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1. Rationale

1.1 This guidance and advice document overviews safety issues in magnetic resonance imaging (MRI) and, while not claiming to be all-inclusive, it provides direction to radiographic staff on where appropriate information can be found. All members of the workforce who are working or intending to work in MRI are recommended to read the literature listed in this document to gain a more in-depth appreciation of the issues involved.

1.2 Purpose

The purpose of this document is to:

- increase awareness and reiterate safety issues that are uniquely associated with MRI
- identify the professional responsibilities in ensuring safe practice in MRI
- offer practical advice for the development of an MR (magnetic resonance) safety framework
- inform departments regarding any relevant legislation relating to MR safety, such as the 2016 Control of Electromagnetic Fields at Work (CEMFAW) regulations.¹

1.3 This document considers areas relating to hazards, safety, good practice and professional responsibilities. It is designed to be a practical reference guide and a pointer to enable radiographic staff to find and access information in busy MR units.

1.4 The Society and College of Radiographers (SCoR) and the British Association of Magnetic Resonance Radiographers (BAMRR) recommend that all departments have an up-to-date copy of the following Medicines and Healthcare products Regulatory Agency (MHRA) publication:

Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use²

1.5 This guidance updates and replaces the previous guidance document produced by the SCoR and BAMRR in 2016.³ The SCoR is grateful to members of the SCoR Magnetic Resonance Advisory Group (MRAG), to the BAMRR policy board and to Geoff Charles Edwards, who contributed to the writing of this document.

2. Defining Areas of Responsibility

Further details on the following roles and the required knowledge and training can be found in *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*.²

2.1 Responsible person

The MR responsible person:

- has day-to-day responsibility for safety in the MRI centre
- is required to have sufficient MRI clinical expertise and safety knowledge (or experience relevant to the nature of the department, e.g. research scanning) to ensure that appropriate levels of MRI safety and training are delivered and updated to relevant staff
- is delegated as **responsible person** by the chief executive or general manager
- may effectively be clinical director or head of department, but more usually an advanced practitioner or consultant radiographer or practitioner in a management role in the MR department
- should not take on the role of an **MR safety expert**² (see section 2.2).

The MHRA² advises that it may be appropriate to have an MR responsible person for each MR system within an organisation.

Duties include:

- ensuring that adequate written safety procedures, ethical approvals, work instructions and emergency procedures (local rules) are issued to all concerned in consultation with the MRI safety expert
- approving certification of authorised persons
- producing and issuing written safety documents, ensuring that they are version controlled and regularly updated.

Note: *This is not an exhaustive list of duties. Please refer to Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use² for further details.*

2.2 MR safety expert (MRSE)

The MRSE:

- provides scientific advice to MR units
- is required to have expert knowledge of the physical principles of MRI and detailed knowledge of MRI techniques.

Please refer to Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use² for further details of the duties of an MRSE.

The Institute of Physics and Engineering in Medicine (IPEM) has published a policy statement⁴ outlining the role of the MRSE. It is the intention of IPEM that the MRSE be accredited. A working party that includes representatives from SCoR and BAMRR is currently defining the required knowledge and competencies and the proposed routes of accreditation for this role.

The IPEM policy statement with further information can be viewed online at:
http://www.ipem.ac.uk/Portals/0/Documents/Publications/Policy%20Statements/IPEM_MRSafetyExpert_PolicyStatement_04102013_SK.pdf

Note: *This role could be undertaken by a suitably qualified radiographer. Further information will be issued as an addendum to this publication.*

2.3 Authorised person

The authorised person is a suitably trained member of staff authorised to have access to the MR controlled access area and also, depending on their role, access to the MR environment (see section 5). All authorised persons must:

- be certified by the MR responsible person following completion of satisfactory training
- be listed on a certified list
- keep an appropriate record of their MR training; an annual screening of all authorised persons is to be kept by the responsible person
- complete and pass a screening questionnaire annually
- satisfy themselves at all times that they conform to the requirements of the screening process.

The MHRA² defines access and supervision rights of MR authorised personnel as follows:

| STAFF GROUP | MR ENVIRONMENT (scan room) | MR CONTROLLED ACCESS AREA outside MR environment |
|--|--------------------------------------|--|
| Authorised person Non-MR environment e.g. clerical staff, management staff, radiologists without formal safety training | May not enter without supervision | May enter and supervise |
| Authorised person MR environment e.g. supporting clinical staff, junior researchers | May enter | May enter and supervise |
| Authorised person - supervisor e.g. radiographer, researcher with appropriate training | May enter and supervise | May enter and supervise |

Access to all other persons, including patients, visitors and unauthorised staff, should only be granted if accompanied by an authorised person, and following appropriate screening processes.

2.4 MR operator

The MR operator is:

- an authorised person who is deemed to have sufficient experience and appropriate training and is responsible for operating the scanner in a safe and appropriate manner
- responsible at all times for the safety of patients and volunteers (and accompanying carers) who are undergoing MRI
- responsible for ensuring that any equipment taken into the MR environment for the examination is suitable.

2.5 Defining categories of staff

All staff required to enter the MR controlled access area and the MR environment to carry out their duties will require training relating to the safety aspects of MRI. The level and depth of this training will differ according to the role of the staff member.

Further information on training requirements can be found in section 4.17.1 of the *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*.²

See also section 3.1.2 of this document.

The MHRA has defined the following categories of staff. Please refer to the MHRA guidance² for further details.

Category (A): MR OPERATOR – Those wishing to operate, maintain or modify the MRI equipment, such as radiographers, radiologists and service engineers

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

Category (C): All staff who are required to enter the MR ENVIRONMENT when scanning is not taking place, e.g. dedicated cleaning staff and estate maintenance staff

Category (D): All other staff who are required to enter the MR CONTROLLED ACCESS AREA but will not enter the MR ENVIRONMENT, e.g. clerical staff.

3. Staffing of MR Units

The SCoR receives many enquiries regarding the staffing of MR units, primarily relating to the suitable skill mix and minimum staffing levels. Generally, SCoR tends not to be prescriptive about staffing levels as configurations will very much vary to meet local circumstances and service delivery models. Rather, we would suggest an approach that considers certain principles in order to provide a quality, safe and effective service for patients and staff.⁵

Under the Health and Safety at Work Act,⁶ employers have a general duty to ensure the health, safety and welfare at work of all employees. Employers are also obliged to carry out risk assessments into all aspects of working, including systems and patterns of work. When considering the staffing requirements of an MR unit, managers should take into account the following factors.

3.1 Safety of patients and staff

Patient safety is paramount. There are particular safety issues associated with MRI: strong magnetic fields, time-varying magnetic fields and radio-frequency pulses.

Staffing levels and competencies should be such that there are no compromises with regard to patient safety. Staffing levels should take account of the fact that MR operators must maintain visual and audio contact with the patient throughout the scan and should not leave the control room during the scan unless it is to enter the scan room.²

The MRI safety screening questionnaire is an essential component in ensuring patient safety. Staffing levels should take account of this process.

3.1.1 Lone working

The MHRA advises that staff should not work alone, especially out of hours. Where it is considered essential that staff do work alone, the lone worker policy of the Trust should be considered.²

The Health and Safety Executive (HSE) advises: “Risk assessment should help employers decide on the right level of supervision. There are some high-risk activities where at least one other person may need to be present. Examples include: ... working in the health and social care sector dealing with unpredictable client behaviour and situations.”⁷

3.1.2 MR safety training

Many categories of staff are required to have contact with the MR unit during the course of their duties. It is essential that these staff receive a level of training in the hazards associated with MRI appropriate to their role. The MHRA² defines what that training should consist of using the categorisation of staff as defined in section 2.5 of this document.

Further information on training requirements can be found in section 4.17.1 of the *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*.²

3.1.3 MR safety knowledge

The SCoR and BAMRR recommend that all staff working in a clinical or clinical support role in MR units should have as a minimum:

- knowledge and understanding of the threats posed by the static magnetic field
- understanding of the MR controlled access area and MR environment
- awareness of MR authorised personnel
- understanding of the screening process and access rights
- emergency procedures within the MR environment
- understanding of the nature of a magnet quench and when a system may need to be quenched by the operator
- understanding the labelling system for MR equipment
- understanding the requirement for hearing protection and correct positioning
- understanding the correct use and positioning of the coils and cables and ancillary equipment.

Radiographers require further post-registration knowledge and understanding in the following areas:

- bio effects of the static magnetic field
- projectile and attractive forces
- bio effects of time-varying gradient magnetic fields
- bio effects of radio-frequency (RF) radiation
- recommended exposure value limits
- sequence selection and parameter manipulation to minimise all of the above
- conditional implants and devices
- medicines used in MRI.

3.1.4 All staff should have adequate training in departmental emergency procedures.

3.1.5 When considering staffing using a radiographer working alongside a non-clinically trained helper, provision must be made for adequate rest periods for the radiographer. This would include a review of the bookings and case type. The helper must be suitably trained, as indicated above, and authorised by the MR responsible person.

3.2 Equitable service provision

Managers should consider whether the service being offered is of the same quality and safety for the patients and staff throughout the whole day, i.e. will there be any difference in the service delivered to a patient attending at 9am and one attending at 9pm?

3.3 Skills, experience and knowledge of staff

When considering staffing using radiographers working with either a non-clinical helper or an assistant practitioner, the radiographer should have the requisite skills, knowledge and experience in MRI in order to take responsibility for the episode of care.

3.4 Assistant practitioners in MR units

The role of an assistant practitioner in MRI relates to providing support for other registered healthcare practitioners, e.g. radiographers and radiologists, and to aspects of patient care.⁸

4. Professional responsibilities

4.1 Referrals for MRI

4.1.1 Referrals for MRI examinations should include a detailed clinical history and clearly state the examination(s) being requested.

4.1.2 Referral forms should be signed and dated.

4.1.3 Referring clinicians have a responsibility to complete the relevant safety section on the referral form and/or submit any safety information known to them about the patient (ideally at the time of referral, in consultation with the patient). However, the person taking the patient/volunteer into the MR environment should be certain that all departmental safety checklists have been carried out and be entirely confident that it is safe to do so.²

See also section 4.2 of this document.

4.1.4 MR departments should ensure that the referral is from an authorised source.

4.1.5 Organisations should have in place a clearly documented referral process which includes an up-to-date list of authorised referrers.

4.2 MRI safety screening questionnaires

4.2.1 Risk-benefit decisions must be taken by the MRI team in consultation with the patient or their guardian. Before the patient is allowed to enter the MR controlled access area, a suitably trained authorised person is responsible for ensuring that the risks are made clear and that the evidence provided is based on the most current and up-to-date literature.

4.2.2 Written documentation, normally in the form of a questionnaire, regarding the risk assessment for each patient should be completed by the patient, and checked through with them by a suitably trained authorised person. Any discrepancies or queries should be discussed with the patient and the decision to scan should be made in conjunction with the local rules and employing authority policies.

4.2.3 The questionnaire should be signed and dated by the patient and countersigned as checked by the MR operator.

4.2.4 There may be occasions when it is not possible for the patient to answer the safety questionnaire directly, for instance in the case of an unconscious patient, or a patient who does not speak English.

4.2.5 In the case of an unconscious patient, close reference should be made to the patient notes and, ideally, the next of kin may be asked to complete the questionnaire. Reference should be made to the employing authority policy on consent, and this should be reflected in the local rules. Please also refer to 4.3 of this document. Any doubt about patient status with regard to MR safety should be rigorously pursued; this may involve, for example, plain radiography to detect a metallic intra-orbital foreign body (IOFB).

4.2.6 Patients who do not speak English as a first language should be accorded the same information and confidentiality as any other patient. Ideally, an employing authority translation service, using an approved translator, should be utilised. This should ensure that the questions put to the patient, and the answers received, are accurate and not changed. A translator may be booked in advance, or a phone translation service approved by the employing authority can be utilised. If the translator is present, they should sign the form to confirm that they asked the patient all the

questions listed, and that the answers noted are a true record of those received. If the translator is not present, a note of their name or identification code should be made on the form. The safety of the patient, however, is the responsibility of the MR operator. In exceptional circumstances, a relative can be used for translation purposes. It is inappropriate for minors to perform this function.

An example safety screening questionnaire is available to view on the BAMRR website:
http://www.bamrr.org/media/uploads/bamrr_mri_safety_questionnaire.pdf

4.3 Consent

Seeking patient consent prior to undertaking an examination or treatment procedure is not only a fundamental, ethical and legal requirement of all healthcare practitioners, it is also a common courtesy as part of the process of creating a relationship of trust between healthcare practitioners and the patient or service user. When carrying out any procedure, the healthcare practitioner is ultimately responsible for ensuring that the patient or service user is genuinely consenting to the procedure being undertaken; it is the practitioner who will be held responsible in law if this is later challenged.

Healthcare practitioners should not assume that patients and service users attending a department for a diagnostic procedure or radiotherapy treatment have already given informed consent because often patients are unaware of the exact nature of the procedure which they will undergo.

In emergency situations where patients are unable to make any decisions and it may not always be possible to gain consent, healthcare practitioners may provide imaging services and radiotherapy, provided it is immediately necessary either to prevent deterioration of a condition or to save a life.⁹

Further information is available on the Society of Radiographers website:
<https://www.sor.org/practice/obtaining-consent>

4.4 Decision to scan

4.4.1 There may be occasions when MRI is requested for patients with implants who are at particular risk (off-label scanning), such as:

- when the patient has an implant for which MRI is contraindicated (*see also section 10.4*)
- when there is insufficient evidence from the implant manufacturer that MRI is safe to perform
- when the conditions for safe scanning of an implant cannot be met
- when it is not possible to determine the make and model of an implant.

4.4.2 The decision to scan these patients should be made on a case-by-case basis, and following a risk assessment and risk-benefit analysis. While it is essential that the referring clinician, patient and reporting clinician are instrumental in this, the decision should be made in consultation with all members involved in the process. This should include, for example, the MR responsible person, MRSE and MR operator. Roles and responsibilities for each member of the team should be clearly defined.

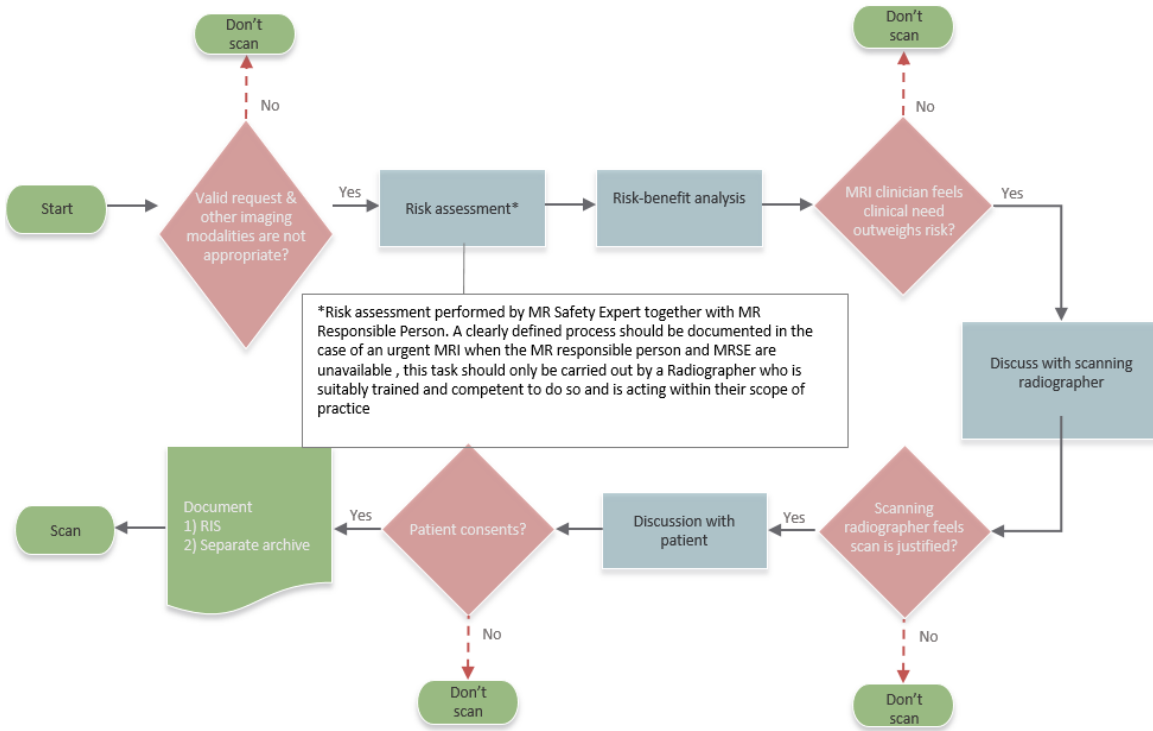
4.4.3 The process for dealing with such patients should be clearly documented and accessible to staff with reference to the local rules.

4.4.4 The radiographer performing the scan should be satisfied that:

- they are acting within their scope of practice and competence (*see 4.6.1*)
- alternative imaging procedures have been considered
- suitable consent has been obtained (*see 4.3*)

- a full risk assessment and risk-benefit analysis has been carried out in accordance with the locally defined process
- by proceeding with the scan, they are acting in the best interests of the patient
- the decision to scan, including the named responsible clinician, is clearly documented.

An example flow chart for off-label scanning



4.5 Reporting of incidents and near misses

All incidents and near misses related to patient or staff safety within the MR unit must be reported in accordance with local employers’ rules. This includes adverse drug reactions. Incidents and near misses involving MR diagnostic equipment should also be reported. This includes burns and overheating, projectile incidents and contrast injector failures.

A full list detailing what should be reported is available in Appendix 4 of the *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*.²

Further information on reporting using the yellow card scheme is available at: <https://www.gov.uk/report-problem-medicine-medical-device>

(This webpage also provides links for the reporting of incidents in Scotland, Wales and Northern Ireland.)

For any queries, contact the Adverse Incident Centre: aic@mhra.gsi.gov.uk

4.6 Knowledge, skills and competency

The science of MRI and technological developments in equipment and device implants evolves rapidly and radiographers must ensure that their knowledge, skills and competencies keep pace with these advances in order to ensure a quality and safe service.

The increase in the scope of MRI applications means that radiographers have extended their roles to incorporate advanced techniques.¹⁰

As registered healthcare professionals, radiographers must ensure that their knowledge and skills are kept up to date and that they act within the limits of their knowledge, skills and experience.¹¹

4.6.1 Scope of practice

In identifying and communicating their individual scope of practice, radiographers must consider the roles and the environments in which they work and ensure that they are educated and competent to operate in their specific roles.¹²

5. Static magnetic field (B_0)

5.1 Definition

Static magnetic field (B_0) is dependent on the field strength of the magnet.

The SI unit used for measuring magnetic field strength is the tesla, and its symbol is T. An alternative unit of measurement is the Gauss; 1 tesla is equal to 10,000 Gauss.

A magnetic field of 1 tesla (1T) is approximately 30,000 times as powerful as the Earth's magnetic field.

5.2 MR controlled access area

Please refer to the *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*² (page 24) for an example layout of an MR unit.

An MR controlled access area is characterised by the MHRA as follows: “A locally defined area of such a size to contain the MR environment. Access to this area should be restricted and controlled by suitable control methods (e.g. keypad entry) with suitable warning signs displayed at all entrances.”²

5.3 MR environment

The MR environment is defined by the MHRA as “the three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.5mT field contour (5 Gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.”²

Note: *The MR environment can include aspects of the technical room and console area.*

- ▲ Owing to the hazards of the static magnetic field described in this section, resuscitation of patients should take place outside the MR environment.
- ▲ Local rules should outline specific procedures to reflect this.

5.4 Fringe field

Every MR scanner has an affiliated fringe field. The extent of this fringe field is dependent upon the static magnetic field strength (B_0), type of shielding (active, passive cladding or whole room shielding) and whether the magnet has an open or closed design.

Fringe field plot diagrams should be displayed in every MR control room highlighting the 0.5mT (5 Gauss line) and the 3mT (30 Gauss line).

5.5 Projectile zone

Some MR units, for example those performing interventional MRI, may wish to define a projectile zone within the MR environment.

A projectile zone is “a locally defined volume containing the full extent of the 3mT magnetic field contour, **or other appropriate measure**, around the MRI scanner”.²

5.6 Biological effects

The interaction of the static magnetic field (B_0) with the body and its functions may result in the creation of electrical potentials, currents generated by body movements and the possible displacement of naturally generated currents within the body by B_0 . Electrical potentials and related effects during physical movements within static magnetic field gradients may induce sensations of vertigo, nausea, phosphenes and a metallic taste in the mouth. Public Health England (PHE), formerly the Health Protection Agency (HPA),¹³ offers the following advice regarding the movement of patients and volunteers in the static field:

- ▲ “The biological effects most likely to occur are the production of vertigo-like sensations and these acute effects are associated with movement in the static field. The sensitivity to these effects varies considerably between individuals. Patients and volunteers should be moved slowly into the scanner, to avoid the possibility of vertigo and nausea.”

Further recommendations, guidance and exposure limits relating to bio effects of B_0 can be found in the following publications:

- Public Health England, *MRI Procedures: Protection of Patients and Volunteers 2008*¹³
- International Commission on Non-Ionizing Radiation Protection (ICNIRP), *Guidelines on Limits of Exposure to Static Magnetic Fields 2009*¹⁴
- ICNIRP, *Amendment to the ICNIRP Statement on Medical Magnetic Resonance (MR) Procedures Protection of Patients 2009*¹⁵

5.7 Projectile and attractive forces

The potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field must be taken very seriously. The HPA reports that serious incidents have occurred, including a patient fatality, when items such as ferromagnetic oxygen cylinders have inadvertently been brought into the scan room.¹³

- ▲ **Extreme caution must be employed, and strict screening protocols be in place and adhered to, to ensure ferromagnetic items do not enter the MR environment. Loose metallic objects can reach considerable velocities.**

5.8 Labelling of equipment

All equipment used or stored within the MR environment should be clearly labelled as one of the following, as defined by the American Society for Testing and Materials.¹⁶



MR safe – Defined as “an item that poses no known hazards resulting from exposure to any MR environment. MR safe items are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic.”

MR conditional – Defined as “an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radio-frequency fields. Additional conditions, including specific

configurations of the item, may be required.”

The MHRA further advises:

“Descriptions of **MR CONDITIONAL** should specify information such as the maximum magnetic field in which the device was tested, the magnitude and location of the maximum spatial gradient, the maximum rate of change of the gradient field, and radio-frequency fields tolerated in terms of RF interference, RF heating and type of transmit mode.”²

MR unsafe – Defined as “an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment”.

All staff should be conversant with the labelling system and understand the conditions for use. Further information on the requirements regarding labelling of equipment can be viewed in the MHRA guidelines.²

▲ Departments should take into account the different field strengths when labelling equipment. For example, if a department is equipped with two MR units of 1.5T and 3T, only equipment which is safe in both units should be labelled as MR safe.

▲ Clear guidance for use should be marked on equipment that is MR conditional.

5.8.1 Ancillary equipment

- Caution should be exercised when assessing, purchasing and authorising equipment for patient support in the MR environment.
- Equipment must be assessed for MR compatibility and clearly labelled as indicated in section 5.8.
- Departments should ensure that an up-to-date inventory is kept of all equipment for use in the MR environment and, where relevant, should also include the maximum weight limit for safe use.

5.8.2 Other items

The MHRA makes the following recommendations regarding other items that may be used in the MR unit (e.g. patient comfort and immobilisation aids):

“Many items such as consumables cannot be reasonably labelled. Sites should have processes in place to ensure that these items are safe.”²

5.9 Procurement

The MR responsible person and/or the MRSE should be involved in all procurement decisions relating to items for use in the MR environment.

6. Time-varying (gradient) magnetic fields (dB/dt)

6.1 Time-varying magnetic field gradients in MR systems provide position-dependent variation in magnetic field strength. The gradients are pulsed and the faster the sequence of imaging, the greater the gradients' fields change rate. The main concerns associated with time-varying magnetic fields are biological effects and acoustic noise.

6.2 Biological effects

6.2.1 Subjecting the human body to time-varying electromagnetic fields leads to induced electric fields and circulating currents in connective tissues. Induced electric currents can be sufficiently large to interfere with normal function of nerve cells and muscle fibres. An example of this is the sensation of flashes of light caused by induced currents stimulating the retina.

6.2.2 Peripheral nerve and muscle stimulation

At low frequencies, induced currents can produce stimulation of nerve and muscle cells.¹⁷ The body is most sensitive up to about 5 kHz. Extreme cases can result in limb movement or ventricular fibrillation.

6.2.3 Implant interaction

Time-varying magnetic field gradients can interact with implants. This may result in device heating and vibration.²

▲ Reference to exposure limits and relevant standards should be made and can be found in the MHRA guidelines.²

6.3 Acoustic noise

Acoustic noise caused by the gradient coils switching on and off during the scan can reach unacceptable levels. In general, the higher the field strength, the higher the acoustic noise level, but this effect is not exponential and is also dependent on pulse sequence. PHE¹³ reports that the threshold of instantaneous and permanent acoustic trauma normally associated with exposure to impulsive noise is 140dB in adults; children may have a lower threshold and maximum peak levels of 120dB are advised.

▲ It is recommended that departments provide adequate hearing protection to **ALL** patients and others remaining in the scan room, e.g. carers, anaesthetic staff, etc.

▲ Radiography staff should be trained in the selection and fitting of hearing protection.

▲ MR operators should be aware of noise-reducing protocols and trained in their utilisation, particularly for those patient groups who are sensitive.

7. Radio-frequency (RF) radiation (B1)

7.1 Biological effects

Exposure to RF radiation results in increased oscillation of molecules and generation of heat. Dissipation of this heat occurs through the dilatation of blood vessels and increased blood flow. Avascular structures are therefore less efficient in removing this heat. RF exposure of patients is usually characterised by means of the specific absorption rate (SAR), which is defined as the average energy dissipated in the body per unit of mass and time.¹⁴

The ICNIRP summarises: “For whole-body exposures, no adverse health effects are expected if the increase in body core temperature does not exceed 1°C. In the case of infants and persons with cardiocirculatory impairment, the temperature increase should not exceed 0.5°C. With regard to localised heating, it seems reasonable to assume that adverse effects will be avoided with a reasonable certainty if temperatures in localised regions of the head are less than 38°C, of the trunk less than 39°C, and in the limbs less than 40°C.”¹⁴

However, good practice should mean that RF deposition should be minimised in all patients. An accurate patient weight and height (if required) should be input into the system and manufacturer software will alert scanner operators to high SAR sequences.

- ▲ All patients should be weighed **prior** to scanning in accordance with manufacturer’s guidelines.

- ▲ The patient’s height may also need to be recorded, depending on the manufacturer’s guidelines.

7.1.1 SAR limits

SAR limits have been defined by the International Electrotechnical Commission (IEC)¹⁸ and ICNIRP¹⁴. The MHRA² recommends that departments make themselves familiar with the SAR limits used by their system from both the IEC standard and the manufacturer’s user’s manual. The use of different operating modes with regard to the varying SAR levels should be recorded within the local rules. Departments should also be aware that the IEC SAR limits are set assuming moderate environmental conditions of relative humidity and ambient temperature. There is a risk of overheating the patient if SAR is not reduced in adverse conditions, i.e. in high ambient temperatures and high relative humidity. PHE recommends that departments follow the ICNIRP guidelines for RF fields for each operating mode and, additionally, that an upper temperature limit be specified for the experimental operating mode.

- ▲ MR operators should ensure that a good airflow is passing through the MR scanner while patients are in situ.

- ▲ MR operators should be aware of the acceptable limits of humidity and ambient temperature for each scanner.

Note: *This information should be provided within the manufacturer’s literature.*

- ▲ MR operators should be aware of the different operating modes available on systems, and of their importance in ensuring that SAR levels remain as low as reasonably possible. Local rules should provide clear guidance on the use of such operating modes.

7.2 Induced current burns

7.2.1 Burns will occur when patients are positioned in such a way as to create a conductive loop

pathway, for example where thighs meet or when hands are clasped. Poor positioning of the patient and associated leads and sensors are the cause of many burns.

7.2.2 Care should be taken to ensure that cables are correctly positioned and to avoid them touching patients. The cables should not be crossed, looped or allowed to lie diagonally across patients. Ideally, cables should lie parallel and as close to the centre of the bore as possible, and should not touch the bore of the magnet at any point.

7.2.3 The patient's skin should be insulated from the bore of the magnet and staff should ensure that there is no skin-to-skin contact. Foam pads 1-2cm thick should be used to insulate the patient from cables and the bore, and between limbs.²

7.3 Contact burns

Contact burns may occur in patients where there is contact with metallic objects that act as conductors, such as coils, cables, monitoring equipment and transdermal patches. Contact burns have been reported due to metallic fibres in clothing.¹⁹ There is a reported case of a patient receiving a serious burn in MRI due to the paramagnetic ink in a wristband.²⁰

- ▲ Careful positioning technique is essential in order to avoid any skin-to-skin contact.
- ▲ Clothing should be checked to ensure it is safe, and ideally patients should change into suitable hospital-provided clothing.
- ▲ Burns from poor patient and cable positioning are entirely avoidable with good practice.
- ▲ Staff should visually inspect patients after imaging to look for any areas of skin redness that may develop into burns.
- ▲ All incidents of burns should be reported as outlined in **section 4.5** of this document.
- ▲ Departments may wish to consider providing patients with an after-care leaflet as it is possible that a burn will develop after the patient has left the department.

7.3.1 Transdermal patches

Some transdermal patches contain metal within the backing which could potentially become conductive, leading to skin burns. Heating may also pose a problem for some medicinal patches, leading to an overdose due to more of the medicine being released into the skin.

- ▲ Transdermal patches should be removed prior to the patient entering the scan room if they contain, or may possibly contain, metal within the backing or may be affected by heat.
- ▲ We recommend that this information, including advice to bring a spare patch, is detailed within the patient information literature.

7.3.2 Make-up, piercings, tattoos

Non-medical objects such as piercings and make-up with a high iron oxide content may cause burning and, wherever possible, should be removed for both patient safety and diagnostic image quality. Some tattoos also have a high ferrous content, and patients should be counselled regarding the possibility of local burns and asked to report any discomfort immediately. If discomfort is reported, scanning should be stopped. Consideration should also be given to patients who have hair extensions as there are certain types that are bonded or tied to the hair using metal components.

8. Cryogen hazards

Cryogenics should only be handled by authorised and trained cryogen suppliers.

8.1 Venting in superconducting magnets

Superconducting magnets offer a potential cryogen hazard. Adequate attention should be paid to the provision of venting for the cryogenics, including ensuring that the external vent pipes are of the correct dimensions and, in the case of a quench, able to withstand pressures above that recommended by the manufacturers, as outlined in the MHRA guidelines.² External vent pipes should also be designed and fitted so that there is no ingress of rain or other detritus, and they should have a regular maintenance and inspection schedule.

- ▲ MR scanner manufacturers are not usually responsible for the maintenance of quench pipes and do not routinely check them during planned preventive maintenance.²
- ▲ Helium levels should be checked and recorded regularly in accordance with manufacturers' recommendations, with mechanisms in place to report any sudden drop or low level.

8.2 Quench hazards in superconducting magnets

There should be no hazards from cryogenics for MR scanning staff, visitors and patients, provided adequate attention has been paid to the provision of venting directly to the air outside the unit. In the event of a quench, low temperature liquefied gases, which are designed to keep the magnet close to absolute zero (-273°C), expand and boil off to the outside. In order to detect any unplanned leakage of helium into the scanner room, suitable low oxygen warning alarms should be placed in the MR room and be regularly checked and maintained. If, for any reason, the gases enter the room instead of exiting to the outside, there will be a risk of asphyxiation (owing to the displacement of oxygen), hypothermia and frostbite. There may also be over-pressurisation in the room due to the rapid expansion of the liquid gas, and this may make it difficult to enter the MR room.

- ▲ If the low oxygen monitor alarms or a quench occurs, the MR environment should be evacuated immediately.
- ▲ Appropriate local emergency procedures should be in place and included in the training programme for all authorised personnel (see also section 15).
- ▲ Departments should adhere to the manufacturers' recommendations regarding maintenance programmes and checking of equipment.
- ▲ Departments must also ensure that a system is in place for handover of responsibility to and from engineers during maintenance checks and system repairs.

9. MR phantoms

MR phantoms are utilised in performance testing of the MR system. They are generally filled with aqueous paramagnetic solutions.

9.1 Storage and handling of phantoms

- MR departments should follow the manufacturers' guidance on the storage and handling of MR phantoms.
- A record should be kept detailing the contents of each phantom; this record should be passed to fire departments in the event of a fire in the MR scanner. The fluid content of some MR phantoms, e.g. nickel, can be toxic.
- Local rules should define protocols for dealing with phantom spillages in accordance with COSHH²¹ regulations.
- Protocols for the general use of phantoms should also be stipulated in the local rules.

10. Implantable medical and non-medical objects

The use of MRI continues to expand in the UK, alongside advances in device technology. In order to ensure good patient management and patient safety, departments should implement robust procedures to ensure the MRI safety status of **any** implanted device.

The SCoR and BAMRR recommend that departments obtain an up-to-date copy of the *Reference Manual for Magnetic Resonance Safety, Implants and Devices*.²² This contains safety advice and guidance and a comprehensive list of implants alongside the field strength under which they have been tested. The list can also be viewed on the website www.mrisafety.com.²³

However, as these are both American-hosted publications, they may not always contain information on a particular device. In this instance, contact should be made directly with the device manufacturer to ascertain the MR safety status of the device.

- ▲ Departments should be aware that the MR compliancy listing of an implant may be changed and should ensure that their information is kept up to date.
- ▲ All visitors and patients should be adequately screened by means of a safety questionnaire prior to entering the MR controlled access area, and should not be allowed to enter if there is any doubt regarding the compliancy of any implants.
- ▲ Departments should have a mechanism for recording and storing details regarding an implant's MR compliancy.
- ▲ For MR conditional devices, departments may need to liaise with an MRSE and the equipment manufacturer to ensure that the conditions can safely be met.
- ▲ Radiographers should be aware of manufacturers' features that assist in meeting conditional specifications. One such example is the Philips *ScanWise* Implant technology.²⁴
- ▲ Manufacturers provide written conditions under which a conditional implant can be scanned. It is very important that the MR operator understands in practical terms the conditions of the spatial magnetic field gradients of their scanners and the SAR limitations.
- ▲ MR operators should be aware that the spatial field gradient of wide bore systems can be higher than the equivalent narrow bore system. This may alter the status of the implant in wide bore systems.
- ▲ The field strengths and other relevant operating parameters at which specific implants have been tested should be noted when assessing the safety of implants.
- ▲ It should be noted that not all implants and devices have been assessed at field strengths of 3T and above.
- ▲ If there is any doubt about an implant, departments should proceed with caution. The SCoR and BAMRR recommend that written evidence regarding an implant's compliancy be obtained prior to scanning.
- ▲ If a department is unable to obtain the required information, scanning should not take place or should be delayed until a risk-benefit analysis and risk assessment has taken place.

See also 4.4 and 10.4

▲ If a department is required to perform off-label scanning for the benefit of the patient, please refer to section 4.4 of this document.

Note: *Manufacturers of implants and devices have a duty to supply safety information. If you are unable to obtain such information, please report it to the MHRA.*

10.1 Active implanted medical devices (AIMD)

Mechanically, electrically and magnetically operated devices may malfunction in the presence of strong magnetic fields. This malfunction may not be obvious at the time of examination but may have serious consequences subsequently. Examples include:

- cardiac pacemakers
- cochlear implants
- programmable hydrocephalus shunts
- implanted neurostimulation systems
- implanted drug infusion pumps.

Note: *This is not an exhaustive list of devices.*

Patients with AIMDs should not enter the MR environment or proceed to MRI unless it has been determined that the AIMD is MR conditional and that the conditional requirements can be safely met.

▲ The process for scanning patients with MR conditional AIMDs should be clearly documented.

▲ Departments should ensure that the process for identifying and assessing implant safety is clearly documented and accessible to relevant staff.

10.2 Scanning MR conditional AIMDs

▲ Departments should ensure that clearly documented processes are in place for scanning MR conditional AIMDs.

▲ AIMDs have multiple components, any of which may be upgraded. Processes should be in place for checking the MR safety status of all components and checking compliance after any upgrade.

Example: MR conditional pacemakers

The manufacture of MR conditional pacemakers is now standard in the UK, allowing for patients with these devices to undergo MRI scanning under certain stated conditions for safe operation.

In addition to complying with the manufacturers' conditions for safe operation, the SCoR advises that departments should formulate a local policy to be referenced within the local rules.

Departments may wish to review their emergency procedures and consider additional training for staff.

Such a policy should include:

- a patient pathway
- clearly defined roles and responsibilities of the radiology department, the radiographic staff and the cardiology department
- a list of any contraindications, potential adverse events and emergency procedures

- a process for obtaining the up-to-date manufacturers' specific operating instructions and any local specific instructions.
- ▲ This should include a mechanism for checking that both the pacemaker and the leads are MR conditional.

Note: *In cases where the leads and the pacemaker are from different manufacturers, the device cannot be considered MR conditional. If a scan is required, the process for off-label scanning should be considered.*

10.3 Non-active devices

There is a risk that implanted ferromagnetic devices will undergo attractive forces such that they can dislodge, causing serious injury or discomfort to the patient or service user. Such devices will be labelled as MR unsafe, MR conditional or MR safe.

Examples include:

- coils, stents and filters
- aneurysm clips
- heart valves
- orthopaedic implants.

Note: *This is not an exhaustive list of devices.*

▲ Departments should ensure that their local rules include information about non-active device implants which are MR unsafe.

▲ For those that are MR conditional, a process for scanning patients with such implants should be clearly documented.

10.3.1 Aneurysm clips

Many departments take the decision not to scan patients with aneurysm clips. The MHRA² advises: *“Scanning must not proceed unless there is positive documented evidence that the aneurysm clip is non-ferromagnetic. For example, titanium, tantalum and vanadium are non-ferromagnetic, whereas stainless steel has varying degrees of para- and ferromagnetism.”*

▲ If your department has a policy to scan MR conditional aneurysm clips, a clearly defined process for ensuring accurate MR compliancy details of the clip and the process for scanning these clips should be documented within the local rules.

10.3.2 Recent implants

10.3.2.1 Care must be taken with regard to recent MR safe or MR conditional **ferromagnetic** implants or clips that are not anchored into bone, before they become embedded with fibrous tissue. Local rules should specify the time which should elapse prior to scanning, but this should not be less than six weeks. In exceptional circumstances, when clinically indicated, a decision may be made to scan prior to the six-week period. This decision should be taken following a risk-benefit analysis and clearly documented.

Please also refer to 4.4.2.

10.3.2.2 Objects such as bone screws or joint replacements which are firmly anchored may safely be scanned immediately, but should be monitored carefully because the object may be subject to temperature rise; scanning should be discontinued if discomfort occurs. Image quality around the

site will, in any case, be seriously degraded and examination may not be of diagnostic quality.

10.3.2.3 Passive implants, i.e. those that contain no electronic or magnetic components and are made of non-ferrous material, are safe to scan immediately at the field strength at which they were tested.²³

10.4 Scanning patients with implants where MRI may be contraindicated

The MHRA has issued guidance relating to the scanning of patients with implants where MRI may be contraindicated: “there may be a need in certain scenarios to perform an MRI exam on such a patient and advise a multi-disciplinary team approach be taken with a full risk assessment”.²

▲ The SCoR and BAMRR advise that the risk assessment and decision to scan should be made on a case-by-case basis. *See also section 4.4.*

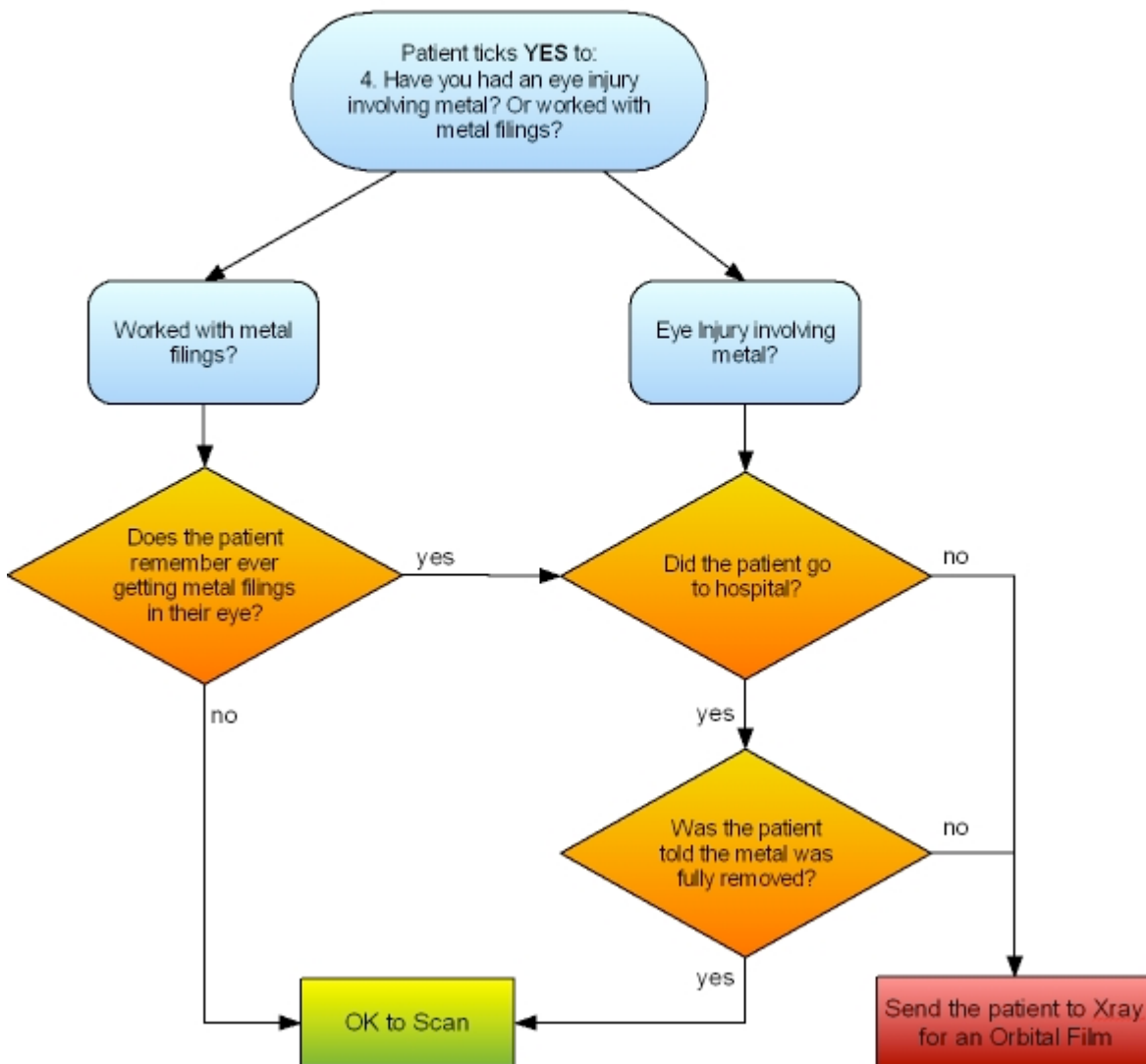
10.5 Intra-orbital foreign bodies (IOFBs)

10.5.1 Patients

IOFBs are of particular concern, and any patient who presents with a history of an IOFB should be treated with caution. The SCoR and BAMRR recommend that departments initiate a clinical screening process. This should be documented within the local rules.

An example of such a process provided by BAMRR is described below.

Orbital Film Decision Process



Note: Referrals for orbital X-Rays should only be made by individuals entitled to act as a referrer by their employer.²⁵

▲ Departments should also investigate the existence of any previous orbital imaging prior to the patient undergoing an X-ray to exclude an IOFB.

10.5.2 Staff or carers accompanying a patient

Staff or carers accompanying a patient should not enter the MR environment or undergo an X-ray if they have a history of an IOFB. In such cases, the department should make alternative arrangements if the patient requires a carer within the scan room.

10.5.3 Volunteers

Volunteers who present with a history of an IOFB should not generally be scanned (although they should be advised that this would not necessarily preclude them from a clinical scan if they were to require one in future). However, if provision has been made within the ethical approval for exposure to ionising radiation, the volunteer may proceed and undergo the clinical screening procedure for IOFB as outlined in 10.5.1.

10.6 Non-medical objects

10.6.1 Bullets and shrapnel

Metallic objects in the body (such as shrapnel and bullets) become fibrosed in tissue within six weeks. Beyond that time, scanning may be safe. However, consideration must be given to the likelihood of heating effects and also the potential for larger ferromagnetic objects to experience significant forces while being positioned within the bore of the magnet.

Any large ($>1\text{cm}^3$) metallic fragments should be assessed on a case-by-case basis. Such objects are of greater concern if they are located near significant soft tissue or vascular structures. Therefore, obtaining current and previous imaging is essential in the risk-benefit assessment required before the MR scan may proceed. Involvement of the patient, the referring clinician and a radiologist or consultant radiographer who can review and comment on related imaging is recommended in such cases.

▲ Consideration should be given to utilising low SAR sequences during scanning of these patients.

11. Pregnancy

11.1 MRI of the pregnant patient

For MR procedures on pregnant women, the safety of both the mother and the developing foetus needs to be considered. There are numerous sources of guidance, and readers should refer to the relevant sections of the guidance listed in 11.2.

- ▲ The decision to scan should be documented in the patient's notes and scanning should usually take place in **normal mode**.

11.1.1 Scanning of the pregnant patient in controlled mode

The MHRA advises: *“If the decision is taken to scan in controlled mode this should be taken following a full risk benefit analysis and made at the time by the referring clinician, consultant radiologist and patient. This decision should be recorded in the patient's notes and steps should be taken to utilise sequences that minimise RF and acoustic noise.”*²

11.2 Current guidance

ICNIRP *Guidelines on Exposure to Static Magnetic Fields 2009*¹⁴

ICNIRP *Amendment to the ICNIRP “Statement on Medical Magnetic Resonance (MR) procedures Protection of Patients” 2009*¹⁵

PHE *Protection of Patients and Volunteers Undergoing MRI Procedures 2008*¹³

MHRA *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*²

11.3 Pulse sequence selection and parameter manipulation

Manufacturers often provide general guidance in their user manual with more specific advice available from applications support teams. If required, seek advice from an MRSE regarding pulse sequence selection and discuss with a radiologist or a suitably qualified radiographer the possibility of utilising a reduced protocol examination.

- ▲ MR operators should utilise low SAR and quiet pulse sequences wherever possible.

11.3.1 Reducing heating effects

Gradient echo sequences are generally less RF intensive, resulting in less heating effects. Where possible, select low SAR pulse sequences.

- ▲ It is essential to ensure the patient's weight is accurately obtained.

11.3.2 Reducing acoustic noise levels

Where possible, switch gradients into reduced acoustic noise mode, such as whisper or soft tone. Longer repetition times (TRs), lower resolution, increased slice width and larger field of views will all reduce the dB/dt and, therefore, the acoustic noise generated. Echo planar imaging and other fast acquisition techniques will produce high acoustic noise levels and these should be carefully considered before they are used.

11.4 Use of contrast agents in pregnant patients

Use of any gadolinium-based contrast agents (GBCAs) during pregnancy is not recommended unless absolutely necessary, owing to the possibility of gadolinium accumulation in human tissues.²⁶

11.5 Pregnant staff

Under the Management of Health and Safety at Work Regulations,²⁷ employers are obliged to undertake a risk assessment for expectant mothers relating to hazards caused by physical agents. *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*² state that:

“In general, it is expected that the level of the time-varying electromagnetic fields, dB/dt, and the radio frequency will be relatively low except in the immediate vicinity of the scanning aperture. This may be of concern in the interventional situation. The level of the static magnetic field exposure is dependent on the field strength and shielding incorporated into the design of the magnet.”

Further information is available in the SCoR publication *Health & Safety and Pregnancy in Clinical Imaging and Radiotherapy Departments: A Guide for pregnant women, breast feeding women*²⁸

- ▲ Risk assessments should be conducted for each MR scanner.

An example risk assessment template is available to view on the British Institute of Radiology’s website:

https://www.bir.org.uk/media/351905/ra_7_pregnant_staff_update2017.pdf

- ▲ The MHRA recommends that throughout their pregnancy, staff should not remain in the scan room while scanning is under way.²

12. Considerations for high field strength scanners (3T and above)

The use of higher field strength units in a clinical setting is increasing. The increased signal-to-noise ratio (SNR) gained offers many advantages in clinical scanning. However, there are also further safety considerations, and employers and staff need to be fully conversant with these. Staff will require further training in order to ensure patient safety. Employers should conduct a comprehensive risk assessment prior to the use of a new high field strength installation and an independent set of local rules should be created.

12.1 Implantable medical and non-medical objects

▲ **It should not be assumed that because a device or implant is safe at 1.5T it will still be safe at field strengths of 3T and above. Departments should proceed with caution and if they are unable to obtain the required information, scanning should not take place.**

Departments should ensure that the implant or device has been tested up to the required field strength. For those listed as conditional at field strengths of 3T, departments should be fully aware of the conditions under which the device or implant can be safely scanned, in liaison with the MRSE and manufacturer. A record of all implants and their MR safety status should be included in the local rules alongside processes for scanning patients with MR conditional implants.

12.2 Projectile and attractive forces

The attractive force on a ferromagnetic object is proportional to the spatial gradient of the magnetic field. This is normally steeper at higher fields, particularly as active shielding is used to reduce the extent of the stray fields around the scanner. Therefore, objects including implants that have been found to be safe to use in the presence of 1.5T systems may not be safe with 3T systems.

▲ **Departments will need to reassess all equipment for use in 3T units that has been proved to be safe in 1.5T units. In particular, any equipment that is found to be conditionally safe at 3T must be carefully assessed, as the distance that an object can be safely kept from the magnet will alter at the higher field strength.**

Equipment should be clearly labelled, as detailed in section 5.8.

12.3 Specific absorption rate (SAR)

SAR is the measurement of energy deposited by an RF field in a given mass of tissue. SAR increases quadratically with field strengths. When using RF-intensive pulse sequences, such as fast spin echo (FSE), echo planar imaging (EPI) and fluid-attenuated inversion recovery (FLAIR), SAR limits can quickly be reached; therefore, extra precautions should be taken to ensure patient safety. Manufacturers have developed many SAR-reducing sequences and staff should be fully conversant with their use. **See also section 7.1.1.**

12.4 Peripheral nerve stimulation (PNS)

This effect is increased at 3T and the radiographer should be aware of methods to reduce this, by means of patient positioning, sequence selection and parameter manipulation if required.

12.5 Acoustic noise

The noise levels generated in a 3T system are almost twice those generated by a 1.5T system and can be in excess of 130dBA. Higher gradient performance at 3T scanning also causes higher sound pressure levels.

12.6 Pregnancy

Please also refer to section 11.

12.6.1 Scanning of pregnant patients at 3T

Departments need to carefully assess the risks and benefits prior to making the decision to scan at the higher field strength: they should consider whether scanning at lower field strength such as 1.5T would adequately answer the clinical question. The need to scan at higher field strengths may be considered in the following instances:

- a pregnant patient who is symptomatic where the outcome of the scan will affect the patient's medical management
- foetal scanning for either clinical or research purposes.

▲ The decision to scan a pregnant patient at 3T should be clearly documented and the risks and benefits discussed with the patient.

▲ In the case of research scanning, any decision to scan at higher field strength would be assessed and approved via the local ethics committee.

12.6.2 Acoustic noise exposure and the foetus

Please refer to section 2.6.2 of the MHRA guidance.²

12.6.3 Pregnant staff in high field strength units

Please refer to section 11.5 of this document.

12.7 Design and planning of a high field strength unit

Where a department has several MR scanners of different field strengths, the design and layout of the unit should reflect the caution needed when imaging a patient who has an implant or device that is safe to scan only at the lower field strength in order to avoid the possibility of the patient entering the higher field strength unit. Accurate and clear labelling of distinct areas should be employed and local rules should reflect the need for a strict pattern of working that avoids patients being inadvertently scanned on the higher field strength scanner.

13. Medicines in MRI

A variety of medicines, including contrast agents and other drugs given before, during or after an MRI scan, are utilised in MR departments. Examples include GBCAs, liver-specific contrast agents, iron oxides, diazepam, antispasmodic agents such as buscopan and glucagon, and diuretics such as furosemide.

13.1 The law currently states that radiographers are allowed to supply and/or administer medicines using patient-specific directions (PSDs) or patient group directions (PGDs) and both diagnostic and therapeutic radiographers can train to become supplementary prescribers.

13.2 A radiographer administering medicines should be trained and assessed as competent to do so, fully understanding the legal framework under which they are working.

13.3 Patient consent should be sought in line with departmental protocols and all staff should be conversant with local emergency procedures.

13.4 Adverse drug reactions should be reported to the MHRA via the yellow card scheme, alongside any local reporting mechanism <https://yellowcard.mhra.gov.uk/>

13.5 Guidance on the use of PGDs continues to evolve and develop. Before developing new or updating old PGDs, current information and resources should be reviewed. Up-to-date information on supply, administration and prescribing of medicines can be accessed from the members' section of the website: <https://www.sor.org/practice/other-groups/prescribing>

13.6 Contrast agents in MRI

13.6.1 PGDs and contrast agents

A statement regarding the use of PGDs for contrast agents was issued by the Specialist Pharmacy Service (SPS)²⁹ and a working group was subsequently set up to determine an interim solution. Template PGDs are being developed by the working group, and any updates will be available on the SoR website:

<https://www.sor.org/practice/other-groups/prescribing>

13.6.2 GBCAs

GBCAs are the most common contrast agents used in MRI. They are linked in varying degrees to a risk of nephrogenic systemic fibrosis (NSF).

The European Medicines Agency (EMA) and its Committee for Medicinal Products for Human Use (CHMP) reviewed the risk of NSF with GBCAs and classified them according to risk as follows:³⁰

High risk

- OptiMARK (gadoversetamide)
- Magnevist (gadopentetic acid)* **Note: only licensed for intra-articular use (see 13.8.2)**

Medium risk

- MultiHance (gadobenic acid)* **Note: licensed for liver imaging and when imaging in the delayed phase is required only (see 13.8.2)**
- Primovist (gadoxetic acid)* **Note: licensed for liver imaging and when imaging in the delayed phase is required (see 13.8.2)**
- Vasovist (gadofosveset)

Low risk

- Gadovist (gadobutrol)

- ProHance (gadoteridol)
- Dotarem (gadoteric acid)

13.7 Risk minimisation methods

The MHRA has issued guidance on minimising the risk of NSF:²⁶

▲ **Departments should have clear written procedures in place regarding the use of GBCAs in order to minimise the risk of NSF to include the locally agreed process for renal function monitoring.**

13.8 Gadolinium retention in the brain and other tissues

13.8.1 Background

The EMA undertook a review of GBCAs at the request of the EU due to emerging evidence of gadolinium retention in the brain.³¹

13.8.2 Removal and restrictions

The EMA recommendations³² were accepted by the EU and licences for gadodiamide (Omniscan) and intravenous gadopentetic acid (Magnevist) were removed from 1 February 2018.

The use of gadobenic acid (MultiHance) and gadoxetic acid (Primovist) is limited to liver imaging and when imaging in the delayed phase is required.

Further information is available at:

<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>

Note: *Gadopentetic acid (Magnevist) can continue to be used for intra-articular administration.*

13.8.3 Considerations for MRI departments

Although the EMA concluded that the risks of gadodiamide and intravenous gadopentetic acid outweigh the benefits, they determined that there is currently no evidence that gadolinium deposition in the brain has caused adverse neurological effects in patients.³¹ However, they do state that data on long-term effects of gadolinium deposition in the brain or other tissues are very limited and have issued information for patients and healthcare professionals:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Gadolinium-containing_contrast_agents/human_referral_prac_000056.jsp&mid=WC0b01ac05805c516f

Departments may wish to review their local protocols, procedures and governance arrangements regarding the use of GBCAs in the light of the following EMA recommendations:

- GBCAs should be used only when diagnostic information is essential and not available with unenhanced MRI.
- The recommended dose per kilogram of body weight should not be exceeded.
- The lowest dose that is effective for diagnosis should be used.

There is a growing awareness among patients and the public regarding gadolinium retention in tissues. Departments may wish to take account of this and review the information provided to patients. This may include providing the product information leaflet and the EMA's guidance for patients.

They may also wish to consider their local consent procedures.

14. Manual handling in MRI

Manual handling within an MR unit frequently involves the moving and positioning of cumbersome coils, heavy phantoms, other equipment and patients.

▲ It is advisable for departments to ensure that there are storage units for coils at a corresponding height to the MR table top to avoid staff frequently lifting coils from floor to table top. If this is not feasible, for example on a mobile unit, appropriate measures should be put in place to minimise risks following a risk assessment. This may include, for example, altering the bookings to minimise coil changes throughout the day.

14.1 Moving patients into and out of the scanner

14.1.1 Care should be taken when moving patients into and out of the scanner that there is no danger of entrapment due to positioning of limbs or any coils and ancillary equipment.

14.1.2 The remote removal function should not be routinely used in MRI for removing a patient. The function may well be required during the course of some examinations (e.g. vascular scanning), and possibly in an emergency. However, this should be carried out with visual contact and verbal instructions at the very least, and ideally under supervision.

15. Fire and emergency safety and training

The static magnetic field means that extra considerations are required in the case of an emergency or fire within an MR unit. MR staff should be conversant with all safety procedures and practised in the safe removal of patients in an emergency situation. We recommend that this is practised a minimum of four times per annum and on induction to the unit for new staff. Staff should be aware of the location of the fire extinguishers, quench buttons, oxygen monitors and departmental crash trolley.

▲ It is recommended that contact is made with the local fire unit to ensure that they are aware of the layout of the unit and safety considerations, including the location of the quench button.

15.1 In the case of a patient emergency, such as cardiac arrest, within the scan room, the patient should be removed from the MR environment prior to the arrival of the resuscitation team and their equipment.

15.2 Clear fire procedures should be kept with the local rules. Staff should be aware of these and, in particular, of the scenarios under which a quench would be required during a fire in the MR unit.

15.3 Staff should be aware of the circumstances under which they should quench a magnet and should understand the implications of a magnet quench.

16. The Control of Electromagnetic Fields at Work (CEMFAW) Regulations

16.1 Background

The European Union Physical Agents Directive³³ concerning worker exposure to Electromagnetic Fields (EMFs) was formally adopted in June 2013 and transposed into law in July 2016 as the CEMFAW regulations.¹ The HSE oversees this for England, Scotland and Wales, and HSENI is responsible for Northern Ireland. Both organisations have only introduced new requirements from the directive that go beyond current UK legislation.

The directive covers the minimum health and safety requirements regarding the exposure of workers to the risks arising from EMFs. The CEMFAW regulations place a duty on employers to assess employees' exposure to EMFs and manage any risks associated with this.

16.2 MRI exemption for medical purposes

The directive includes a derogation for activities relating to the installation, testing, use, development, maintenance of or research related to MRI equipment for patients in the health sector from the exposure limit values (ELVs), subject to certain conditions. This is referred to as the MRI exemption for medical purposes within CEMFAW.

Employers will not be required to use measurements or calculations in their exposure assessment, or undertake an action plan, in relation to activities that are included in the exemption. All other requirements of the regulations still apply to that work activity.

However, employers must ensure that:

- ▲ exposure is as low as is reasonably practical
- ▲ employees are protected against health effects and safety risks arising from that exposure.
- ▲ Employers must still carry out risk assessments and ensure that workers are given appropriate information and training.

Sample risk assessment templates produced by members of the MR special interest group (SIG) of the British Institute of Radiology (BIR) are available on the BIR website:

<https://www.bir.org.uk/get-involved/special-interest-groups/bir-magnetic-resonance/emf-risk-assessments/risk-assessments/>

16.3 Exemption certificates

The directive also includes a general temporary conditional derogation for specific activities subject to agreement with the overseeing authority for each member state.

The HSE and HSENI have published exemption certificates^{34, 35} containing information about activities that are exempt (under general temporary conditional derogation). This currently includes the use of MRI equipment other than for patients in the health sector.

Further information is available on the SoR website:

<https://www.sor.org/practice/cross-sectional-imaging/control-electro-magnetic-fields-work-regulations-cemfaw>

17. Design and planning of units

17.1 It is essential that an MR radiographer is, from the outset, part of the project team for the design and planning of a new or additional MR unit, along with an MRI physicist, NHS estates or private company estates person, vendor's project manager and architect, etc. It is also useful to include a member from the hospital's infection control team, nursing team, medical physics, manual handling and risk assessment departments to gain their input to the project, as any equipment will need to be tested/certified and furniture/fittings should be ergonomically designed and should comply with current standards.

17.2 It is important to obtain a copy of the pre-installation guidelines document from the magnet vendor as soon as possible, as that will give the specifics/particular requirements for the system.

17.3 There are numerous safety considerations relating to site selection, site location, site access, quench pipe design considerations, location of scan rooms, control rooms, preparation rooms, storage of equipment, emergency equipment, etc. For further information please refer to the MHRA guidelines.²

18. Imaging Services Accreditation Scheme ISAS³⁶

This guidance relates to the following Standard Statements: SA3 SA6 SA7 LM1 LM2 PE1 PE3 CL5 FR1 FR2 FR3 FR4.

19. Further resources

The Society and College of Radiographers MRI web pages

<https://www.sor.org/practice/cross-sectional-imaging/mri>

The Society and College of Radiographers Magnetic Resonance Advisory Group

<https://www.sor.org/practice/cross-sectional-imaging/mr-advisory-group>

The Society and College of Radiographers and the Royal College of Radiologists Imaging Services Accreditation Scheme

<https://www.sor.org/about-radiography/imaging-services-accreditation-scheme-isas>

The British Association of MR Radiographers (BAMRR)

<http://www.bamrr.org/home>

The Institute of Physics and Engineering in Medicine (IPEM)

<http://www.ipem.ac.uk/>

British Institute of Radiology

<http://www.bir.org.uk/>

Medicines and Healthcare products Regulatory Agency (MHRA)

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

International Society for Magnetic Resonance in Medicine (ISMRM)

<http://www.ismrm.org/>

ISMRM British Chapter

<http://www.ismrm.org/british/index.htm>

Society for MR Radiographers and Technologists (SMRT)

www.ismrm.org/smrt/

Royal College of Radiologists

<https://www.rcr.ac.uk/>

Public Health England Non-Ionising Radiation Services

<https://www.phe-protectionservices.org.uk/nir>

MRIsafety.com is the premier information resource for magnetic resonance safety

<http://www.mrisafety.com/>

Health and Care Professions Council

<http://www.hcpc-uk.co.uk/>

Health and Safety Executive (HSE)

<http://www.hse.gov.uk/index.htm>

<http://www.hse.gov.uk/radiation/nonionising/directive.htm>

<http://www.hse.gov.uk/aboutus/europe/euronews/dossiers/emf-directive.htm>

Health and Safety Executive Northern Ireland (HSENI)

<https://www.hseni.gov.uk>

CEMFAW

<http://www.hse.gov.uk/radiation/nonionising/emf-faqs.htm>

<http://www.hse.gov.uk/radiation/nonionising/emf.htm>

<http://www.hse.gov.uk/radiation/nonionising/emf-exemptions.htm>

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