due to RF exposure (see Appendix 2). Please refer to manufacturer advice when the recommended limits are exceeded.

Temperature and humidity of the MR examination room must be monitored, displayed and labelled.

6.2.8 Lockers

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

Security lockers should be provided for patient personal belongings.

6.2.9 Nurse Call / Panic Alarms

Suitable alarms and call systems should be incorporated into the MR examination room, control room, anaesthetic areas, changing rooms and other relevant areas to alert others of an emergency which may be medical or non-medical in origin. Telephones should be provided in the control room and anaesthetic areas. Consideration must be given for a procedure to follow in case of catastrophic communication failure. Lone working is not advised.

6.3 Installation

The installation of an MRI unit requires careful consideration by the project team responsible for planning the supply and installation of the equipment and its immediate environment. 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.

It is strongly recommended for the project team to refer to the IPEM guidance for planning and acceptance of new MRI installations [216], and to take technical advice from potential suppliers and relevant professionals at an early stage. The guidance builds on NHS England's HBN6 [217]. It is also recommended to review manufacturer planning guides and installation documents.

6.3.1 Shielding of the Static Magnetic Field

There are a number of approaches designed to contain the static magnetic field, which are dependent on the strength of the static magnetic field. 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 field plots and diagrams should be made available from the manufacturers and suppliers of the MRI equipment.

6.3.2 Static Magnetic Fields and their Influence on Ferromagnetic Equipment

In planning a new MR installation, it is necessary to consider the impact of the static magnetic fields relative to the position of any ferromagnetic equipment. Hazards related to the static magnetic field are listed in Chapter 2

6.3.3 Static Magnetic Fields and their Influence on Sensitive Hospital Devices

In planning a new MR installation, it is necessary to consider the impact of the static magnetic field, in all directions, in relation to the position of any equipment that is sensitive to external magnetic fields. Examples of such devices include computing, ionising and non-ionising medical equipment (e.g. CT and PET systems; radiotherapy, nuclear medicine and ultrasound equipment), ancillary medical equipment, radiotherapy, electrical distribution transformers and power transformers.

- Information on the impact of static magnetic field on the specific devices must be obtained from the manufacturer where possible. If in doubt, consult the MR SAFETY EXPERT.

6.3.4 The Influence of External Objects on Static Magnetic Field Homogeneity

Ferromagnetic objects present in the static magnetic field may distort the field distribution within the magnet and can impact image quality.

6.3.5 Radio frequency (RF) 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. Installation of MR equipment must comply with legal requirements for the level of radio frequency emitted from industrial, scientific, and medical equipment.

Where available, 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 MR examination room that might be picked up by the receive coil and give rise to artefacts.

Co-siting: On sites with more than one MR system of the same field strength cross-talk has to be taken into consideration. This is where the RF generated in one system is picked up as signal by the other and overlaid onto the image. Co-sited systems should be ramped such that the resonant frequencies of the two systems are sufficiently different to keep this from happening. Manufacturer guidance should be followed.

6.4 Commissioning and Acceptance

6.4.1 Site Acceptance Testing

Acceptance testing of engineering services, including shielding, should be carried out in conjunction with the MR supplier prior to installation of the equipment [150,217].

The manufacturer or supplier should provide written evidence for the compliance of the equipment with the procurement specifications and with their own performance specifications.

6.4.2 Acceptance Testing – Independent of the Manufacturer

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

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

The acceptance process may also include:

- Verification of independent electrical safety testing
- RF cabin testing
- Site safety audit (section 4.1.11)
- Independent confirmation of magnetic fringe field within MR examination room and vicinity, which should include the MR ENVIRONMENT.
- Independent confirmation of noise levels

6.4.3 Training

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. More information on training can be found in Appendix 3.

6.5 Maintenance

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

6.5.1 Quality Assurance Programme

Each site operating MRI equipment should maintain a documented quality assurance (QA) programme as part of its wider imaging governance framework. The programme should define responsibilities, test schedules, acceptance criteria, and escalation procedures for any out-of-tolerance results.
Routine QA must include quantitative assessments of image quality, covering parameters such as signal-to-noise ratio (SNR), geometric accuracy, slice thickness, uniformity, ghosting, and artefacts. Tests should be performed using recognised phantoms and traceable measurement methods consistent with IPEM Report 112 [218], IEC 62464-1:2018 [219], BS 70000 [51] and the Quality Standard for Imaging (QSI [48]).

A quality assurance programme should be maintained as part of an imaging governance framework.

6.5.2 Equipment Incident Reports

Incidents and near misses involving MR diagnostic equipment must be reported using the local incident reporting system, to the vendor/manufacturer, and to the MHRA (or the equivalent body in the devolved administrations). Electronic reporting is available via the MHRA website, with guidance on what to report provided in Appendix 4. Relevant incidents should also be documented in the patient record or equipment log.

Equipment incidents and near misses must be reported using local incident reporting systems, to the vendor/manufacturer and to the MHRA or equivalent body.

6.5.3 Equipment Handover Procedure

A formal handover procedure should be agreed and followed when equipment is passed in and out of maintenance. An example of a handover form can be found on the AXREM website [220].

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

6.6 Potential Equipment Failure

6.6.1 Equipment Modifications

Hospitals and clinical institutions must ensure that any modifications to the hardware or the software of the MR diagnostic equipment are performed by the manufacturer, supplier or a qualified party. Adequate records of the changes together with test results should be provided to the hospital or clinical institution. If appropriate, any modifications should be recorded in an equipment log. Equipment modifications to hardware or software could affect the UKCA / UKNI / CE marking as discussed in section 6.1.2.

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

6.6.2 Spontaneous quench

Whilst rare, a spontaneous quench could happen. Magnet quench emergency procedures are covered in section 4.4.6.

6.6.3 Time-Varying Magnetic Field Gradients

Gradient systems are the source of many of the artefacts in images. Failure or loss of performance in any gradient axis typically results in pronounced and easily recognisable artefacts within the acquired images.

6.6.4 Radiofrequency Magnetic Fields

The radio frequency (RF) coils are generally close to the patient and require great care in preparation, handling 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. Faults in radio-frequency (RF) coils could cause patient burns. Damaged/faulty coils, cables or connectors should not be used. Patient burns are covered in section 5.3.7. It is essential to ensure that the total RF exposure of the patient remains within the recommended limits (see section 3.3).

6.6.5 RF Cabin/Faraday Cage

The RF Cabin/Faraday cage may degrade over time and fail. This may cause artefacts in images.

6.6.6 Patient Table/Couch

The main risks associated with the system table/couch are:

- 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, when needed. The patient couch must be free to move during a power failure and care should be taken to avoid any trapping of tubes, ties, straps, fingers, etc.
Any patient weight restrictions imposed by the manufacturer must be followed.

6.6.7 Patient Monitoring Equipment

Patient monitoring equipment in MRI includes visual and audio monitoring to observe the patient during the scan, as well as physiological monitoring such as ECG and pulse oximetry covered in section 5.3.10. 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.

6.6.8 MR Examination Room Door Failure

There have been multiple incidents reported of MR examination room door failures [221]. It is recommended to have a local emergency procedure in place in the event of the MR examination room door malfunctioning and potentially trapping staff and/or patients, outlined in section 4.4.7. All doors to the MR examination room should have a strategy in place for maintenance and/or inspection in keeping with the RF door manufacturer's recommendations.

6.6.9 Air Handling

Air handling in the MR examination room is essential not only for patient comfort but, more importantly for patient safety. In the case of conventional superconducting 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.

6.7 Planning for Upgrade, Replacement or Decommissioning

A policy on removal from service is an essential part of equipment management. At some point all equipment will need to be replaced, upgraded or decommissioned. Sustainability requirements of the organisation should be considered.

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.
Factors to consider for MR system upgrade, replacement or decommissioning include:

- Whether the device is damaged or worn out beyond economic repair
- Its reliability / downtime (check service history)
- Changes in service provision
- Clinical or technical obsolescence / changes in clinical recommendations/standards
- Device has reached end of support from the manufacturer
- Possible benefits of new model (features, usability, clinical effectiveness, running costs)
- Disposal costs / revenue generation potential

6.7.1 Sustainability

To reduce environmental impact, full upgrade on an existing system or selling/donating MRI equipment to other centres may be considered instead of replacement and/or disposal as waste.

Upgrade/Refurbishment

MR systems that are broken down into constituent parts and fully upgraded are covered by Medical Devices Regulations, requiring new CE/UKCA certification [209]. It is important to ensure RF cabin quality and that any quench pipes meet current requirements at upgrade/refurbishment.

Selling/Donating

There is no legislation which specifically covers the resale or reuse of medical devices or equipment. Note that devices not deemed to be safe for current patient use are therefore not safe for use by anybody to whom the device is donated to. If the device is risk assessed as safe to use and working according to specification, it must be supplied with all relevant documentation (e.g. IFU, service history etc).

Before sale or transfer of ownership of medical devices, both parties should be clear about their legal liabilities. It is recommended that the Clinical Engineering team are contacted for more information. Further details can be found in given in 'Managing Medical Devices' [209]. A toolkit on medical equipment donations to low-resource settings has also been published by Global Health Partnerships [222].

6.7.2 Safe Decommissioning and Disposal

Consult the manufacturer for the best methods of safe decommissioning and waste disposal. They should be able to provide details of the current techniques and processes applicable to their products. Some waste products need specialised disposal. Examples relevant to MRI include (non-exhaustive):

- Waste containing certain metals (e.g. mercury above 3%)
- Oil waste (including polychlorinated biphenyls – PCBs)
- Waste from coolants (e.g. helium)

When returning medical devices to the manufacturer at end of life, or when transporting devices, ensure that they are properly packaged and secured. Issues that should be addressed include strength of packing materials, protecting sharp edges, ensuring the device is not damaged in transit.

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 (eg when the thermal insulation of the dewar has broken down).

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

A1.1.6 Signage

Adequate, clearly visible warnings must be displayed where necessary (an example is shown in Figure 6). For examples of recognised warning and prohibitive signs users should refer to the Health & Safety (Safety Signs & Signals) Regulations 1996 [223] and BS ISO 7010 [224].

Figure 6 Cryogen Hazard sign

A1.1.7 Oxygen enrichment

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

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

A1.1 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.

A1.1.8 Overview of the regulations

The aim of PSSR [40,225] 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. HSE is currently reviewing the PSSR [226]. The application of these regulations to MRI is summarised here.

A1.1.9 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.

A1.1.10 The Competent Person

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

The competent person has 2 principal duties under the regulations:

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

The competent person should have:

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

A1.1.11 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.

A1.1.12 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.

A1.1.13 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.

A1.1.14 Maintenance

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

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

A1.1.15 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.

A1.2 Basic guide to installation and specification of quench piping

A1.2.1 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.

A1.2.2 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.

A1.2.3 Construction and checks

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

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

Appendix 2 Exposure Limits

The following appendix details exposure limits outlined by ICNIRP and IEC. As these two sources draw upon a similar evidence base, recommendations often align. Areas of difference are highlighted.

- The International Commission on Non-Ionizing Radiation Protection (ICNIRP) is an independent scientific body that publishes guidelines regarding the physiological safety of exposure to non-ionising radiation including extrapolated exposure limits. Publications referred to are:
  - Statement on Medical Magnetic Resonance (MR) Procedures: Protection of Patients (2004, amended 2009) [69,227]
  - Guidelines on Limits of Exposure to Static Magnetic Fields (2009) [68]
  - Guidelines for Limiting Exposure to Electric Fields Induced by Movement of the Human Body in a Static Magnetic Field and by Time-Varying Magnetic Fields below 1 Hz (2014) [72]
  - Guidelines for Limiting Exposure to Time-varying Electric and Magnetic Fields (1 Hz to 100 kHz) (2010) [76]
  - Guidelines for Limiting Exposure to Electromagnetic Fields (100 kHz to 300 GHz) (2020) [87]
- The International Electrotechnical Commission (IEC) standards are widely adopted by national legislators, technical committees, and MR manufacturers. Where relevant to MRI, these standards may apply or specify obligation to ICNIRP guidance.

Where relevant, it also covers relevant text within, and publications associated with, the following UK legislation:

- The Health and Safety at Work etc Act 1974 (HSW) [1]
- The Management of Health and Safety Regulations 1999 (MHSR) [3]
- The Control of Electromagnetic Fields at Work Regulations 2016 (CEMFAW) [5]
- The Control of Noise at Work Regulations 2005 (CNAW) [7]

Practicable recommendations for their adherence and application can be found in section 3.4

A2.1 Patients, Volunteers and Carers Exposure

A2.1.1 Modes of Operation

Operating modes are defined by limits for patient exposure to static magnetic fields (B_0) (A2.1.3), time-varying magnetic field gradients (A2.1.5), and radio-frequency magnetic fields (A2.1.7), as well as for temperature rise limits (A2.1.9). These measures are independent, and breaching any one of these limits for a lower level operating mode defines the MR examination as performed under the higher level operating mode, e.g. an examination with static field and RF field exposure within Normal Operating Mode, but a gradient slew rate in First Level Operating Mode, would be considered an examination at First Level Operating Mode.

The broader definitions for the level of risk and context/use of each operating mode, presented in each of the examined standards and guidelines, are summarised below.

Normal Operating Mode

Normal Operating Mode is broadly defined as the baseline operation level for routine clinical use. Its use is characterised by negligible physiological risk to exposed persons.

- **ICNIRP 2004/2009:** Context and use defined as for ‘routine MRI procedures for all patients’ [69].
- **IEC 2022:** Regarding risk, the ‘Biological effect [of exposure] …typically presents negligible risk’. Regarding context and use, Normal Operating Mode ‘…should be the default state of the MR equipment when initiating an MR Examination’. It is specified that patients scanned in

any operating mode, including Normal Mode, 'shall receive at least routine monitoring by qualified staff' [77].

First Level Controlled Operating Mode

First Level Controlled Operating Mode (ICNIRP: 'Controlled Operating Mode') outlines specific conditions and risks associated with MRI procedures that exceed routine exposure levels, i.e., Normal Mode, requiring increased oversight and awareness.

- **ICNIRP 2004/2009:** Regarding risk, 'discomfort and/or adverse effects for some patients may occur', such that a 'clinical decision must be taken to balance such effects against foreseen benefits' [69]. Defined context and use as for 'specific MR examinations outside the normal operating mode/range', where exposure must be carried out 'under medical supervision' [75]
- **IEC 2022:** Context and use are dependent on a 'medical assessment that considers the patient's potential risk versus benefit' where use requires 'medical supervision' and 'a deliberate action' to enter the operating mode. Regarding risk, such precautions are aimed to 'mitigate risks associated with biophysical effects induced by exposure to electromagnetic fields' [77].

Second Level Controlled Operating Mode

Second Level Controlled Operating Mode (ICNIRP: 'Experimental Operating Mode') represents the highest tier of exposure reserved strictly for research purposes under rigorous ethical and medical oversight.

- **ICNIRP 2004/2009:** Context and use require 'special ethical approval', and 'security measures' granted 'only under the authorisation of the responsible medical person' [69]. There should also be 'permanent supervision of the volunteer's state of health (e.g., circulation, respiration, subjective state) …along with continuous optical and acoustical contact' [69]. Regarding risk, additional considerations given for static magnetic fields exceeding 8 T, suggesting a 'progressively cautious approach' due to uncertainties around 'flow potentials on heart function', necessitating 'appropriate clinical monitoring' [68].
- **IEC 2022:** Context and use are dependent on a defined 'risk acceptability as part of a human or animal studies protocol approved according to local requirements' by the responsible organisation, including by an ethics committee or investigational review board where applicable. Such approval must specifically state 'study-specific limits' for static magnetic field strength, SAR, gradient output, acoustic exposure, and thermal exposure. Use requires 'medical supervision' to mitigate risk, and deliberate 'deactivation' of 'specific security measures' (such as a key-lock, combination lock, or software password) to enter the mode. Regarding risk, additional considerations made in relation to indirect effects like acoustic noise, displacement forces, or interference with other medical devices [77].

A2.1.2 MR Output Conditioning (MROC)

IEC 2022 introduces a standardised method of tailoring exposure values to the requirements of individual examinations in addition to any limitation on exposure applied by the modes of operation, and recording the limitations imposed. This is intended to permit MR OPERATORs to clearly and demonstrably comply with the conditions for performing MR examinations on patients or volunteers with MR CONDITIONAL implants [77]. Implementation of MROC is required for 1.5 and 3 T MR systems unless the MR manufacturer explicitly excludes scanning patients with MR CONDITIONAL implants; it may also be implemented in other systems.

- **IEC 2022:** MROC 'shall enable the operator to select (limit) values for [RF transmit coil type, RF polarisation, maximum $B_1{}^+_{RMS}$, maximum gradient slew rate per axis], within a range pre-defined by the [MR] manufacturer', and MR manufacturers may include controls on exposure other than this, such as limiting whole-body or head SAR, enforcing pauses between sequences to allow for cooling, or highlighting areas of the bore above a given spatial gradient [77].

A2.1.3 Static Magnetic Fields (B_0)

Both the IEC and ICNIRP define operating mode limits for patient exposure to the nominal static magnetic field strength (B_0) of MRI equipment [68,77]. These are summarised in Table A2.1

Table A2.1 Patient Static Magnetic Field Exposure Limits and Operating Modes

	Normal Mode	First Level Controlled Mode	Second Level Controlled Mode
IEC 2022 [77]	≤ 3 T	3 - 8 T	> 8 T
ICNIRP 2009 [76]	≤ 4 T	4 - 8 T	> 8 T

IEC define operating mode limits for patient exposure to the nominal static magnetic field strength (B_0) of MRI equipment. Conversely, ICNIRP define operating mode limits corresponding to true exposure, which can exceed the nominal field strength in certain regions around the scanner. Equipment operating at nominal field strengths of ≤3.0 T will not produce field strengths >4 T at any accessible point when the scanner is in normal use, and thus scanners utilising a nominal field strength of ≤3.0 T may be considered to be operating in Normal Mode according to both ICNIRP and IEC definitions for static field exposure.

In considering the risk from adverse events, IEC 2022 mandates the definition of a hazard area as the region around the system defined by a 0.9 mT isocontour [77]. This is considered applicable to inadvertent patient, occupational, and public exposure. This hazard zone is set at 0.9 mT to provide an adequate safety margin for medical devices that still use a reed switch or Hall-effect sensor for control of therapy which are required to be resistant to interference from static fields of 1.0 ± 0.1 mT [140] as per ISO 14117 and EN 50527 [228,229]. Previous versions of the IEC standard specified that the hazard area was defined as a more cautious 0.5 mT isocontour [77].

A2.1.4 Low-Frequency Time Varying Magnetic Fields (ΔB_0)

Movement in environments with strong static magnetic fields may induce electric fields in the human body, causing transient sensory effects.

- **ICNIRP 2009:** Studies are cited that evidence transient sensory effects for individuals exposed to static magnetic fields above 2–3 T, but notes that ‘sensitivity to these effects varies considerably between individuals’, and that ‘the occurrence and severity of these symptoms can be decreased by slowing the rate of motion of an individual through the magnetic field gradient’ [68].
- **IEC 2022:** For MRI equipment, the allowed speed of motion for the transport of the patient into the magnet bore must be limited such that the maximum dB/dt value the patient is exposed to shall be no more than 3 T/s [77].

A2.1.5 Time-varying Magnetic Field Gradients

Cardiac and Peripheral Nerve Stimulation (PNS)

Both ICNIRP and the IEC provide recommendations concerning patient exposure to time-varying magnetic field gradients, primarily focussed on preventing cardiac and peripheral nerve stimulation. In doing so, both the IEC and ICNIRP provide limits corresponding to definitions of operating modes based on the average perception threshold for PNS – though IEC use the mean whilst ICNIRP use the median. This has been empirically derived as a function of the effective stimulus duration, $t_{s,eff}$ (the peak-to-peak field variation divided by the greatest time derivative of the gradient during that variation, in milliseconds), as shown in Equation 1 [69,77].

$$\frac{dB}{dt} = 20\left(1 + \frac{0.36}{t_{s,eff}}\right) Ts^{-1}$$

Equation 1. Average Perception Threshold for Peripheral Nerve Exposure (PNS)

The IEC also permits a direct determination method for deriving a figure for average PNS threshold through empirical human trials. Use of this alternative method for output monitoring and conditioning may be used preferentially by MR manufacturers.
Subsequent to this determination, limits for exposure levels to time-varying magnetic field gradients are defined for Normal and Controlled modes of operation.

Table A2.2 Patient Time-varying Magnetic Field Gradient Exposure Limits and Operating Modes

	Operation	Exposure Limit
IEC 2022 [77], ICNIRP 2004 [69]	Normal Mode	80% of the average PNS perception threshold
IEC 2022 [77], ICNIRP 2004 [69]	First Level Controlled Mode	100% of the average PNS perception threshold

Both IEC and ICNIRP do not directly advise a limit for Second Level Controlled Operating Mode. ICNIRP advise that the gradient output should never exceed 100% of the median perception threshold. Through this stipulation, the output is sufficiently limited to effectively prevent cardiac fibrillation [69].
In considering exposure to time-varying magnetic field gradients in excess of First Level Controlled Mode, the IEC standards places stronger onus on MR manufacturers to design systems that automatically control gradient waveforms to prevent cardiac stimulation in the patient and MR worker in any operating mode, including Second Level Controlled Operating Mode. The gradient output of all gradient units combined must satisfy limits in Equation 2.

$$\frac{dB}{dt} < \frac{20}{\sqrt{1 - \exp\left(-\frac{t_{s,eff}}{3}\right)}} Ts^{-1}$$

Equation 2. Cardiac Stimulation Gradient Output Limit

Regarding the output of multiple gradient units, for whole-body cylindrical gradient systems, the IEC define the cumulative aggregate using a combination in quadrature of each unit's output weighted by factors relative to the patient coordinate system (Anterior-Posterior (w_{AP}), Left-Right (w_{LR}), Head-Feet (w_{HF})) Equation 3. These weights, too, may instead be directly determined through empirical human trials.

$O = \sqrt{\sum_i (\omega_i 0_i)^2}$, where w_{AP}=1.0, w_{LR}=0.8 and w_{HF}=0.7

Equation 3. Cumulative Gradient Output

Where direct determination is used for setting median perception threshold or gradient unit weights, the MR manufacturer must make available the report on this trial to compliance organisations and national regulatory bodies but does not need to include it in documentation available to system owners or users. Given that operating mode dB/dt limits and gradient unit weightings may be set independently via the direct determination method, these may differ in absolute value between MR manufacturers, system models, or system software versions.

A2.1.6 Acoustic Noise

ICNIRP guidance recommends that patients are 'offered' hearing protection 'when a noise level of 80 dB(A) is exceeded', and that hearing protection 'should always be worn' for MR procedures at levels 'exceeding 85 dB(A)'. Protection should preferably be headphones that allow for verbal communication. The use of earplugs is also mentioned; however it is noted that earplugs may offer non-uniform attenuation, and hamper communication [69]. Use of earplugs should consider adolescents and infants, where smaller earplugs are required to offer effective protection. No guidance is offered on the suitable

value rating (e.g., NRR, SNR, or SLC80) needed to provide sufficient protection. ICNIRP also strongly recommends the design of “quiet” gradient coils (e.g., increasing coil stiffness, damping, and balancing Lorentz forces) to reduce mechanical vibration and associated noise [69].

IEC standards mandate that under ‘normal use’ patient, public or occupational exposure must not exceed a sound pressure level of 140 dB(C) for $LC_{peak(/pk)}$ for impulsive or impact acoustic energy, or 99 dB(A) for $LA_{eq,1h}$. Where MRI equipment is capable of producing $LA_{eq,1h}$ in excess of 99dB(A), MR manufacturers are required to state the minimum rated hearing protection value (e.g., NRR, SNR, or SLC80) required to reduce $LA_{eq,1h}$ to ≤99dB(A) in their instructions for use (IFU).

The IEC stipulates that measurements to determine the acoustic noise output of MRI equipment should follow the methodology defined in NEMA MS 4 [77,80]. The NEMA standard gives two methods for the measurement of acoustic noise: the Maximum Clinical Acoustic Noise (MCAN) and Maximum Gradient Acoustic Noise (MGAN). MCAN gives a measurement which represents the loudest output of the system in using clinical pulse sequences. For results of MCAN testing, NEMA advises that testers report "a summary of the set of candidate sequences assessed, initial SPL, and maximized SPL measurements” [80]. MGAN gives a measurement which represents the loudest possible output of the system under the performance constraints applied to clinical use. MR manufacturers may quote a single figure for acoustic noise output, and associated minimum rated hearing protection value, without listing which measurement method was used.

MR manufacturers are also required to provide guidance on dual-hearing protection, i.e., the use of over-ear and in-ear protection, including that combining two forms of protection provides attenuation equivalent to ‘the first and presumed superior primary means of protection’ (usually the in-ear protection, i.e. earplugs) plus an additional 5 dB(A). Furthermore, MR manufacturers’ instructions for use (IFU) will explain that dedicated training should be established for MR workers to ‘ensure proper application of hearing protection on the patient’, especially when ‘earmuffs cannot be applied’ [77]. Note that MR ‘entertainment’ system headphones should have an explicit hearing protection value, otherwise they cannot be considered to add the additional 5 dB(A).

A2.1.7 Radio-frequency Magnetic Fields

Specific Absorption Rate (SAR) limits

Both ICNIRP and the IEC provide recommendations concerning patient exposure to radiofrequency magnetic fields, primarily focussed on limiting heating of localised tissue and the whole-body [69,77]. In doing so, they provide limits corresponding to definitions of operating modes based on the specific SAR for whole-body, partial body, and head regions (See Table A2.3).

With respect to these limits, IEC defines ‘Volume RF transmit coil’ to include any transmit coil that produces a homogeneous RF field over an extended volume encompassed by the coil; this therefore includes both the integrated whole-body coil and most head and extremity local transmit/receive coils.

‘Local RF transmit coil’ includes any other transmit coils not fitting this definition, e.g. surface transmit coils. Currently no MR manufacturer offers local RF transmit coils, but third party manufacturers or research projects may develop these, particularly for MR spectroscopy using non-Hydrogen nuclei.

Table A2.3 Patient Limits for SAR (Wkg^{-1}) for RF field exposure

	Volume RF transmit coil			Local RF transmit coil		
	Whole-body	Partial body		Local		
		Head	Other	Head	Trunk	Extremities
Normal Mode	2	3.2	2 – 10	10	10	20
First Level Controlled Operating Mode	4	3.2	4 – 10	20	20	40
Second Level Controlled Operating Mode	> 4	> 3.2	> (4 – 10)	> 20	> 20	> 40

Note. SAR values are integrated over an averaging time of 6 minutes.

Partial-body SAR limits are scaled with the ratio, r, of the exposed patient mass (the mass which is the recipient of 95% of the deposited RF power from the transmit coil) to the total patient mass (see Equations 4 and 5)

Normal Mode: $SAR = (10 - 8r)\ Wkg^{-1}$

Equation 4. Partial Body Normal Mode SAR Limit

Controlled Mode: $SAR = (10 - 6r)\ Wkg^{-1}$

Equation 5. Partial Body Controlled Mode SAR Limit

IEC 2022 requires that the whole-body SAR limit for First Level Controlled Mode is derated when the ambient temperature is above 25°C, reducing to equivalent to Normal Mode above 32°C (see Table A2.4)

Table A2.4 Controlled Mode SAR Limits Depending on Ambient Temperature

	Ambient Temperature (t)		
	≤ 25℃	$25 - 32$℃	> 32℃
First Level Controlled Operating Mode SAR Limit (W kg^{-1})	4	$4(t - 25) \times 0.25$	2

IEC 2022 places additional restrictions for local RF coils (commonly known as surface coils) used in transmit mode [77]. Firstly, SAR over any 10 s period is limited to two times the stated limit (e.g. 20 W/kg for a local head exposure). Secondly, in cases where the eye is in the field of a local coil, IEC advise that care should be taken to ensure that the temperature rise is limited to 1°C. Assuming a bespoke coil developed for a research project, the coil's handling and use will need to be addressed as part of a coil's certification for human use and integration with the MR system.

A2.1.8 $B_1^+{}_{RMS}$

The value of $B_1^+{}_{RMS}$ indicates the RF magnetic field intensity responsible for tipping the nuclear magnetisation in the rotating frame and is, by design, entirely patient-independent. This measure more closely reflects the B_1 field intensity experienced by implanted devices and thus the risk of RF-induced currents and resultant heating. B_1 field intensity can vary from measured $B_1^+{}_{RMS}$ by an order of magnitude: manufacturers of implanted devices including MR CONDITIONAL limits on $B_1^+{}_{RMS}$ are responsible for accommodating this variation [77], and this is included in implanted device testing methods for deriving MR CONDITIONAL limits [98].

IEC 2022 mandates that equipment MR manufacturers display $B_1^+{}_{RMS}$ on the system's control panel, for scans using volume RF transmit coils, to provide a supplemental metric to SAR for the RF power deposition. In doing so, the metric will represent the highest average value for any 10s period, evaluated over the duration of the sequence [77].

System operating modes (see section A2.1.1) are defined for limits related to SAR (and therefore, indirectly, temperature rise) and gradient output, and do not directly limit $B_1^+{}_{RMS}$. However, enabling MROC allows the operator to select limits for the $B_1^+{}_{RMS}$, and additionally limits the instantaneous $B_1^+{}_{peak}$ of any sequence as specified in Table A2.5

Table A2.5 $B_1^+{}_{peak}$ Limitation Under MROC

	$B_1^+{}_{peak}$ limit (μT)	
RF transmit coil type	1.5 T	3 T
Whole-body RF transmit coil	30	24
Other volume RF transmit coil	45	35

A2.1.9 Temperature Rise

Both ICNIRP and IEC highlight that the primary concern of limitations on RF exposure is to minimise temperature rises in tissue to acceptable levels (See Table A2.6) [69,77]. SAR limit recommendations are derived from modelling of these factors.

These SAR limit recommendations interact with other temperature-related environmental factors, such as ambient temperature and humidity. ICNIRP states that its SAR limit recommendations include 'reduction factors' as margins to accommodate this variability. IEC requires that recommendations to minimise heating are included in MR manufacturers' instructions for use, and states that whole-body SAR limits are only valid if the MR examination room temperature is within the range specified by the MR manufacturer.

Table A2.6 Temperature Rise Operating Mode Limits

	Whole-body (°C) (IEC)	Whole-body (°C) (ICNIRP)	Local		
			Head (°C)	Trunk (°C)	Extremities (°C)
Normal Operating Mode	0.7	0.5	38	39	40
First Level Controlled Operating Mode	1.3	1	38	39	40
Second Level Controlled Operating Mode	> 1.3	> 1	> 38	> 39	> 40

A2.2 Occupational Exposure

In the UK, occupational exposure to electromagnetic fields is managed under The Control of Electromagnetic Fields at Work (CEMFAW) Regulations 2016 [5,6], as detailed in section 3.4.2. The Regulations exempt exposure limits "*during the development, testing, installation, use and maintenance of, or research related to, magnetic resonance imaging equipment for patients in the health sector*" where the exposure of employees to electromagnetic fields is as low as reasonably practicable, and employees are protected against the health effects and safety risks arising from their exposure to electromagnetic fields [5,6,141].

The HSE can certify other areas of work as following a similar exemption. Since CEMFAW has come into force, a certificate of exemption has applied to all other uses of MRI not covered by the existing exemption in the Regulations. This certificate is valid for five years and may be revoked or amended at any time by issue of a further certificate. Organisations using MRI for purposes covered by this certificate are advised to periodically check that the certificate is still in force. Certificates are published on HSE's website.

In addition to general guidance published by HSE [138], the British Institute of Radiology has published professional body guidance for interpreting the requirements of CEMFAW in the context of MRI [139,230]. This details the nature of the exemption for MRI which requires risk assessment of the hazards present and working practices to reduce exposure as low as reasonably practicable (ALARP), particularly in avoiding deterministic effects unless necessary. This includes a requirement for detailing these limits in associated staff training.

To this end, the Action Levels (AL) and Exposure Limit Values (ELV) from CEMFAW, intended to define the thresholds for 'specific indirect effects' and 'direct biophysical effects of exposure to electromagnetic fields', are included for consideration in risk assessments and in training, but are not quantities that MR organisations need to measure or ensure workers are not exposed to. Some ALs (AL5, AL7) and ELVs (ELV6) are not listed here as they are concerned with contact currents or GHz frequency ranges not relevant to MRI.

IEC requires that MR manufacturers provide a plot 'with (at least) a single isocontour of the (combined) worst case of the Exposure Level Values (ELVs) with respect to B_0 (2 T) and the internal electric field related to health effects (1.1 Vm^{-1}) induced by the simultaneous switching of the gradient units...this plot represents an overview of the ELVs in the MR examination room for compliance with the EU physical agents Directive 2013/35/EU' upon which CEMFAW is based [77].

A2.2.1 Static Magnetic Fields (B_0)

Regarding static magnetic field exposure, CEMFAW [5] retains advisory ALs in keeping with earlier IEC standards for the avoidance of indirect effects [68] (AL6, see Table A2.7).

Table A2.7 CEMFAW Occupational Static Magnetic Field Limits

Action Level (mT)	Notes
0.5	The maximum field value at any place where an employee may be working considering the possibility of 'interference with active implanted medical devices'
3.0	'Attraction and projectile risk in the fringe field of high field strength sources (> 100 mT)'

ICNIRP static magnetic field exposure limits are defined for different body regions (See Table A2.8), with more permissible limits for specific work where movement induced effects are mitigated, defined as controlled exposures (See section A2.2.2) [68]. The CEMFAW direct effect ELVs (ELV1) agree with these limits and include similar language on the mitigations required for specific work which exceeds them [5].

Table A2.8 ICNIRP Occupational Static Magnetic Field Limits

Body Region	Static Magnetic Field (B_0) Limit	Notes
Head and Trunk	2 T	Limit set to prevent vertigo, nausea, and other sensations (See section A2.2.2)
Head and Trunk (Specific Work)	8 T	Permitted only if the environment is controlled and appropriate work practices are implemented to control movement-induced effects (See section A2.2.2)
Limbs	8 T	Adverse effects on limbs are not expected up to 8 T

The exposure limits published by ICNIRP only consider the direct biological effects of exposure, and ICNIRP guidance 'recognizes that practical policies need to be implemented to prevent inadvertent harmful exposure of persons with implanted electronic medical devices and implants containing ferromagnetic material, and dangers from flying objects, which can lead to much lower restriction levels such as 0.5 mT [68].

In considering the risk from adverse events, the IEC mandates the definition of a hazard area as the region around the system defined by a 0.9 mT isocontour. This is considered applicable to inadvertent patient, occupational, and public exposure. Additionally, IEC requires that MR manufacturers provide a plot of static field distribution which includes the 2 T isocontour, where this is accessible outside the MR system's fixed covers [77].

A2.2.2 Low-Frequency Time Varying Magnetic Fields (dB/dt)

Since the magnitude of the electric fields generated by movement cannot be readily determined, ICNIRP guidance includes more applicable reference levels. For these reference levels, a distinction is made between 'controlled' and 'uncontrolled' exposures, where controlled exposures are relevant to 'workers who have been trained to understand the biological effects that may result from exposure', and where the workers are able to 'control their movements in order to prevent [transient effects]'. Exposure of workers without such training is considered uncontrolled and an upper limit on whole-body exposure is advised (See Table A2.9) [72].

For MRI equipment capable of operation above Normal Mode for static magnetic field (≤ 3 T) IEC 2022 mandates that the equipment's instructions for use must explain to workers that possible physiological effects of static magnetic field exposure include dizziness, vertigo, and a metallic taste, may occur. They will also explain that and that these acute symptoms can be lessened by avoiding rapid movements of the head, and that workers should be advised to limit the speed of motion to minimise physiological effects (See Table A2.9) [77].

CEMFAW includes no comparable limits, instead limiting exposure based upon the magnitude of the induced electric field (see A2.2.3) [5].

Table A2.9 Occupational Low Frequency Time-Varying Magnetic Field Limits

	Limit
ICNIRP [72]	ΔB < 2 T*
IEC 2022 [77]	ΔB < 3 T/s

**This limit may be exceeded for controlled exposures.*

A2.2.3 Time-varying Magnetic Field Gradients

Central and Peripheral Nerve Stimulation (PNS)

IEC 2022 notes that 'MR worker exposure limits are the same as the maximally allowed limits for the patients. Compliance with the gradient output limits for patients therefore automatically implies compliance for the MR workers. MR manufacturers are required to provide a plot of the maximum gradient output stray field along the bore surface – representing the worst case exposure – and extending out by at least 1 m [77].

ICNIRP recommends that workers are prevented from experiencing peripheral and myelinated nerve stimulation (i.e. to nerves in the central nervous system) by limiting exposure of 'all parts of the body' [72]. In doing so, restrictions are provided for induced internal electric field across various frequency ranges assuming sinusoidal and single frequency exposure. These are extrapolated using mathematical modelling for the condition of maximum coupling of the field to the exposed individual to giving a contingency for the worst-case scenario (See Table A2.10). CEMFAW ALs (AL2) agree with these limits [5].

Table A2.10 Occupational Time-Varying Magnetic Field Gradient Exposure

Frequency Range*	Magnetic Flux Density B(T)
1 − 8 Hz	$0.2 / f^2$
8 Hz − 25 Hz	$2.5\times10^{-2} / f$
25 Hz − 300 Hz	1×10^{-3}
300 Hz − 3 kHz	$0.3 / f$
3 kHz − 10 MHz	1×10^{-4}

**For frequencies >100 kHz, additional RF-specific reference levels need to be considered (See A2.1.7)*

CEMFAW includes several ALs and ELVs for induced internal electric fields within workers which span a wide frequency range, denoting thresholds for sensory and nerve stimulation effects (AL1, ELV2, ELV3, see Tables A2.11, A2.12 and A2.13) [5]. The ALs are RMS values, using a weighted peak method for non-sinusoidal fields, whereas the ELVs are time- and spatial- peak values.

Table A2.11 External electric field action level

Frequency Range	External Electric Field Strength E (Vm^{-1})
1 – 25 Hz	2.0×10^4
25 – 3 kHz	$5.0\times10^5 / f$
3 kHz – 10 MHz	1.7×10^2

Table A2.12 Internal electric field exposure limits for the whole-body

Frequency Range	Internal Electric Field Strength E (Vm^{-1})
1 Hz – 3 kHz	1.1
3 kHz – 10 MHz	$3.8\times10^{-4} f$

Table A2.13 Internal electric field exposure limits in the head

Frequency Range	Internal Electric Field Strength in the Head E (Vm^{-1})
1 – 10 Hz	0.7 / f
10 – 25 Hz	0.07
25 – 400 Hz	0.0028 f

A2.2.4 Acoustic Noise

The ICNIRP guidelines recommend consulting national guidelines for thresholds for occupational acoustic noise exposure (see below). However, in view of the chronic nature of occupational exposure and the minimal inconvenience of effective protection, ICNIRP guidelines additionally advise that MR staff should follow the same rules for wearing hearing protection that are recommended for patients [69]. This requirement to follow the same limits for public and patient exposure is also reflected in the IEC standards.
The Control of Noise at Work (CNAW) Regulations [7] state that employers must manage risk based on the exposure levels in Table A2.14. Limits in CNAW are derived for occupational exposure over the course of 8-hours, typical to other professions, but likely exceeding exposure times for infrequently exposed occupational groups like staff in MRI departments.

Table A2.14 CNAW Occupational Acoustic Noise Limits

	Daily / Weekly Personal Noise Exposure (LA_{eq})	Equivalent $LA_{eq,1h}$*	Equivalent Time Limit at 99dB(A) (hh:mm)*	Peak Sound Pressure ($LC_{peak(/pk)}$)	Notes
Lower Exposure Action Value (EAV)	80 dB(A)	~89 dB(A)	~00:06	135 dB(C)	Hearing protection must be available upon request
Upper Exposure Action Value (EAV)	85 dB(A)	~94 dB(A)	~00:19	137 dB(C)	Hearing protectors must be worn. Area must be designated as a Hearing Protection Zone.
Exposure Limit Value (ELV)	87 dB(A)	~96 dB(A)	~00:30	140 dB(C)	Must not be exceeded

**Figures for equivalent $LA_{eq,1h}$ and exposure time limit at 99dB(A) extrapolated using the HSE Noise Exposure Calculator.*

In the selection and use of hearing protection for occupational exposure, all protection should carry the appropriate conformity marking indicating that it meets the essential requirements of relevant standards, i.e. BS EN 352. Additionally, organisations are required to ensure that protection provided in compliance with CNAW is 'maintained in an efficient state, in efficient working order and in good repair'. As such there is also a requirement for the organisation to arrange periodic inspection of reusable hearing protection and to repair or replace them if necessary.

In managing the risk, the employer's 'primary duty' is stated as being to eliminate noise exposure 'at source', or if not reasonably practicable, to reduce exposure to 'as low a level as is reasonably practicable'. In doing so, the selection of hearing protection must at least reduce exposure to below the ELVs. The regulations also state that the use of dual protection in practice will offer 'no more than 6 dB over the higher rated individual protection.'

Employers must designate any area likely to exceed the upper EAV as a Hearing Protection Zone. Access to the area must be restricted and employers must ensure, so far as reasonably practicable, that employees wear protection when entering the zone. Hearing protection is not required when the hazard is not present, i.e. the scanner is not scanning. The employer must also ensure that the zone is demarcated and identified by means of signage specified for the purpose of indicating that ear protection must be worn. This must be in keeping with paragraph 3.3 of Part II of Schedule 1 to the Health and Safety (Safety Signs and Signals) Regulations 1996 [223]. An example can be found in Figure 7.

Figure 7 Appropriate signage for demarcation of hearing protection zone

A2.2.5 Radio-frequency Magnetic Fields

The ICNIRP guidelines suggest that exposure at the entrance to the bore is negligible and that 'the exposure of the operator to RF fields is well below existing recommended limits' [69].

IEC 2022 requires that MR manufacturers provide a 'Plot displaying drop-off of the B_1 transmit field along the centreline of the empty RF transmit coil, to support MR worker exposure assessment' [77]. RF hazards can be considered to be contained to this volume.

ICNIRP recommends that pregnant workers are classified as members of the public for the purposes of assessing occupational exposure to RF heating as exposure to occupational limits is likely to breach the public limits for the foetus [87].

A2.2.6 Specific Absorption Rate (SAR)

The ICNIRP guidelines derive exposure limits for workers from the targeted maximum temperature rise of 1°C, applying a reduction factor of 10 to the operational adverse health effect threshold of 4 W/kg [87] (See Table A2.15) CEMFAW health effect ELVs (ELV4) agree with these limits, with the exception that the averaging period for all three limits is set at 6 minutes [5].

Table A2.15 Occupational SAR Limits

Exposure	Sar Limit (W/kg)	Tissue Mass (g)	Averaging Time Period (mins)
Whole-body[1]	0.4	-	30
Local (Head and Torso)[2]	10	10	6
Local (Limbs)[2]	20	10	6

1. Applicable to RF fields across a frequency range of 100 kHz to 300 GHz
2. Applicable to RF fields across a frequency range of 100 kHz to 6 GHz

CEMFAW includes ALs for thermal effects in terms of $B_1{}^+{}_{RMS}$ (AL3, see Table A2.16) [5].

Table A2.16 Thermal effect ALs for electromagnetic fields from 100 kHz to 300 GHz

Frequency Range	Magnetic Flux Density B (μT)
100 kHz − 1 MHz	2.0×10^6 / f
1 − 10 MHz	2.0×10^6 / f
10 − 400 MHz	0.2
400 MHz − 2 GHz	1.0×10^{-5} $f^{1/2}$
2 − 300 GHz	0.45

CEMFAW also describes thermal risk to the limbs in terms of RMS induced current, specifying an AL (AL4) of 100 mA [5].
For high field systems, CEMFAW also defines a sensory effect ELV (ELV5) for exposure to electromagnetic fields from 300 MHz to 6 GHz in terms of specific energy absorption (SA, also known as specific energy dose, SED) to the head of 10 $mJkg^{-1}$ [5]..

A2.2.7 $B_1{}^+{}_{RMS}$

Neither ICNIRP guidelines, the IEC standard, nor CEMFAW contain any limitation on $B_1{}^+{}_{RMS}$ for workers (but see the B_1-related ALs in A2.2.6).

A2.3 Public Exposure

Employers have a general obligation under The Health and Safety at Work Act 1974 [1] and The Management of Health and Safety Regulations 1999 [3] to minimise 'the risks to the health and safety of persons not in [their] employment' who may be affected by their work, including members of the public.

CEMFAW includes no provision for specific limitation of public exposure but falls under the umbrella of MHSR [138].

Carers and comforters who accompany the patient into the MR examination room during scanning are consented and screened to experience exposure up to the relevant patient limits (see 3.3, 5.3.4, A2.1).

A2.3.1 Static Magnetic Fields (B_0)

ICNIRP static magnetic field exposure limits are defined for exposure to the general public. These are derived by applying a reduction factor of 5 with respect to the occupational Head and Trunk limit (See Table A2.17) [68].

Table A2.17 Public Static Magnetic Field Exposure Limits

Body Region	Static Magnetic Field (B_0) Limit	Notes
Any part of the body	400 mT (0.4 T)	Based on direct biological effects

Outside of direct health effects, ICNIRP 'recognizes that practical policies need to be implemented to prevent inadvertent harmful exposure of persons with implanted electronic medical devices and implants containing ferromagnetic material, and dangers from flying objects, which can lead to much lower restriction levels such as 0.5 mT [68].

In considering the risk from adverse events, the IEC mandates the definition of a hazard area as the region around the system defined by a 0.9 mT isocontour [77]. This is considered applicable to inadvertent patient, occupational, and public exposure.

IEC requires MR manufacturers to provide a plot of static field distribution [77]. This must include the 0.5 mT and 0.9 mT isocontours. It does not include the 400 mT isocontour, but the 200 mT isocontour is required so can be considered the threshold of safe approach in the absence of measurement for persons otherwise screened to exclude the presence of ferromagnetic objects or implanted electronic medical devices (e.g. for foetal exposure for an MR worker where their proximity to the system is not otherwise controlled).

A2.3.2 Time-varying Magnetic Field Gradients

Central and Peripheral Nerve Stimulation (PNS)

IEC 2022 notes that 'MR worker exposure limits are the same as the maximally allowed limits for the patients. Compliance with the gradient output limits for patients therefore automatically implies compliance for the MR workers.' Members of the public would be protected by the same limitation provided they are similarly restricted in access. MR manufacturers are required to provide a plot of the maximum gradient output stray field along the bore surface – representing the worst-case exposure – and extending out by at least 1 m.

ICNIRP also recommends limits for general public exposure to time-varying electric and magnetic fields. As with the limits for exposure to static magnetic fields, generally these observe the occupational limits with a reduction factor of 5 [76] (See Table A2.18).

Table A2.18 Public Time-Varying Magnetic Field Gradient Limits

Frequency Range	Magnetic Flux Density B(T)
1 − 8 Hz	$4\times10^{-2} / f^2$
8 Hz − 25 Hz	$5\times10^{-3} / f$
25 Hz − 400 Hz	2×10^{-4}
400 Hz − 3 kHz	$8\times10^{-2} / f$
3 kHz − 10 MHz	2.7×10^{-5}

Note. In the frequency range above 100 kHz, RF specific reference levels need to be considered additionally.

Acoustic Noise

Neither the ICNIRP guidelines nor IEC 2022 include specific limitation of acoustic noise exposure for the public. Instead, limitation of acoustic noise exposure for patients (see A2.1.6) contains no indication that patients are to be considered differently to the general public in this regard, so the same limits can be construed to apply to both populations [69,77].

CNAW states that 'the employer shall, so far as is reasonably practicable, be under a like duty [to their employees] in respect of any other person at work who may be affected by the work carried out by the employer', but does not specify separate limits for members of the public [7].

Epidemiological studies have failed to show hearing damage in populations exposed to a $LA_{eq,24h}$ of less than 70dB, though advise that impulse noise exposures should never exceed 140dB LC_{peak} for adults and 120dB LC_{peak} for children [231].

A2.3.3 Radio-frequency Magnetic Fields

The ICNIRP guidelines suggest that exposure at the entrance to the bore is negligible with regard to worker exposure limits, and that 'the exposure of the operator to RF fields is well below existing recommended limits' [69]. Members of the public would be protected by the same limitation provided they are similarly restricted in access.

IEC 2022 requires that MR manufacturers provide a plot 'displaying drop-off of the B_1 transmit field along the centreline of the empty RF transmit coil, to support MR worker exposure assessment' [77]. RF hazards can be considered to be contained to this volume.

ICNIRP recommends that pregnant workers are classified as members of the public for the purposes of assessing occupational exposure to RF heating as exposure to occupational limits is likely to breach the public limits for the foetus [87].

A2.3.4 Specific Absorption Rate (SAR)

ICNIRP recommends a reduction factor of 50 is applied to the operational adverse health effect whole-body SAR threshold of 4 W/kg (corresponding to a 1°C temperature rise), justifying that 'the general public cannot be expected to be aware of exposures and thus to mitigate risk' (See Table A2.19)[87].

Table A2.19 Public SAR Limits

Exposure	Sar Limit (W/kg)	Tissue Mass (g)	Averaging Time Period (mins)
Whole-body[1]	0.08	-	30
Local (Head and Torso)[2]	2	10	6
Local (Limbs)[2]	4	10	6

1. Applicable to RF fields across a frequency range of 100 kHz to 300 GHz
2. Applicable to RF fields across a frequency range of 100 kHz to 6 GHz

A2.3.5 $B_1{}^+{}_{RMS}$

The ICNIRP guidelines contain no limitation on $B_1{}^+{}_{RMS}$ for members of the public.

Appendix 3 Training

A3.1 Staff Training within MRI Units

All staff involved in the operation or support of MRI services must receive training before first accessing the MR ENVIRONMENT and prior to undertaking any MRI-related duties. This includes both their normal responsibilities and their actions in the event of an emergency.

Training should be role-specific, such as radiographers, clinicians, clinical support workers, physicists, anaesthetists, porters, and maintenance teams, and proportionate to the level of risk associated with each staff group. The MR RESPONSIBLE PERSON supported by the MR SAFETY EXPERT, should ensure that all staff complete an initial induction, competency assessment and MR safety training before being granted unsupervised access to controlled areas.

Annual review and refresher training should be provided to maintain competence and ensure awareness of any changes in safety procedures, equipment, or site configuration. Records of training completion, updates, and competency assessments should be maintained by the MR RESPONSIBLE PERSON and be auditable as part of the MRI unit's quality management system.

A3.2 Recommended Knowledge for Staff Working in MRI Units

Categories of MR AUTHORISED PERSON(s) are discussed in section 4.3. Table A3.1 shows a recommended level of knowledge for the categories of MR AUTHORISED PERSON(s).

Table A3.1 Categories of MR AUTHORISED PERSON(s).

	MR AUTHORISED PERSON (SUPERVISOR)	MR AUTHORISED PERSON (MR ENVIRONMENT)	MR AUTHORISED PERSON (NON-MR ENVIRONMENT)
Persons in this category should receive full training and instructions for the equipment in use, including its hazards and emergency procedures. This should occur at induction.	✓	✓	-
They must be aware of the location of the MR ENVIRONMENT and its hazards	✓	✓	✓
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 the significance of the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT 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 (active and passive) and wearable health monitoring devices. – The effect of magnetic fields upon personal effects such as hair extension, phones and watches.	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓
They must understand the consequences and effects of quenching of magnets (including superconducting and sealed/low helium magnets)	✓	✓	–
They must be fully aware of the recommendations on exposure to MR for patient, escorts and staff.	✓	✓	-
They must be aware of the local MR safety screening process and understand their responsibility and role within it.	✓	✓	✓
They must understand the consequences of the correct selection, fitting, and use of hearing protection. They must understand MR Conditions and MR labelling, and how to meet them on their available systems. They must understand system operating modes. They must understand the correct coil selection and patient positioning	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	 -

A3.3 Training Framework for Radiographic Staff

MRI education and training should align with the HCPC Standards of Proficiency (2023) [232] and the College of Radiographers (CoR) Education and career framework [233] and the Society of Radiographers expectations for safe MR practice [153].

The radiographic workforce includes clinical support workers, assistant practitioners, and radiographers. MRI is predominantly used as a diagnostic imaging tool and is typically operated by diagnostic radiographers. However, its use is increasingly expanding within radiotherapy departments, where it is applied in treatment planning and delivery. In these settings, MRI is primarily used by therapeutic radiographers.
Radiographers, both diagnostic and therapeutic, are autonomous, registered healthcare professionals regulated by the Health and Care Professions Council (HCPC). They may practise at practitioner, enhanced, advanced, or consultant level, depending on their education, training, and experience, each requiring MR safety knowledge proportionate to their scope of practice:

- Assistant practitioners: should receive structured induction and task-specific MR safety training, practising under a supervision framework,
- Registered practitioners enhanced advanced and consultant practitioners: should maintain and extend knowledge and competence through postgraduate education, in-house programmes, and CPD-endorsed courses.

Competence in MR safety is a shared responsibility of the employer and practitioner.

Each service should define an MR RESPONSIBLE PERSON. This is usually the Principal / Lead MRI Radiographer who ensures safe and effective provision of MR Imaging services for patients and staff. While certification as an MR Safety Officer (MRSO) is not mandatory, it can support professional development.

Additional considerations for training and competence can include:

- Induction and refreshers: covering Local Rules, emergency procedures, and annual updates.
- Scope and supervision: clearly defined tasks and supervision levels for assistant practitioners, learners, apprentices, and temporary staff.
- MR Safety competencies: screening for implants/devices, understanding implant interaction ferromagnetic control, access management, medicines management including contrast agent interactions, paediatric and pregnancy considerations, and lone or out-of-hours working.
- Competency assessment and records: documented sign-off, periodic re-validation, and inclusion of learning from incidents or simulation exercises.

A3.4 Training Framework for Clinical Scientists

Training for Clinical Scientists, working in clinical units, should align with national curricula and HCPC standard of proficiency [234,235]. Clinical Scientists play a key role in ensuring the safe design, operation, and governance of MRI services.

- Trainee / Early-career MRI Scientist: should gain supervised experience in MR safety and biological effects (static field, gradients, RF), Local Rules and screening processes.
- Registered MRI Clinical Scientist: should practise independently providing MR safety advice (including review of device conditionality), contribute to off-label risk assessments, advise on acceptance and performance testing, and participate in MR safety governance.
- Consultant MRI Clinical Scientist: should demonstrate training and competence equivalent to the Higher Specialist Scientist standards of proficiency. Consultant-level scientists should be able to provide service leadership, lead MR safety policy, and contribute to organisational governance, supported by ongoing CPD. Consultant Clinical Scientists in NHS Wales must be on the Higher Specialist Scientific Register. Employing organisations in Wales need to follow these recommendations for action [236] for Consultant Clinical Scientist appointment in terms of job profile (e.g. Agenda for Change Band 8C) and professional development.

The IPEM MR SAFETY EXPERT Certificate of Competence requires a knowledge component (IBMRS MR SAFETY EXPERT exam [237] plus a portfolio of evidenced experience; the certificate is valid for 5

years with renewal via portfolio/CPD. IPEM's MR SAFETY EXPERT courses support learning but do not, by themselves, meet the knowledge requirement. More details can be found here [146]. When Clinical Scientists carry out duties within the scope of practice of an MR SAFETY EXPERT, the responsibility should be within a supervisory framework from an MR SAFETY EXPERT.

All roles should include regular safety refreshers, and documented competency reviews to ensure ongoing assurance of safe MR practice.

A3.5 Training Framework for Radiologists

MR safety is included in the FRCR Part 1 curriculum [238] and examinations, covering magnetic field hazards, bioeffects, and safety principles.

Consultant radiologists should maintain MR safety competence through ongoing CPD, annual appraisal, and participation in local MR safety governance and refresher training.

A3.6 Training for Referrers

Organisations should ensure that MR safety training forms part of the process by which referrers are authorised to request MRI examinations.

Training should be proportionate to the role and focus on:

- Local policies for scanning patients with implants, devices, or foreign bodies.
- The importance of accurately providing medical implanted devices and foreign bodies.
- How to advise patients with medical devices to contact the MRI department before attendance, if safety details are uncertain.
- Regular updates reflecting changes in local policy and national guidance.

A3.7 e-Learning for Healthcare (e-LfH) — MR Safety

The e-LfH MR Safety programme [239] provides nationally standardised, role-based online training aligned with the guidance and local MR safety roles (e.g. MR RESPONSIBLE PERSON: MR ENVIRONMENT / Non-MR ENVIRONMENT, Supervisor, Referrers and MRI Clinician).

It includes modules on MR safety principles, risk management, and managing patients undergoing general anaesthesia in the MRI unit. The programme can be used for induction and refresher training, and completion records can serve as evidence of compliance within organisational governance systems.

Appendix 4 Incidents to Report to the MHRA

A4.1 Device Failures (Adverse Incident)

The following issues if they result in, or may result in, direct or indirect harm to the patient or users:

- Burns and overheating
- Software errors
- Unexpected and/or serious artefacts (caused by MR system)
- Inadequate / inaccurate instructions for use
- Unexpected interactions between devices and the MR system:
    - Projectile incidents
    - Change of device function
- Cryogen and quench issues
- Noise issues
- Mechanical failures
- Contrast injector failures
    - Failure of contrast injector consumables.
- Indirect harm:
    - Misdiagnosis,
    - Delayed diagnosis,
    - Delayed treatment,
    - Inappropriate treatment,
    - Absence of treatment and
    - Transfusion of inappropriate materials.

Report online at Yellow Card.

A4.2 Defective Medicines

- issues with medicinal gasses
- failures of pre-filled syringes containing contrast agents.

Report online at Yellow Card.

A4.3 Side Effect with a Medicine (Adverse Drug Reaction)

- side effects from contrast agents.

Report online at Yellow Card.

Appendix 5 Example Labels

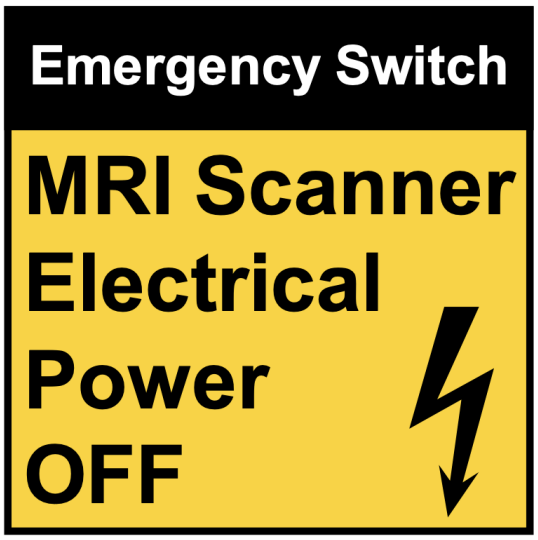
Table A5.1 shows examples of typical labels for equipment within an MRI unit.

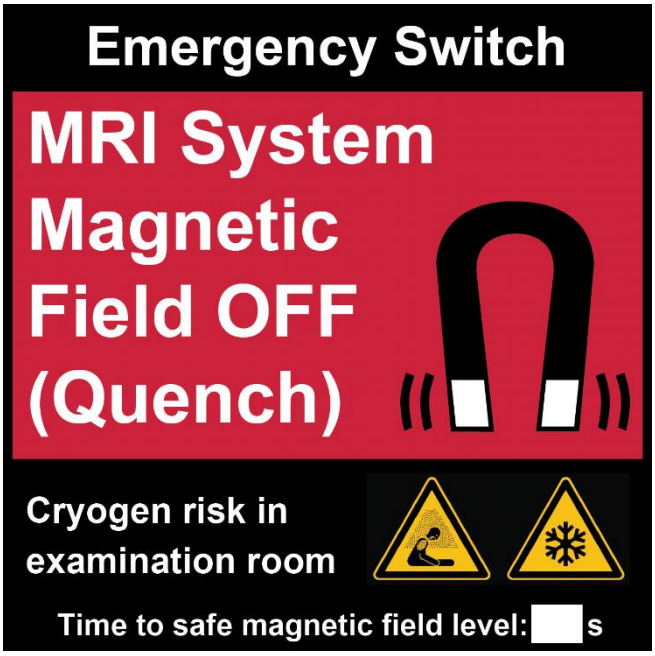
Table A5.1 Typical labels

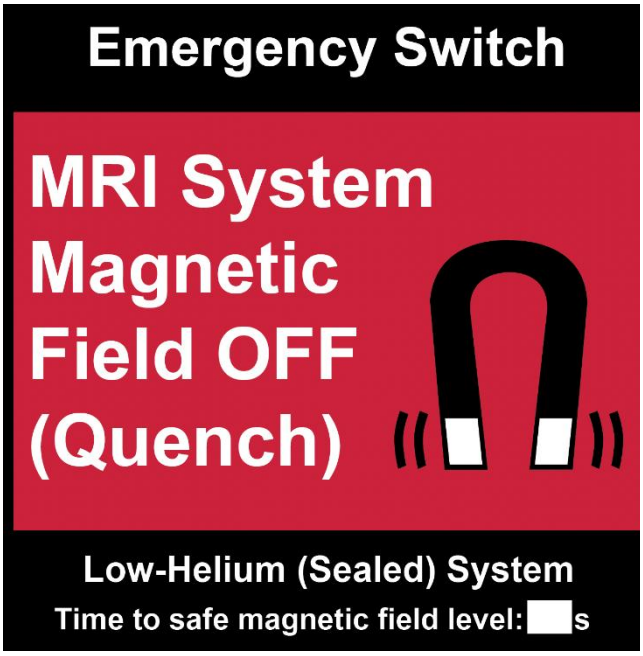
	
	

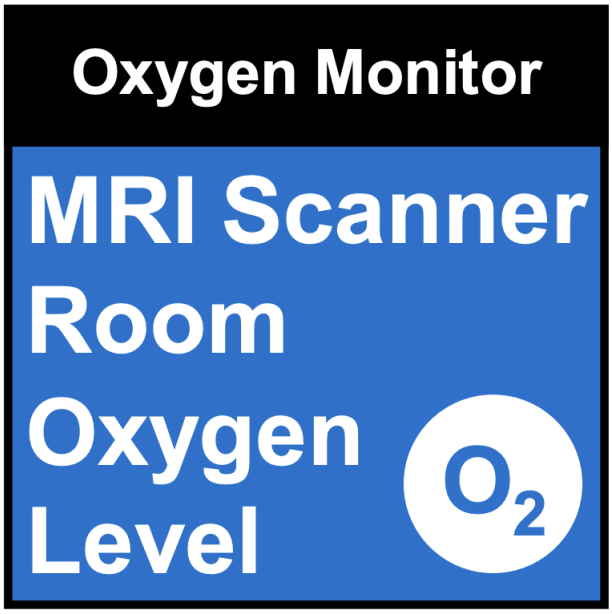
Table A5.2 show examples of signage developed by IPEM which can be used in MRI units. High quality versions are available from IPEM

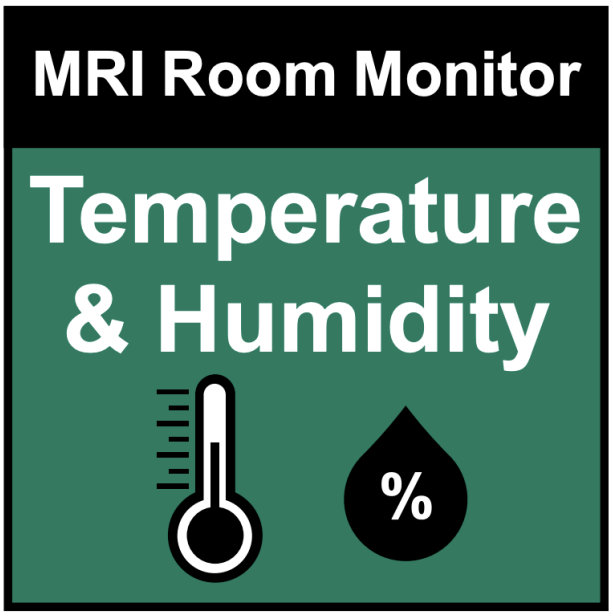
Table A5.2 IPEM signage








Oxygen Monitor
MRI Scanner Room Oxygen Level
O2


MRI Room Monitor
Temperature & Humidity
%

Appendix 6 Relevant Websites

Name	Site
Association of Anaesthetists	https://anaesthetists.org/
British Association of MR Radiographers (BAMRR)	www.bamrr.org
British Institute of Radiology (BIR)	www.bir.org.uk
British Standards Institute (BSI)	www.bsigroup.com
Department of Health and Social Care (DH)	www.gov.uk/government/organisations/department-of-health-and-social-care
Department of Health for Northern Ireland (DoH)	www.health-ni.gov.uk
European Committee for Electrotechnical Standardization (CENELEC)	www.cencenelec.eu
Food and Drug Administration (FDA)	www.fda.gov
Health Facilities Scotland	www.nss.nhs.scot/departments/health-facilities-scotland
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.org
International Electrotechnical Commission (IEC)	www.iec.ch
International Organization for Standardization (ISO)	www.iso.org
International Radiation Protection Association (IRPA)	www.irpa.net
International Society of Magnetic Resonance in Medicine (ISMRM)	www.ismrm.org
Medicines and Healthcare products Regulatory Agency (MHRA)	www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
NHS Supply Chain	www.supplychain.nhs.uk
NHS in Wales	www.nhs.wales
Royal College of Radiologists (RCR)	www.rcr.ac.uk
Society and College of Radiographers	www.sor.org

Sites last checked September 2025

7 References

1 UK Parliament. Health and Safety at Work etc. Act 1974. 1974 c.37 [Internet]. 1974 Jul. Available from: https://www.legislation.gov.uk/ukpga/1974/37/

2 UK Parliament. Health and Safety at Work (Northern Ireland) Order 1978. 1978 No. 1039 / N.I. 9 [Internet]. 1974 Jul. Available from: https://www.legislation.gov.uk/nisi/1978/1039/

3 UK Parliament. The Management of Health and Safety at Work Regulations 1999. SI1999/3242 [Internet]. 1999 Dec. Available from: https://www.legislation.gov.uk/uksi/1999/3242/

4 Northern Ireland Assembly. Management of Health and Safety at Work Regulations (Northern Ireland) 2000. NISR2000/388 [Internet]. 2000 Dec. Available from: https://www.legislation.gov.uk/nisr/2000/388/

5 UK Parliament. The Control of Electromagnetic Fields at Work Regulations 2016. SI2016/588 [Internet]. Statute Law Database; 2016 Jul. Available from: https://www.legislation.gov.uk/uksi/2016/588/

6 Northern Ireland Assembly. The Control of Electromagnetic Fields at Work Regulations (Northern Ireland) 2016. NISR2016/266 [Internet]. Statute Law Database; 2016 Aug. Available from: https://www.legislation.gov.uk/nisr/2016/266/

7 UK Parliament. The Control of Noise at Work Regulations 2005. SI2005/1643 [Internet]. 2006 Apr. Available from: https://www.legislation.gov.uk/uksi/2005/1643/

8 Northern Ireland Assembly. The Control of Noise at Work Regulations (Northern Ireland) 2006. NISR2006/1 [Internet]. Statute Law Database; 2006 Jan. Available from: https://www.legislation.gov.uk/nisr/2006/1/

9 UK Parliament. National Health Service Act 2006 [Internet]. legislation.gov.uk; 2006 Nov 8. Available from: https://www.legislation.gov.uk/ukpga/2006/41/

10 Department of Health and Social Care. The NHS Constitution for England [Internet]. GOV.UK; 2023. Available from: https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england

11 UK Parliament. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. SI2014/2936 [Internet]. 2014 Nov 6. Available from: https://www.legislation.gov.uk/uksi/2014/2936/contents/made

12 UK Parliament. National Health Service (Scotland) Act 1978. ukpga1978/29 [Internet]. Available from: https://www.legislation.gov.uk/ukpga/1978/29/contents

13 Scottish Parliament. Patient Rights (Scotland) Act 2011. ASP2011/5 [Internet]. 2011 Mar. Available from: https://www.legislation.gov.uk/asp/2011/5/

14 Scottish Parliament. Public Services Reform (Scotland) Act 2010. 2010/asp8 [Internet]. 2010 Apr. Available from: https://www.legislation.gov.uk/asp/2010/8/contents

15 Scottish Government. Health and Social Care Standards: my support, my life [Internet]. The Scottish Government; 2017. Available from: https://www.gov.scot/publications/health-social-care-standards-support-life/documents/

16 UK Parliament. National Health Service (Wales) Act 2006 [Internet]. legislation.gov.uk; 2006 Nov 8. Available from: https://www.legislation.gov.uk/ukpga/2006/42/

17 Senedd Cymru. Health and Social Care (Quality and Engagement) (Wales) Act. 2020/asc1 [Internet]. 2020 Jun. Available from: https://www.legislation.gov.uk/asc/2020/1/contents

18 National Assembly for Wales. The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. SI2011/704 / W. 108 [Internet]. 2011 Mar. Available from: https://www.legislation.gov.uk/wsi/2011/704/contents/made

19 Welsh Government. NHS Wales complaints and concerns: Putting Things Right [Internet]. 9/92025 [cited 2026 Apr 17]. NHS Wales complaints and concerns: Putting Things Right. Available from: https://www.gov.wales/nhs-wales-complaints-and-concerns-putting-things-right

20 National Assembly for Wales. Regulation and Inspection of Social Care (Wales) Act 2016. 2016/anaw2 [Internet]. 2016 Jan. Available from: https://www.legislation.gov.uk/anaw/2016/2/contents

21 Northern Ireland Assembly. The Health and Social Care (Reform) Act (Northern Ireland) 2009 [Internet]. legislation.gov.uk; 2009 Jan 21. Available from: https://www.legislation.gov.uk/nia/2009/1

22 Northern Ireland Assembly. The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003. 2003 No. 431 / N.I. 9 [Internet]. 2003 Feb. Available from: https://www.legislation.gov.uk/nisi/2003/431/contents/made

23 HSE. Essentials of Health and Safety at Work. 4th edn. HSE; 2006.
24 United Kingdom Government. Medical Devices Regulations 2002 [Internet]. London, United Kingdom: The Stationery Office; 2002. Available from: https://www.legislation.gov.uk/uksi/2002/618/contents
25 European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices [Internet]. Brussels, Belgium: Official Journal of the European Union; 2017. Available from: https://eur-lex.europa.eu/eli/reg/2017/745/oj
26 UK Parliament. The Provision and Use of Work Equipment Regulations 1998. SI1998/2306 [Internet]. 1998 Dec. Available from: https://www.legislation.gov.uk/uksi/1998/2306/
27 UK Parliament. Provision and Use of Work Equipment Regulations (Northern Ireland) 1999. NISR1999/305 [Internet]. 1999 Sep. Available from: https://www.legislation.gov.uk/nisr/1999/305/
28 UK Parliament. The Manual Handling Operations Regulations 1992. SI1992/2793 [Internet]. 1992 Dec. Available from: https://www.legislation.gov.uk/uksi/1992/2793/
29 UK Parliament. The Manual Handling Operations Regulations (Northern Ireland) 1992. NISR1992/535 [Internet]. 1992. Available from: https://www.legislation.gov.uk/uksi/1992/2793/
30 UK Parliament. The Workplace (Health, Safety and Welfare) Regulations 1992. SI1992/3004 [Internet]. 1992. Available from: https://www.legislation.gov.uk/uksi/1992/3004/
31 UK Parliament. The Workplace (Health, Safety and Welfare) Regulations (Northern Ireland) 1993. NISR1993/37 [Internet]. 1993 Feb. Available from: https://www.legislation.gov.uk/nisr/1993/37
32 UK Parliament. The Health and Safety (Display Screen Equipment) Regulations 1992. SI1992/2792 [Internet]. 1992 Dec. Available from: https://www.legislation.gov.uk/uksi/1992/2792/
33 UK Parliament. The Health and Safety (Display Screen Equipment) Regulations (Northern Ireland) 1992. NISR1992/513 [Internet]. 1992 Dec. Available from: https://www.legislation.gov.uk/nisr/1992/513
34 UK Parliament. The Personal Protective Equipment at Work Regulations 1992. SI1992/2966 [Internet]. 1992 Dec. Available from: https://www.legislation.gov.uk/uksi/1992/2966/
35 UK Parliament. The Personal Protective Equipment at Work Regulations (Northern Ireland) 1993. NISR1993/20 [Internet]. 1993 Jan. Available from: https://www.legislation.gov.uk/nisr/1993/20
36 UK Parliament. The Electricity at Work Regulations 1989. SI1989/635 [Internet]. 1990 Apr. Available from: https://www.legislation.gov.uk/uksi/1989/635/
37 UK Parliament. The Electricity at Work Regulations (Northern Ireland) 1991. NISR1991/13 [Internet]. 1991 Jan. Available from: https://www.legislation.gov.uk/uksi/1989/635/
38 UK Parliament. The Control of Substances Hazardous to Health Regulations 2002. SI2002/2677 [Internet]. 2002 Nov. Available from: https://www.legislation.gov.uk/uksi/2002/2677/
39 Northern Ireland Assembly. The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2002. NISR2003/34 [Internet]. 2003 Jan. Available from: https://www.legislation.gov.uk/nisr/2003/34/
40 UK Parliament. The Pressure Systems Safety Regulations 2000. SI2000/128 [Internet]. 2000 Jan. Available from: https://www.legislation.gov.uk/uksi/2000/128/contents/made
41 UK Parliament. The Health and Safety (First-Aid) Regulations 1981. SI1981/917 [Internet]. 1982 Jul. Available from: https://www.legislation.gov.uk/uksi/1981/917/
42 UK Parliament. The Health and Safety (First-Aid) Regulations (Northern Ireland) 1982. NISR1982/429 [Internet]. 1982 Dec. Available from: https://www.legislation.gov.uk/id/nisr/1982/429
43 HSE. Moving and handling in health and social care - HSE [Internet]. 2026 [cited 2026 Mar 10]. Available from: https://www.hse.gov.uk/healthservices/moving-handling/manage-the-risk.htm
44 HSE. Protecting pregnant workers and new mothers - HSE [Internet]. 2026 [cited 2026 Mar 10]. Available from: https://www.hse.gov.uk/mothers/
45 HSE. Stress and mental health at work - HSE [Internet]. 2025 [cited 2025 Dec 22]. Available from: https://www.hse.gov.uk/stress/index.htm
46 HSE. Violence and aggression at work - HSE [Internet]. 2025 [cited 2025 Dec 22]. Available from: https://www.hse.gov.uk/violence/index.htm
47 HSE. Protecting lone workers: How to manage the risks of working alone [Internet]. 4th edn. 2020. Available from: https://www.hse.gov.uk/pubns/indg73.htm
48 The Royal College of Radiologists, The College of Radiographers. Quality Standard for Imaging [Internet]. 2024. Available from: https://www.rcr.ac.uk/media/ertlfuth/250508_qsi_standards-2024-v6-1.pdf

49 The Royal College of Radiologists. Quality Standard for Imaging Quality Mark (QSI) | The Royal College of Radiologists [Internet]. [cited 2025 Dec 9]. Available from: https://www.rcr.ac.uk/our-services/management-service-delivery/quality-standard-for-imaging-qsi/quality-standard-for-imaging-qsi-quality-mark/
50 The United Kingdom Accreditation Service (UKAS). www.ukas.com
51 BS 70000:2017 Medical physics, clinical engineering and associated scientific services in healthcare. Requirements for quality, safety and competence https://knowledge.bsigroup.com/products/medical-physics-clinical-engineering-and-associated-scientific-services-in-healthcare-requirements-for-quality-safety-and-competence
52 UKAS accreditation for Diagnostic Imaging Services Imaging Services Accreditation
53 ACR Committee on MR Safety. ACR Manual on MR Safety [Internet]. American College of Radiology; 2024. Available from: https://edge.sitecorecloud.io/americancoldf5f-acrorgf92a-productioncb02-3650/media/ACR/Files/Clinical/Radiology-Safety/Manual-on-MR-Safety.pdf
54 ASTM. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. 2026. doi:10.1520/F2503-26
55 IEC. Standard practice for marking medical devices and other items for safety in the magnetic resonance environment [Internet]. 2025. Available from: https://webstore.iec.ch/en/publication/105574
56 ASTM. Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants. 2024. doi:10.1520/F2119-24
57 BS EN ISO 14971:2019+A11:2021 Medical devices. Application of risk management to medical devices. https://knowledge.bsigroup.com/products/medical-devices-application-of-risk-management-to-medical-devices-5
58 McRobbie DW. Essentials of MRI Safety [Internet]. John Wiley & Sons, Ltd.; 2020. Available from: https://doi.org/10.1002/9781394322169
59 Schenck JF. Physical interactions of static magnetic fields with living tissues. Prog Biophys Mol Biol. 2005 Mar;87(2–3):185–204. doi:10.1016/j.pbiomolbio.2004.08.009.
60 Siemens Healthcare GmbH. System Owner Manual – MAGNETOM Avantofit. 2018. Print No. M6-02402G.629.07.02.02.
61 Chen D. Boy, 6, Dies Of Skull Injury During M.R.I. New York Times [Internet]. 2001 Jul 31. Available from: https://www.nytimes.com/2001/07/31/nyregion/boy-6-dies-of-skull-injury-during-mri.html
62 Agence France-Presse. Man dies after being sucked into MRI scanner at Indian hospital. The Guardian [Internet]. 2018 Jan 30 [cited 2025 Dec 22]. Available from: https://www.theguardian.com/world/2018/jan/30/mri-scanner-india-death
63 Madden Yee K. Oxygen cylinder kills South Korean man in MRI accident. Aunt Minnie [Internet]. 2021 Oct 17 [cited 2025 Dec 22]. Available from: https://www.auntminnie.com/clinical-news/mri/article/15629448/oxygen-cylinder-kills-south-korean-man-in-mri-accident
64 Halpert M. Man wearing heavy metallic necklace dies after being sucked into MRI machine. BBC News [Internet]. 2025 Jul 21. Available from: https://www.bbc.co.uk/news/articles/cx2n39dvp0po
65 Aunt Minne Staff Writers. MRI accident in India injures 2 employees. Aunt Minnie [Internet]. 2014 Nov 10 [cited 2025 Dec 22]. Available from: https://www.auntminnie.com/clinical-news/mri/article/15610888/mri-accident-in-india-injures-2-employees
66 Ward P. Police report reveals mystery of vest in Swedish MRI case. Aunt Minnie [Internet]. 2020 Mar 12. Available from: https://www.auntminnieeurope.com/medical-legal-and-practice/article/15654342/police-report-reveals-mystery-of-vest-in-swedish-mri-case
67 Hales H. Nurse crushed in MRI machine freak accident. The Independent [Internet]. 2023 Nov 3. Available from: https://www.independent.co.uk/news/world/americas/mri-machine-nurse-crushed-accident-b2441370.html
68 ICNIRP. Guidelines on Limits of Exposure to Static Magnetic Fields. Health Phys. 2009 Apr;96(4):504–14. doi:10.1097/01.HP.0000343164.27920.4a
69 ICNIRP. Medical Magnetic Resonance (MR) Procedures: Protection of Patients. Health Phys. 2004 Aug;87(2):197–216. doi:10.1097/00004032-200408000-00008
70 Glover PM, Cavin I, Qian W, Bowtell R, Gowland PA. Magnetic-field-induced vertigo: a theoretical and experimental investigation. Bioelectromagnetics. 2007 Apr 11;28:349–61. doi:10.1002/bem.20316

71 Roberts DC, Marcelli V, Gillen JS, Carey JP, Della Santina CC, Zee DS. MRI Magnetic Field Stimulates Rotational Sensors of the Brain. Curr Biol. 2011 Oct 11;21(19):1635–40. doi:10.1016/j.cub.2011.08.029
72 ICNIRP. Guidelines for Limiting Exposure to Electric Fields Induced by Movement of the Human Body in a Static Magnetic Field and by Time-Varying Magnetic Fields below 1 Hz. Health Phys. 2014 Mar;106(3):418–25. doi:10.1097/HP.0b013e31829e5580
73 Casale J, Browne T, Murray IV, Gupta G. Physiology, Vestibular System [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. Available from: https://www.ncbi.nlm.nih.gov/books/NBK532978/
74 Kraff O, Quick HH. Chapter 3: MRI Physics and Safety at 7 Tesla. In: MRI Bioeffects, Safety, and Patient Management: Second Edition - Hardcover. 2nd edn. Biomedical Research Publishing Group; 2022.
75 ICNIRP. ICNIRP Statement on Diagnostic Devices Using Non-ionizing Radiation: Existing Regulations and Potential Health Risks. Health Phys. 2017 Mar;112(3):305–21. doi:10.1097/HP.0000000000000654
76 ICNIRP. Guidelines for Limiting Exposure to Time-varying Electric and Magnetic Fields (1 Hz to 100 kHz). Health Phys. 2010 Dec;99(6):818–36. doi:10.1097/HP.0b013e3181f06c86
77 IEC. Medical Electrical Equipment. 60601 Part 2-33, Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis [Internet]. Geneva, Switzerland: International Electrotechnical Commission; 2022. Available from: https://webstore.iec.ch/en/publication/67211
78 McRobbie DW. Chapter 4: Bio-effects 2: time-varying gradient fields. In: Essentials of MRI Safety [Internet]. John Wiley & Sons, Ltd.; 2020 [cited 2025 Dec 22]. p. 79–106. Available from: https://doi.org/10.1002/9781394322169.ch4 doi:10.1002/9781394322169.ch4
79 BS EN 352-1:2020 Hearing protectors. General requirements - Earmuffs
80 NEMA. Acoustic Noise Measurement Procedure for Magnetic Resonance Imaging Devices [Internet]. National Electrical Manufacturers Association; 2024. Available from: https://www.nema.org/standards/view/Acoustic-Noise-Measurement-Procedure-for-Diagnostic-Magnetic-Resonance-Imaging-Devices
81 Steckner M. A Review of MRI Acoustic Noise Outputs and Hearing Protection Device Performance. J Magn Reson Imaging. 2025 May 1;61(5):2083–93. doi:10.1002/jmri.29665
82 Mehrotra A, Shukla SP, Shukla AK, Manar MK, Singh SK, Mehrotra M. A Comprehensive Review of Auditory and Non-Auditory Effects of Noise on Human Health. Noise Health [Internet]. 2024;26(121). Available from: https://journals.lww.com/nohe/fulltext/2024/26210/a_comprehensive_review_of_auditory_and.1.aspx
83 Le TN, Straatman LV, Lea J, Westerberg B. Current insights in noise-induced hearing loss: a literature review of the underlying mechanism, pathophysiology, asymmetry, and management options. J Otolaryngol - Head Neck Surg. 2017 May 23;46(1):41. doi:10.1186/s40463-017-0219-x
84 Muluk NB, Oguztürk O. Occupational noise-induced tinnitus: does it affect workers' quality of life? J Otolaryngol - Head Neck Surg J Oto-Rhino-Laryngol Chir Cervico-Faciale. 2008 Feb;37(1):65–71. PubMed PMID: 18479630.
85 Natarajan N, Batts S, Stankovic KM. Noise-Induced Hearing Loss. J Clin Med. 2023;12(6):2347. doi:10.3390/jcm12062347
86 Zaman M, Muslim M, Jehangir A. Environmental noise-induced cardiovascular, metabolic and mental health disorders: a brief review. Environ Sci Pollut Res. 2022 Nov 1;29(51):76485–500. doi:10.1007/s11356-022-22351-y
87 ICNIRP. Guidelines for Limiting Exposure to Electromagnetic Fields (100 kHz to 300 GHz). Health Phys. 2020 May;118(5):483–524. doi:10.1097/HP.0000000000001210
88 Foster KR, Ziskin MC, Balzano Q. Time-temperature Thresholds and Safety Factors for Thermal Hazards from Radiofrequency Energy above 6 GHz. Health Phys. 2021;121(3):234–47. doi:10.1097/HP.0000000000001447
89 HPA. Protection of Patients and Volunteers Undergoing MRI Procedures. Health Protection Agency Centre for Radiation, Chemical and Environmental Hazards: Health Protection Agency (HPA); 2008 Aug. Report RCE-7
90 World Health Organization. Environmental Health Criteria 232: Static Fields. Geneva: World Health Organization, 2006.

91 IEEE. IEEE Standard for Safety Levels with Respect to Human Exposure to Electric, Magnetic, and Electromagnetic Fields, 0 Hz to 300 GHz. IEEE Std C951-2019 Revis IEEE Std C951-2005 Inc IEEE Std C951-2019Cor 1-2019. 2019 Oct 4;1–312. doi:10.1109/IEEESTD.2019.8859679
92 Shellock FG, Crues JV. MR procedures: biologic effects, safety, and patient care. Radiology. 2004 Sep;232(3):635–52. doi:10.1148/radiol.2323030830 PubMed PMID: 15284433.
93 van Rhoon GC, Samaras T, Yarmolenko PS, Dewhirst MW, Neufeld E, Kuster N. CEM43°C thermal dose thresholds: a potential guide for magnetic resonance radiofrequency exposure levels? Eur Radiol. 2013 Aug 1;23(8):2215–27. doi:10.1007/s00330-013-2825-y
94 ASTM. Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging. ASTM; 2020. doi:10.1520/F2182-19E02
95 Dempsey MF, Condon B. Thermal injuries associated with MRI. Clin Radiol. 2001 Jun;56(6):457–65. doi:10.1053/crad.2000.0688 PubMed PMID: 11428795
96 Baker KB, Tkach JA, Nyenhuis JA, Phillips M, Shellock FG, Gonzalez-Martinez J, et al. Evaluation of specific absorption rate as a dosimeter of MRI-related implant heating. J Magn Reson Imaging. 2004 Aug 1;20(2):315–20. doi:10.1002/jmri.20103
97 Hand JW. Modelling the interaction of electromagnetic fields (10 MHz–10 GHz) with the human body: methods and applications. Phys Med Biol. 2008;53(16):R243. doi:10.1088/0031-9155/53/16/R01
98 ISO. ISO/TS 10974:2018(E). Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device. Edition 2.0. Geneva, Switzerland: International Organisation for Standardization; 2018. Located at: WorldCat
99 Winter L, Seifert F, Zilberti L, Murbach M, Ittermann B. MRI-Related Heating of Implants and Devices: A Review. J Magn Reson Imaging. 2021 Jun 1;53(6):1646–65. doi:10.1002/jmri.27194
100 Al-Dayeh L, Rahman M, Venook R. Practical Aspects of MR Imaging Safety Test Methods for MR Conditional Active Implantable Medical Devices. MR Saf. 2020 Nov 1;28(4):559–71. doi:10.1016/j.mric.2020.07.008
101 BSI. BS EN 45502-2-1:2003 Active implantable medical devices. Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers). BSI; 2004.
102 BSI. BS EN 45502-2-2:2008 Active implantable medical devices. Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators). BSI; 2008.
103 Winter L, Seifert F, Zilberti L, Murbach M, Ittermann B. MRI-Related Heating of Implants and Devices: A Review. J Magn Reson Imaging. 2021 Jun;53(6):1646–65. doi:10.1002/jmri.27194
104 Neufeld E, Kuster N. Systematic Derivation of Safety Limits for Time-Varying 5G Radiofrequency Exposure Based on Analytical Models and Thermal Dose. Health Phys [Internet]. 2018;115(6). Available from: https://journals.lww.com/health-physics/fulltext/2018/12000/systematic_derivation_of_safety_limits_for.17.aspx
105 Chartier AL, Bouvier MJ, McPherson DR, Stepenosky JE, Taysom DA, Marks RM. The Safety of Maternal and Fetal MRI at 3 T. Am J Roentgenol. 2019 Nov 1;213(5):1170–3. doi:10.2214/AJR.19.21400
106 Tocchio S, Kline-Fath B, Kanal E, Schmithorst VJ, Panigrahy A. MRI evaluation and safety in the developing brain. Semin Perinatol. 2015 Mar 1;39(2):73–104. doi:10.1053/j.semperi.2015.01.002
107 Little JT, Bookwalter CA. Magnetic Resonance Safety: Pregnancy and Lactation. Magn Reson Imaging Clin N Am. 2020 Nov 1;28(4):509–16. doi:10.1016/j.mric.2020.06.002
108 Rodegerdts EA, Grönewäller EF, Kehlbach R, Roth P, Wiskirchen J, Gebert R, et al. In Vitro Evaluation of Teratogenic Effects by Time-Varying MR Gradient Fields on Fetal Human Fibroblasts. J Magn Reson Imaging. 2000 Jul 1;12(1):150–6. doi:10.1002/1522-2586(200007)12:1<150::AID-JMRI16>3.0.CO;2-9
109 Knobel. Fetal and Neonatal Thermal Physiology. Newborn and Infant Nursing Reviews. Volume 14, Issue 2, June 2014, Pages 45-49. https://doi.org/10.1053/j.nainr.2014.03.003
110 Yetisir F, Abaci Turk E, Guerin B, Gagoski BA, Grant PE, Adalsteinsson E, et al. Safety and imaging performance of two-channel RF shimming for fetal MRI at 3T. Magn Reson Med. 2021 Nov 1;86(5):2810–21. doi:10.1002/mrm.28895
111 Yetisir F, Abaci Turk E, Adalsteinsson E, Wald LL, Grant PE. Local SAR management strategies to use two-channel RF shimming for fetal MRI at 3 T. Magn Reson Med. 2024 Mar 1;91(3):1165–78. doi:10.1002/mrm.29913

112 Murbach M, Neufeld E, Samaras T, Córcoles J, Robb FJ, Kainz W, et al. Pregnant women models analyzed for RF exposure and temperature increase in 3T RF shimmed birdcages. Magn Reson Med. 2017 May 1;77(5):2048–56. doi:10.1002/mrm.26268
113 HSE. Noise and the Foetus: A Critical Review of the Literature. HSE Books; 1994. (Research Reports; no. RR063).
114 HSE. Working safely with ionising radiation; Guidelines for expectant or breastfeeding mothers [Internet]. HSE; 2015. Available from: ww.hse.gov.uk/pubns/indg334.htm
115 Committee on Environmental Health. Noise: A Hazard for the Fetus and Newborn. Pediatrics. 1997 Oct 1;100(4):724–7. doi:10.1542/peds.100.4.724
116 Reeves MJ, Brandreth M, Whitby EH, Hart AR, Paley MNJ, Griffiths PD, et al. Neonatal Cochlear Function: Measurement after Exposure to Acoustic Noise during in Utero MR Imaging. Radiology. 2010 Dec 1;257(3):802–9. doi:10.1148/radiol.10092366
117 Strizek B, Jani JC, Mucyo E, De Keyzer F, Pauwels I, Ziane S, et al. Safety of MR Imaging at 1.5 T in Fetuses: A Retrospective Case-Control Study of Birth Weights and the Effects of Acoustic Noise. Radiology. 2015 May 1;275(2):530–7. doi:10.1148/radiol.14141382
118 Bouyssi-Kobar M, du Plessis AJ, Robertson RL, Limperopoulos C. Fetal magnetic resonance imaging: exposure times and functional outcomes at preschool age. Pediatr Radiol. 2015 Nov 1;45(12):1823–30. doi:10.1007/s00247-015-3408-7
119 Jaimes C, Delgado J, Cunnane MB, Hedrick HL, Adzick NS, Gee MS, et al. Does 3-T fetal MRI induce adverse acoustic effects in the neonate? A preliminary study comparing postnatal auditory test performance of fetuses scanned at 1.5 and 3 T. Pediatr Radiol. 2019 Jan 1;49(1):37–45. doi:10.1007/s00247-018-4261-2
120 Perez R, Priner R, Cohen D, Freeman S, Sohmer H. An Animal Model for Assessment of Amniotic Fluid Clearance from the Middle Ear. Otol Neurotol. 2002 Jan;23(1):29–33. doi:10.1097/00129492-200201000-00008
121 Ehman EC, Rossman PJ, Kruse SA, Sahakian AV, Glaser KJ. Vibration safety limits for magnetic resonance elastography. Phys Med Biol. 2008 Feb 21;53(4):925–35. doi:10.1088/0031-9155/53/4/007
122 Ray JG, Vermeulen MJ, Bharatha A, Montanera WJ, Park AL. Association Between MRI Exposure During Pregnancy and Fetal and Childhood Outcomes. JAMA. 2016 Sep 6;316(9):952–61. doi:10.1001/jama.2016.12126
123 ACR Committee on Drugs and Contrast Media. ACR Manual on Contrast Media [Internet]. ACR; 2025. Available from: https://www.acr.org/clinical-resources/clinical-tools-and-reference/contrast-manual
124 Flanagan E, Bell S. Abdominal Imaging in pregnancy (maternal and foetal risks). Best Pract Res Clin Gastroenterol. 2020 Feb 1;44–45:101664. doi:10.1016/j.bpg.2019.101664
125 Lum M, Tsiouris AJ. MRI safety considerations during pregnancy. Clin Imaging. 2020 Jun 1;62:69–75. doi:10.1016/j.clinimag.2020.02.007
126 Jabehdar Maralani P, Pai V, Ertl-Wagner BB. Safety of Magnetic Resonance Imaging in Pregnancy. Radiol. 2023 Nov 1;63(2):34–40. doi:10.1007/s00117-023-01207-7
127 Mervak BM, Altun E, McGinty KA, Hyslop WB, Semelka RC, Burke LM. MRI in pregnancy: Indications and practical considerations. J Magn Reson Imaging. 2019 Mar 1;49(3):621–31. doi:10.1002/jmri.26317
128 Wiles R, Hankinson B, Benbow E, Sharp A. Making decisions about radiological imaging in pregnancy. BMJ. 2022 Apr 25;377:e070486. doi:10.1136/bmj-2022-070486
129 Gatta G, Di Grezia G, Cuccurullo V, Sardu C, Iovino F, Comune R, et al. MRI in Pregnancy and Precision Medicine: A Review from Literature. J Pers Med. 2021 Dec 23;12(1). doi:10.3390/jpm12010009 PubMed PMID: 35055324; PubMed Central PMCID: PMC8778056.
130 Jabehdar Maralani P, Kapadia A, Liu G, Moretti F, Ghandehari H, Clarke SE, et al. Canadian Association of Radiologists Recommendations for the Safe Use of MRI During Pregnancy. Can Assoc Radiol J. 2022 Feb 1;73(1):56–67. doi:10.1177/08465371211015657
131 Choi JS, Ahn HK, Han JY, Han YJ, Kwak DO, Velazquez-Armenta EY, et al. A case series of 15 women inadvertently exposed to magnetic resonance imaging in the first trimester of pregnancy. J Obstet Gynaecol. 2015 Nov 17;35(8):871–2. doi:10.3109/01443615.2015.1017559

132 Prayer D, Malinger G, De Catte L, De Keersmaecker B, Gonçalves LF, Kasprian G, et al. ISUOG Practice Guidelines (updated): performance of fetal magnetic resonance imaging. Ultrasound Obstet Gynecol. 2023 Feb;61(2):278–87. doi:10.1002/uog.26129
133 Shellock FG, Crues, John V. Chapter 9: Screening Patients Before MR Procedure. In: MRI Bioeffects, Safety, and Patient Management: Second Edition. 2nd edn. Biomedical Research Publishing Group; 2022.
134 IEC. Medical Electrical Equipment. Part 2-33, Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis. Edition 2.0. Geneva, Switzerland: International Electrotechnical Commission; 2002. 183 p.
135 British Institute of Radiology. MRI Risk Assessments Templates [Internet]. 2025 [cited 2025 Nov 5]. Available from: https://www.bir.org.uk/get-involved/special-interest-groups/bir-magnetic-resonance/risk-assessments.aspx
136 European Parliament. Directive 2013/35/EU of the European Parliament and of the Council. 2013/35/EU [Internet]. 2013 Jun. Available from: https://www.legislation.gov.uk/eudr/2013/35/
137 HSE CEMFAW Regulations. Certificate of exemption No.1 of 2026. https://www.hse.gov.uk/radiation/assets/docs/emf-exemption-certificate.pdf
138 HSE. Electromagnetic fields at work: A guide to the Control of Electromagnetic Fields at Work Regulations 2016 [Internet]. 1st edn. 2016. Available from: https://www.hse.gov.uk/pubns/priced/hsg281.pdf
139 Bainbridge A, Keevil S. MRI and the control of electromagnetic fields at work regulations 2016 – professional body guidance. Br J Radiol. 2023 Nov;96(1151):20220692. doi:10.1259/bjr.20220692
140 Steckner MC, Grainger D, Charles-Edwards G. Transitioning from 0.5 to 0.9mT: Protecting Against Inadvertent Activation of Magnet Mode in Active Implants. Magn Reson Med. 2024 Nov;92(5):2237–45. doi:10.1002/mrm.30153
141 HSE. The Control of Electromagnetic Fields at Work Regulations - HSE [Internet]. [cited 2025 Nov 5]. Available from: https://www.hse.gov.uk/radiation/nonionising/emf-regulations.htm
142 HSE. Controlling noise at work. 3rd edn. HSE; 2021.
143 HSE. A step by step guide to COSHH assessment [Internet]. 2nd edn. HSE; 2004. Available from: https://www.hse.gov.uk/pubns/priced/hsg97.pdf
144 International Electrotechnical Commission. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance [Internet]. IEC 60601-1:2005+A1:2012+A2:2020 (Consolidated), editor. 2020. Available from: https://webstore.iec.ch/publication/67497
145 Kershaw L, McLean J, Wilson D. Position Statement: Scientific Safety Advice to Magnetic Resonance Imaging Units that Undertake Human Imaging [Internet]. 2023 [cited 2025 Nov 5]. Available from: https://www.ipem.ac.uk/media/0hyj1rrv/2023-position-statement-mri-units-that-undertake-human-imaging.pdf
146 IPEM. MRSE Certificate of Competence - IPEM [Internet]. [cited 2025 Nov 5]. Available from: https://www.ipem.ac.uk/your-career/professional-registration/mrse-certificate-of-competence/
147 Ipem. Policy Statement: The role of the Clinical Scientist in Magnetic Resonance Imaging the-role-of-the-clinical-scientist-in-magnetic-resonance-imaging_june-2023.pdf
148 HCPC. Professional standards: https://www.hcpc-uk.org/standards/
149 Multi-professional working group. Guidance for the planning of new MRI installations [Internet]. 2026 [cited 2026 Mar 3]. Available from: https://www.ipem.ac.uk/resources/mri/mr-installation-guidance/
150 British Standards Institution. Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis [Internet]. BS EN IEC 60601-2-33:2024, editor. 2024. Available from: https://knowledge.bsigroup.com/products/medical-electrical-equipment-particular-requirements-for-the-basic-safety-and-essential-performance-of-magnetic-resonance-equipment-for-medical-diagnosis-4
151 Condon B, Hadley DM, Hodgson R. The Ferromagnetic Pillow: a Potential MR Hazard not Detectable by a Hand-held Magnet. Br J Radiol. 2001 Sep;74(885):847–51. doi:10.1259/bjr.74.885.740847 PubMed PMID: 11560834.
152 UK Parliament. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data (United Kingdom General Data Protection Regulation) [Internet].

679. King's Printer of Acts of Parliament; 2016. Available from: https://www.legislation.gov.uk/eur/2016/679/2025-08-20
153 The Society and College of Radiographers (SCOR). SoR [Internet]. 2019 [cited 2025 Dec 5]. Safety in Magnetic Resonance Imaging. Available from: https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/policy-guidance-document-library/safety-in-magnetic-resonance-imaging
154 The Royal College of Radiologists (RCR), British Society of Skeletal Radiologists (BSSR), Institute of Physics and Engineering in Medicine (IPEM), British Society of Neuroradiologists (BSNR), Society of Radiographers (SoR). MRI provision for cauda equina syndrome [Internet]. 2023 [cited 2026 Mar 3]. Available from: https://www.rcr.ac.uk/our-services/all-our-publications/clinical-radiology-publications/mri-provision-for-cauda-equina-syndrome/
155 Steckner MC, Ashmore J, Charles-Edwards G, Grainger D, Graves MJ, Jones E, et al. Commentary: The MRI scanner room door is a latent safety issue. Magn Reson Mater Phys Biol Med. 2025 Dec 22. doi:10.1007/s10334-025-01310-x
156 UK Parliament. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) (EU Exit) Regulations 2021 [Internet]. King's Printer of Acts of Parliament; 2021. Available from: https://www.legislation.gov.uk/uksi/2021/1370/contents/made
157 Speight R, Dubec M, Eccles CL, George B, Henry A, Herbert T, et al. IPEM Topical Report: Guidance on the Use of MRI for External Beam Radiotherapy Treatment Planning. Phys Med Biol. 2021 Feb 25;66(5). doi:10.1088/1361-6560/abdc30 PubMed PMID: 33450742.
158 Fagan AJ, Bitz A, Björkman-Burtscher IM, Collins CM, Kimbrell V, Raaijmakers AJE. 7T MR Safety. J Magn Reson Imaging. 2021;53(2):333–46. 7T MR Safety - Fagan - 2021 - Journal of Magnetic Resonance Imaging - Wiley Online Library
159 Shellock FG, Rosen MS, Webb A, Kimberly WT, Rajan S, Nacev AN, et al. Managing Patients With Unlabeled Passive Implants on MR Systems Operating Below 1.5 T. J Magn Reson Imaging JMRI. 2024 May;59(5):1514–22. doi:10.1002/jmri.29002 PubMed PMID: 37767980.
160 Wang Y, Wu P, Wang W, Wang H, Chen S, Sun J, et al. Cryogen-free superconducting magnetic resonance imaging system: A review. Fundam Res. 2025 May;S2667325825002250. doi:10.1016/j.fmre.2025.05.006
161 UK Government. The Ionising Radiation (Medical Exposure) Regulations 2017 [Internet]. legislation.gov.uk; 2017 Feb 6. Available from: https://www.legislation.gov.uk/uksi/2017/132/contents
162 UK Government. The Ionising Radiations Regulations 2017 [Internet]. legislation.gov.uk; 2017 Apr 6. Available from: https://www.legislation.gov.uk/uksi/2017/1075/contents
163 Tijssen RHN, Philippens MEP, Paulson ES, Glitzner M, Chugh B, Wetscherek A, et al. MRI commissioning of 1.5T MR-linac systems – a multi-institutional study. Radiother Oncol. 2019 Mar 1;132:114–20. doi:10.1016/j.radonc.2018.12.011
164 Exemptions from Exposure Limits in the Control of Electromagnetic Fields at Work Regulations - HSE [Internet]. [cited 2025 Nov 5]. Available from: https://www.hse.gov.uk/radiation/nonionising/emf-exemptions.htm
165 Haifley KA, Hecht S. Functionality of Implanted Microchips Following Magnetic Resonance Imaging. J Am Vet Med Assoc. 2012 Mar 1;240(5):577–9. doi:10.2460/javma.240.5.577
166 Piesnack S, Frame ME, Oechtering G, Ludewig E. Functionality of Veterinary Identification Microchips Following Low- (0.5 Tesla) and High-field (3 Tesla) Magnetic Resonance Imaging. Vet Radiol Ultrasound. 2013 Jun 13;54(6):618–22. doi:10.1111/vru.12057 PubMed PMID: 23763334.
167 Lichtenauer EA, Santifort KM, Bergknut N, van Soens I, Beukers M, Carrera I. Case report: Radiofrequency-induced Thermal Burn Injury in a Dog after Magnetic Resonance Imaging. Front Vet Sci. 2024 May 13;11. doi:10.3389/fvets.2024.1364635
168 The Society of Radiographers. Position-Statement-The-use-of-virtual-support-technology-(VST)-in-Computed-Tomography-(CT)-and-M [Internet]. The Society of Radiographers; 2025 [cited 2025 Nov 28]. Report Position statement. Available from: https://www.sor.org/getmedia/36995dc0-216f-4cf8-82f2-9dd48c44d410/Position-Statement-The-use-of-virtual-support-technology-(VST)-in-Computed-Tomography-(CT)-and-Magnetic-Resonance-Imaging-(MRI)_D1-3
169 The Society of Radiographers. Guiding principles for departments implementing virtual support technology (VST) in Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) [Guiding principles] [Internet]. The Society of Radiographers; 2025. Available from:

https://www.sor.org/getmedia/df619153-f7b7-4367-85a3-97617680999e/Guiding-principles-for-implementing-VST-in-CT-and-MRI-D1-4
170 The Royal College of Radiologists. Implementing Ordercomms (Electronic Requesting) in Radiology [Internet]. 2022. Available from: https://www.rcr.ac.uk/our-services/all-our-publications/clinical-radiology-publications/implementing-ordercomms-electronic-requesting-in-radiology/
171 Reeder SB, Kimbrell V, Owman T, Steckner M, Calamante F. Guidelines for Documentation and Consent for Nonclinical, Nonresearch MRI in Human Subjects. J Magn Reson Imaging JMRI. 2017 Jan;45(1):36–41. doi:10.1002/jmri.25333 PubMed PMID: 27312969; PubMed Central PMCID: PMC5164877.
172 Health Protection Agency. Protection of Patients and Volunteers Undergoing MRI Procedures. 2008. (Documents of the Health Protection Agency Radiation, Chemical and Environmental Hazards). Report nos: 978-0-85951-623–5.
173 The Royal College of Radiologists. Management of Incidental Findings Detected During Research Imaging [Internet]. 2011. Available from: https://www.rcr.ac.uk/our-services/all-our-publications/clinical-radiology-publications/management-of-incidental-findings-detected-during-research-imaging/
174 Health Research Authority. Governance Arrangements for Research Ethics Committees [Internet]. 2020. Available from: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/governance-arrangements-research-ethics-committees/
175 Health Research Authority. UK Policy Framework for Health and Social Care Research [Internet]. 2017. Available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
176 Society of Radiographers. Preventing Patient Identification Incidents in Diagnostic Imaging, Nuclear Medicine and Radiotherapy [Internet]. 2025. Available from: https://www.sor.org/getmedia/df7737c0-bb12-4423-a35a-e065175d73f0/Preventing-Patient-Identification-Incidents_D2-4
177 British Association of MR Radiographers [Internet]. Available from: http://www.bamrr.org
178 Shellock FG. MRISafety.com Screening Form [Internet]. Available from: https://www.mrisafety.com
179 E-learning MRI Safety - Implant Recognition [Internet]. [cited 2026 Feb 23]. Available from: http://portal.e-lfh.org.uk/Component/Details/847926
180 Welsh Language Standards: https://www.welshlanguagecommissioner.wales/regulation/welsh-language-standards
181 Pietryga JA, Fonder MA, Rogg JM, North DL, Bercovitch LG. Invisible metallic microfiber in clothing presents unrecognized MRI risk for cutaneous burn. Am J Neuroradiol. 2013;34:E47–50.
182 Knopp MV, Essig M, Debus J. Unusual burns of the lower extremities caused by a closed conducting loop in a patient at MR imaging. Radiology. 1996;200(2):572–5.
183 BAMRR Suggested RF burn procedure. https://www.bamrr.org/wp-content/uploads/2022/03/BAMRR-suggested-RF-burn-procedure.pdf
184 Tang M, Yamamoto T. Progress in Understanding Radiofrequency Heating and Burn Injuries for Safer MR Imaging. Magn Reson Med Sci. 2023;22(1):7–25.
185 UK Government. The Control of Noise at Work Regulations 2005 [Internet]. 2005. Available from: https://www.legislation.gov.uk/uksi/2005/1643/contents
186 Bhuva A, Charles-Edwards G, Ashmore J, et al. Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices. Heart. 2024;110:e3.
187 SoR Pause and Check [Internet]. [cited 2026 Feb 23]. Available from: https://www.sor.org/getmedia/b776fd2c-842d-4854-a73a-b3136662e521/pause_check_practitioner_checklist_for_mri_examinations_a4.pdf
188 NHS England. Records Management Code of Practice [Internet]. 2023. Available from: https://transform.england.nhs.uk/media/documents/NHSE_Records_Management_CoP_2023_V5.pdf
189 Klucznik R, Carrier D, Pyka R, Haid R. Placement of a ferromagnetic intracerebral aneurysm clip in a magnetic field with a fatal outcome. Radiology. 1993;187(3):855–6.
190 Bartsch C, Irnich W, Risse M, Weiler G. Unexpected sudden death of pacemaker patients during or shortly after magnetic resonance imaging (MRI). In: Proceedings of the XIX Congress of the International Academy of Legal Medicine [Internet]. Milan, Italy; 2003. p. Abstract 114. Available from: https://link.springer.com/collections/ddfbjcabii

191 Tanaka R, Yumoto T, Shiba N, et al. Overheated and melted intracranial pressure transducer as cause of thermal brain injury during magnetic resonance imaging. J Neurosurg. 2012;117(6):1100–9.
192 Ashmore JP, Prescott SJ, McLean K, et al. A framework for developing generic implant safety procedures for scanning patients with medical implants and devices in MRI. Br J Radiol. 2025;98:336–44.
193 Institute of Physics and Engineering in Medicine. Generic Implant Safety Procedures (GISPs) [Internet]. 2024. Available from: https://www.ipem.ac.uk/resources/mri/generic-implant-safety-procedures-gisps-task-and-finish-group/
194 British Cochlear Implant Group: MRI Safety [Internet]. Available from: https://www.bcig.org.uk/safety_and_mri.aspx
195 SoR [Internet]. [cited 2026 Feb 23]. Safety in Magnetic Resonance Imaging. Available from: https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/policy-guidance-document-library/safety-in-magnetic-resonance-imaging
196 ASTM International. Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging. 2019.
197 Medicines and Healthcare products Regulatory Agency. Drug Safety Update: Fentanyl patches – serious and fatal overdose from dosing errors, accidental exposure, and inappropriate use [Internet]. 2019. Available from: https://www.gov.uk/drug-safety-update/serious-and-fatal-overdose-of-fentanyl-patches
198 Kelly WM, Paglen PG, Pearson JA, et al. Ferromagnetism of intraocular foreign body causes unilateral blindness after MR study. Am J Neuroradiol. 1986;7:243.
199 Society of Radiographers. Safety in Magnetic Resonance Imaging [Internet]. 2019. Available from: https://www.sor.org/getmedia/b7d1db7a-5b04-492e-ad4d-6b188f0d9cb0/safety_in_magnetic_resonance_imaging_3.pdf_2
200 Neuro Anaesthesia and Critical Care Society of Great Britain and Ireland. Safe Provision of Anaesthesia in Magnetic Resonance Units [Internet]. 2019. Available from: https://anaesthetists.org/Home/Resources-publications/Guidelines/Safe-provision-of-anaesthesia-in-magnetic-resonance-units
201 Patient group directions (PGDs) - GOV.UK [Internet]. [cited 2026 Feb 24]. Available from: https://www.gov.uk/government/publications/patient-group-directions-pgds
202 Radiology – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice [Internet]. [cited 2026 Feb 24]. Available from: https://www.sps.nhs.uk/?cat%5B0%5D=3787&s=&order=DESC
203 Royal College of Radiologists, Society and College of Radiographers. Team Working within Clinical Imaging: A Contemporary View of Skills Mix [Internet]. 2007. Available from: https://www.sor.org/learning/document-library/team-working-within-clinical-imaging
204 Royal College of Radiologists. Guidance on Gadolinium-based Contrast Agent Administration to Adult Patients [Internet]. 2019. Available from: https://www.rcr.ac.uk/our-services/all-our-publications/clinical-radiology-publications/guidance-on-gadolinium-based-contrast-agent-administration-to-adult-patients/
205 Society of Radiographers, Royal College of Radiologists. Position Statement for Patients Who Are Breastfeeding [Internet]. 2022. Available from: https://www.rcr.ac.uk/our-services/all-our-publications/clinical-radiology-publications/rcr-and-sor-statement-on-patients-who-are-breastfeeding-who-require-a-ct-or-mri-with-contrast/
206 The Breastfeeding Network. MRI Scans and Breastfeeding [Internet]. Available from: https://www.breastfeedingnetwork.org.uk/mri/
207 Medicines and Healthcare products Regulatory Agency. Gadolinium-containing contrast agents: removal of Omniscan and IV Magnevist, restrictions to the use of other linear agents [Internet]. 2017. Available from: https://www.gov.uk/drug-safety-update/gadolinium-containing-contrast-agents-removal-of-omniscan-and-iv-magnevist-restrictions-to-the-use-of-other-linear-agents
208 UKHSA incident taxonomy guidance https://www.gov.uk/government/publications/user-guidance-and-application-of-the-national-taxonomy-for-incident-learning-in-clinical-imaging-mri-and-nuclear-medicine
209 GOV.UK [Internet]. 2021 [cited 2025 Dec 9]. Managing medical devices. Available from: https://www.gov.uk/government/publications/managing-medical-devices

210 GOV.UK [Internet]. [cited 2025 Dec 9]. Off-label use of a medical device. Available from: https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device
211 GOV.UK [Internet]. [cited 2025 Dec 18]. Health Institution Exemption for general medical devices. Available from: https://www.gov.uk/government/publications/health-institution-exemption-for-general-medical-devices
212 IPEM. IPEM Best-practice guidance for the in-house manufacture of medical devices and non-medical devices, including software in both cases, for use within the same health institution [Internet]. 2024 [cited 2025 Dec 9]. Available from: https://www.ipem.ac.uk/media/yvdhwxw4/ipem-best-practiceguidance-on-ihmu-v2-2_final.pdf
213 MGCD. MGCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 [Internet]. 2023 [cited 2025 Dec 9]. Available from: https://health.ec.europa.eu/system/files/2023-01/mdcg_2023-1_en.pdf
214 MRI Safety Notices [Internet]. [cited 2025 Dec 9]. Available from: https://www.ipem.ac.uk/resources/mri/mri-safety-notices-magnetic-resonance-imaging/
215 BS EN 12021:2014 | 30 Sep 2014 | BSI Knowledge [Internet]. [cited 2025 Dec 9]. Available from: https://knowledge.bsigroup.com/products/respiratory-equipment-compressed-gases-for-breathing-apparatus
216 MR Installation Guidance - IPEM [Internet]. [cited 2025 Dec 9]. Available from: https://www.ipem.ac.uk/resources/mri/mr-installation-guidance/
217 England NHS. NHS England » Health Building Note 6: Designing facilities for diagnostic imaging [Internet]. 2001 [cited 2025 Dec 9]. Available from: https://www.england.nhs.uk/publication/designing-facilities-for-diagnostic-imaging-hbn-6/
218 IPEM Report 112: Quality Control and Artefacts in MRI. 2017
219 International Electrotechnical Commission. Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters [Internet]. IEC 62464-1:2018, editor. Geneva, Switzerland: International Electrotechnical Commission; 2018. Available from: https://webstore.iec.ch/publication/67497
220 General Equipment (Non X-Ray) Handover Form. AXREM [Internet]. [cited 2025 Dec 9]. Available from: https://www.axrem.org.uk/resource/general-equipment-handover-form/
221 Steckner MC, Ashmore J, Charles-Edwards G, Grainger D, Graves MJ, Jones E, et al. Commentary: The MRI scanner room door is a latent safety issue. Magn Reson Mater Phys Biol Med. 2025 Dec 22. doi:10.1007/s10334-025-01310-x
222 Mullally S. A toolkit for medical equipment donations to low-resource settings.: making It work. London: Tropical Health and Education Trust; 2013.
223 UK Parliament. The Health and Safety (Safety Signs and Signals) Regulations 1996. 341 [Internet]. Statute Law Database; 1996. Available from: https://www.legislation.gov.uk/uksi/1996/341
224 BSI. Graphical symbols. Safety colours and safety signs. Registered safety signs. https://knowledge.bsigroup.com/products/graphical-symbols-safety-colours-and-safety-signs-registered-safety-signs-3
225 Approved Code of Practice 'Safety of pressure systems' (document L122) ISBN 0 7176 1767 X https://www.hse.gov.uk/pubns/books/l122.htm
226 Pressure Safety Systems Regulations (PSSR) Call for Evidence (CfE). https://consultations.hse.gov.uk/hse/pssr-call-for-evidence/
227 ICNIRP. Amendment to the ICNIRP “Statement on Medical Magnetic Resonance (MR) Procedures: Protection of Patients”. Health Phys. 2009 Sep;97(3):259–61. doi:10.1097/HP.0b013e3181aff9eb.
228 International Electrotechnical Commission. ISO 14117:2019 Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices. 2nd edn. International Electrotechnical Commission; 2019.
229 BSI. BS EN 50527-1:2016 Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General. BSI; 2016.
230 Keevil S, Lomas D. The Control of Electromagnetic Fields at Work Regulations 2016 and medical MRI. Br J Radiol. 2017 Feb 23;90(1070):20160813. doi:10.1259/bjr.20160813
231 Berglund B, Lindvall T, Schwela D. Guidelines for Community Noise [Internet]. WHO; 1999. Available from: https://www.who.int/publications/i/item/a68672

232 Health & Care Professions Council (HCPC). The standards of proficiency for radiographers [Internet]. 2023 [cited 2025 Dec 5]. HCPC Standards of Proficiency. Available from: https://www.hcpc-uk.org/standards/standards-of-proficiency/radiographers/
233 The College of Radiographers. Education and Career Framework (ECF) (fourth edition) [Internet]. 2025 [cited 2025 Dec 5]. Education and Career Framework (ECF) (fourth edition). Available from: https://www.collegeofradiographers.ac.uk/education-and-career-framework-ecf
234 Health & Care Professions Council (HCPC). The HCPC [Internet]. 2023 [cited 2025 Dec 5]. The standards of proficiency for clinical scientists. Available from: https://www.hcpc-uk.org/standards/standards-of-proficiency/clinical-scientists/
235 The Academy For Healthcare Science (AHCS). AHCS standards. The Academy For Healthcare Science [Internet]. [cited 2025 Dec 5]. Available from: https://www.ahcs.ac.uk/education-training/standards/
236 Healthcare Science Cymru. Consultant Clinical Scientists in NHS Wales. https://heiw.nhs.wales/files/consultant-clinical-scientist-recommendations-englishpdf/
237 American Board of Magnetic Resonance Safety (ABMRS). ABMRS | American Board of Magnetic Resonance Safety [Internet]. [cited 2025 Dec 5]. Now International Board of Magnetic Resonance Safety https://ibmrs.org/
238 The Royal College of Radiologists. Clinical radiology curriculum | The Royal College of Radiologists [Internet]. 2023 [cited 2025 Dec 10]. Available from: https://www.rcr.ac.uk/exams-training/specialty-training/clinical-radiology-curriculum/
239 NHS England. elearning for healthcare [Internet]. [cited 2025 Dec 10]. E-Learning for Health: MRI Safety. Available from: https://www.e-lfh.org.uk/programmes/mri-safety/