University Hospitals of North Midlands NHS
NHS Trust

Magnetic Resonance Imaging

Local Rules

University Hospitals of North Midlands

MRI systems

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Contents

1 Introduction

These local rules outline the necessary precautions all personnel should take to ensure that the MRI scanner is operated safely, and that the risks to staff, patients and the public are minimised.

The local rules should be reviewed annually. All staff should read and sign the local rules on an annual basis, as part of their appraisal. Any member of staff who has not read the current local rules will not be eligible for their pay progression.

These local rules should be read in conjunction with the following Trust policies:

Policy HS01:	Health & Safety (H&S) Policy
Policy C12:	Trust Policy for Ensuring Correct Patient Identification
Policy C11:	Trust Policy for Interpreters
Policy C43:	Consent to Treatment (incorporating Mental Capacity Act)
IRMER A:	Protocol for correct patient identification and correct area of examination.
IRMER C:	Protocol for making enquiries of individuals of childbearing age to establish whether the individual is, or may be, pregnant or breastfeeding.
MR17/SOP/004	Scanning of Volunteers in MRI
RES 003	A pathway for the use of healthy volunteers for research test scans within the Imaging department
MR18/SAF/004	Temperature and Humidity Flow Charts
C09	Trust Resuscitation Policy
EF01	Trust Fire Policy
MR19/SWP/001	SED warning procedure
MR21/SOP/027	Unexpected metal artefact seen on MRI scan
MR21/SOP/028	Actions to be taken in the event of a MRI related burn

In addition, all Category A staff must be aware of the implant safety policies. The latest versions of these can be found on SharePoint.

2 Description of Facility

The following indicates the location of all MRI systems within the University Hospitals of North Midlands NHS Trust:

Royal Stoke University Hospital (RSUH)

- Two 3T MRI systems located in the X-Ray Department, Main Building on level LG1.
- One 1.5T MRI system located in the X-Ray Department, Main Building on level LG1.
- Two 1.5T MRI systems located in the Valley Centre adjacent to the Cancer Centre.

County Hospital

- One 1.5T MRI system located in the X-ray Department.
- One 3T MRI system located in the X-ray Department.

Mobile Scanners

- Mobile MRI scanners may be temporarily on site at both County and Royal Stoke sites.
- In this event temporary additions to the local rules will be published to cover these facilities.

3 Hazards

The MRI scanner is a complex and expensive piece of equipment. It poses a number of hazards: some of these are present at all times, whereas others are only present during an MRI examination.

3.1 Hazards present at all times

Static Magnetic Field

It is important to note that the static magnet remains on **continuously,** even when the scanner is not in use**.**

The static magnetic field is maximum within the bore of the magnet but extends beyond the magnet housing in all directions. Plots of the fringe field (0.5mT and 3mT) for the static MRI systems covered by these local rules are shown in Appendix A.

The static magnetic field may have an adverse effect on implanted biomedical devices or foreign objects in patients or staff that enter the MR environment. This includes people with cardiac pacemakers, aneurysm clips and other sensitive biomedical equipment.

The static magnetic field will exert powerful forces on any loose ferromagnetic objects causing them to become projectiles. This may result in injury to persons close by or within the bore of the magnet as well as causing damage to the MRI system.

The strong static magnetic fields may cause irreversible damage to certain personal items. This can include bank cards, access cards, watches, pagers and mobile phones. This list is non-exhaustive.

Cryogens

Liquefied helium (a cryogen) is used by the magnet to cool the magnet windings to superconducting temperatures. The cryogen is contained within the magnet itself and poses a potential hazard in the event of a quench.

Sudden collapse of the magnetic field (quenching) can occur without warning causing immediate boil off of the liquid helium. The MRI scanner has a quench pipe which should vent the helium gas outside into a designated area, which has been deemed safe. In the event that the quench system fails, the helium may fill the scan room and could cause persons within the scan room to experience asphyxiation and hypothermia.

Electrical Hazards

Electrical hazards exist due to the powerful amplifiers and high voltage devices associated with the MRI scanner, contained in the MRI equipment room. For this reason, only authorised engineers may operate the high voltage equipment in the MRI equipment room. Hazards present during MRI scanning

Time varying magnetic field gradients

Time varying magnetic field gradients are generated in certain parts of the MRI bore by rapid switching of the gradient magnetic fields. These can cause currents in nerves, potentially resulting in peripheral nerve stimulation. Time varying gradients can also create currents in conductive components of implants, potentially resulting in device malfunction or tissue burns. This will only affect people within the bore of the magnet.

Exposure to these magnetic field gradients is regulated by strict controls. The scanner will warn the operator if the patient is likely to experience any PNS and levels can be restricted for scanning MR Conditional implants in line with manufacturer guidelines.

The time varying magnetic field gradients also generate high levels of acoustic noise. Anyone within the magnet room during scanning will experience these high levels of noise and must therefore wear the ear plugs provided.

Radiofrequency (RF) electromagnetic fields.

RF electromagnetic fields deposit energy into the person being scanned at a given rate, depending on the pulse sequence and parameters used.

Energy deposited into the patient through RF fields can cause a rise in core body temperature as well as the possibility of localised heating (for example around metallic implants, RF coils or monitoring cables). The energy deposited into the patient is defined per kilogram of tissue (Wkg^{-1}) known as the Specific Absorption Rate (SAR).

4 Responsibilities and Organisation

These local rules refer to various titles and organisations that are listed below. A list of named personnel for these roles is given in Appendix B.

Employing Authority

Ultimate responsibility for the implementation and maintenance of procedures to ensure the health and safety of all persons entering the MRI unit lies with the employer, University Hospitals of North Midlands NHS Trust. The Chief Executive of this organisation is responsible for Health and Safety and delegates the authority for the effective management of MRI safety through the arrangements set out in the Trust Health and Safety Policy (HS01).

MR Responsible Person

Under the above arrangements the MR Responsible Person shall ensure that a set of local rules is in place and is adhered to. These local rules will define specific roles, responsibilities and management arrangements. The MR Responsible Person is also responsible for ensuring the requirements of this policy are communicated to all relevant staff and systems are in place to ensure all necessary training is provided and recorded.

During periods of absence the duties of MR Responsible person required for day to day provision of the service can be carried out by those persons so listed in Appendix B.

MR Safety Expert

The MR Safety Expert should be a registered clinical scientist with adequate training, knowledge and experience of MRI equipment in clinical use. The MR Safety Expert should support the MR Responsible Person by providing advice on the following areas: site planning, development of a safety framework, advising on monitoring the effectiveness of local safety procedures, procurement, adverse incident investigation and advising on specific patient examinations. The MRI Safety Expert should also assist with the training of staff in the area of MRI safety. The MRI Safety Expert should hold an IPEM MRSE Certificate of Competence.

The MR Safety Expert will work with a team of MRI physicists. The MRI physicists are able to undertake any of the tasks performed by the MR Safety Expert that are within their knowledge and experience.

MRI Clinical Safety Advisor

The MRI Clinical Advisor is a consultant radiologist familiar with up to date knowledge of MRI safety. They can act as an arbitrator in cases of dispute relating to MRI safety.

MR Safety and Quality Committee

The MRI Safety and Quality Committee meets regularly to discuss issues relating to MRI safety. Local safety incidents, national/international incidents and staff training are all discussed at this meeting. The committee reports back to the Trust Radiation Protection Committee, Imaging Clinical Governance and the Clinical Director of Imaging. Membership can be found in the Terms of Reference for this committee.

Referring Clinicians

It is the responsibility of the referrer to identify those patients with implants and/or contraindications to MR before referral, and to provide sufficient relevant medical data for the accepting clinician to identify any hazard associated with the exam.

Operator

The operator (usually a radiographer) is responsible for adhering to these Local Rules, as well as to other relevant Trust policies and departmental processes and procedures thereby ensuring the safety of all patients, staff and visitors in the MRI suite.

Supervising Radiologist

The supervising radiologist must be adequately informed of the patient's state of health and medical history when accepting requests for scans. Patients should be exposed only with the approval of a registered medical practitioner who should be satisfied either that the exposure is likely to contribute to the treatment of the patient or that it is part of a research project that has been approved by a research ethics committee. This justification can be delegated via authorised protocols.

5 Authorised Personnel

There are three categories of authorised personnel. A list of individually named authorised personnel is given in Appendix B. The MR Responsible Person should approve certification of staff as authorised personnel once the member of staff has satisfactorily completed the appropriate training. The list of authorised personnel with be reviewed at least annually by the MR Responsible Person.

Category A: MR Operator

Category A authorised personnel have access to the MR Environment and Controlled Access Areas **AND** to admit unauthorised persons into these areas after they have completed the relevant screening process.

Category B: MR Environment

Category B authorised personnel have access to the MR Environment and Controlled Access Areas but **MUST NOT** admit any unauthorised persons into the MR Environment. They may admit unauthorised personnel into the Controlled Access Area, after completing the relevant screening process.

Category C: MR Non-Environment

Category C authorised personnel have access to the Controlled Access Area but must be supervised when working in the MR Environment. They **MUST NOT** admit any unauthorised persons into the Controlled Access Area or MR Environment. Staff fit into this category if they regularly work in MRI (at least once a week) and have attended MRI safety training. Staff who work in MRI less frequently, but have a longstanding history of working safely in MRI may be granted Category C authorisation at the discretion of the MR Responsible Person.

6 Control of Access

Access to the MRI scanner must be strictly controlled. There are two designated areas:

6.1 The Controlled Access Area.

The Controlled Access Area contains the magnet room, control room and associated areas. This area wholly contains the 0.5 mT (5 G) magnetic field contour. A diagram indicating the extent of the Controlled Access Area is shown in Appendix C.

The Controlled Access Area is accessed through a set of self-locking double doors with entry controlled by means of an access card. This door should remain closed other than when people are entering or leaving the MRI Unit. Control of access to this area is strictly supervised to prevent unauthorised persons having unsupervised access to the MR Environment.

In the event of a fire alarm the security on the doors into the Controlled Access Area will be disabled, so a Category A or B authorised member of staff should ensure that access is restricted to this area, until the surrounding area has been appropriately evacuated.

All persons except authorised personnel wishing to enter the Controlled Access Area must be verbally screened for the presence of a cardiac pacemaker or aneurysm clips.

Although the 0.5 mT magnetic field line does not extend outside of the MR Environment, persons fitted with cardiac pacemakers should not be allowed to enter the Controlled Access Area until investigated by a Category A authorised person.

All non-authorised persons permitted within the MRI Controlled Access Area must be informed not to enter the MR Environment, and must be under the supervision of a Category A authorised person.

6.2 The MR Environment

The MR Environment is the three dimensional volume of space surrounding the MRI scanner that contains both the faraday shielded volume and the 0.5mT field contour. A diagram indicating the extent of the MR Environment for each scanner is shown in Appendix C.

The MR Environment includes the room in which each magnet is housed (the magnet room) and in some cases the MRI control and equipment rooms. The doors to the MR Environment (magnet room) should remain closed at all times other than when authorised personnel need access.

Access to the magnet room can only be gained by first entering the Controlled Access Area. Where the MR Environment extends into the MRI equipment room, the doors to the equipment room must be kept locked at all times and only accessed by staff with appropriate authorisation. Anyone else wishing to enter the equipment room must be appropriately screened and supervised by a Category A member of staff.

The static magnetic field within the MR Environment may cause cardiac pacemakers, other biomedical implants and life support systems to malfunction. Persons fitted with any such device must not enter this area until it has been established that it is safe for them to do so by

a Category A authorised person.

No ferromagnetic materials or personal effects that are sensitive to static magnetic fields should be taken into the MR Environment. It is the responsibility of the authorised personnel to ensure that this is enforced by themselves and any others that they are supervising.

All persons wishing to enter the MR Environment must, ***without exception,*** have completed the screening form relevant to their category and it must be completed before entering the MR Environment.

7 Labelling of Equipment

Equipment used in the MRI department will fit into one of the following categories:

MR Safe: An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic

MR Conditional: An item with demonstrated safety in the MR environment within defined conditions. The conditions must be clearly labelled on the device.

MR Unsafe: An item which poses an unacceptable risk to patient, staff or other persons with the MR environment.

MR Unlabelled: An item without an MR Safe, MR Conditional or MR Unsafe label. **No label**

All mobile/portable equipment that could be taken into the MR Environment should be clearly labelled using ISO approved labels, shown above, with appropriate descriptive text if necessary. Any unlabelled equipment should be treated as MR unsafe until appropriately checked by a Category A authorised person.

8 Screening

The screening process is designed to detect and identify foreign materials within persons and to establish whether it is safe for them to enter the MR Environment and undergo an MRI scan. The screening form and any investigations resulting from this process must be documented on CRIS.

8.1 Patients Able to Complete the Screening Form

All patients are required to complete the patient screening form (Appendix E) which should be checked by a Category A authorised person. For confidentiality the form may be completed in the Controlled Access Area, provided that the patient is verbally screened for the presence of a cardiac pacemaker or aneurysm clips prior to entry into the Controlled Access Area.

A new patient screening form must be completed for each repeat examination to confirm that there have been no changes since the last scan.

Patients should only proceed to the MR Environment once they have fully completed the patient screening form, and a Category A authorised person confirms they are safe to do so.

If there is any doubt over whether a patient is safe to enter the MR Environment, investigations must be completed and safety established before they are allowed to enter. If necessary the appointment should be postponed to allow a complete investigation to take place.

Patients should keep all valuables in the lockers provided in the Controlled Access Area.

8.2 Patients Unable To Complete the Screening Form

Where patients are to be anaesthetised or sedated for the MRI examination, the screening form should be completed beforehand when fully conscious.

Where a communication barrier to the screening process exists, staff must follow the Trust Policy for Interpreters (policy C11). This does not rule out the use of departmental staff who speak an appropriate language in emergency situations.

A parent or guardian must complete the screening form for patients who are under the age of 16 years.

In any other circumstance where it is not possible to satisfactorily complete the screening form it is necessary for a clinician to complete the supplementary safety form given in Appendix I on behalf of the patient. The clinician completing the form must have registrar status or above.

A new Appendix I form must be completed for each repeat scan, or the referrer must confirm in writing that there have been no changes to the previous Appendix I form.

A radiographer must check that Appendix I has been fully completed. When the patient arrives in the department a radiographer must screen for any additional equipment (e.g. ECG dots) and verify that these are MR safe or MR conditional before proceeding with the examination. This should be documented on CRIS.

8.3 Pregnant Patients

There is currently no evidence that static or time-varying magnetic fields up to the levels used for clinical MRI can cause any detrimental effect to the embryo or foetus. However, it is prudent to avoid unnecessary or excessive exposure.

For all patients of potentially childbearing age the radiographer should follow the UHNM IRMER C policy. The 28 day rule should be applied, as for low dose ionising radiation procedures.

As in IRMER C, a radiologist should assess the need and extent of a routine MRI examination if a patent is known to be pregnant. There are occasions when MRI would be more appropriate than exposure to ionising radiation. For research projects pregnancy is a bar to scan participation unless explicitly indicated in the research ethics.

The patient should read the pregnant patient information sheet (Appendix F) and the radiographer must obtain informed verbal consent, documented on CRIS, before proceeding with the examination.

MRI contrast media should only be administered in exceptional circumstances at the discretion of the supervising radiologist and after formal consent has been obtained from the patient. The radiologist decision and patient consent must be documented on CRIS.

Unless clinical indications dictate otherwise, if a pregnant patient is scanned then noise exposure and SAR should be minimised by utilising the lowest available field strength and adopting appropriate scanner parameters, as hearing protection cannot be given to the foetus and heating is also a concern for the developing foetus. The radiographer should remain in normal SAR mode throughout the scan.

8.4 Volunteers

All volunteers should complete the patient screening form which should be checked by a Category A authorised person.

If a volunteer is scanned for image optimisation or protocol development then the procedure MR17/SOP/004 must be followed. If a volunteer is being scanned as part of a research trial then procedure RES 003 should be followed.

8.5 Authorised Personnel

Authorised personnel are required to complete the MRI Screening Form for Staff and Visitors (Appendix G) prior to commencing work in the department. It is the responsibility of the member of staff to report any changes to their screening form to the MR Responsible Person at the earliest opportunity. All authorised personnel should undergo repeat safety screening annually at their appraisal and on return to work following surgery.

8.6 Unauthorised Persons including Staff, the General Public and Patient Escorts

The term ‘patient escort’ includes nurses, friends and relatives accompanying the patient. This allows friends and relatives to accompany the patient into the scan room where necessary.

Unauthorised staff will not be granted swipe card access to the MRI unit.

Unauthorised persons entering the MR Controlled Access Area should be verbally screened for the presence of a cardiac pacemaker or aneurysm clip and must be supervised by a Category A or B authorised person. Unauthorised persons entering the MR Environment may only do so after completing the staff and visitor screening form (Appendix G), which must be checked by a Category A authorised person. These forms are kept for a maximum of 2 years before being disposed of. They must be supervised by a Category A authorised person and must be visible to the Category A authorised person at all times. Pregnant individuals within this category should be excluded from entering the MR Environment.

In the event the supervising staff member needs to leave the MRI suite it is their responsibility to handover supervision to another authorised person.

8.7 Engineers Employed by the MRI System Manufacturer and/or Liquid Cryogen Supplier

For persons in this category it is the responsibility of their employer to ensure that adequate training in safe practice for the maintenance of the MRI Equipment and / or performance of cryogen fill has been fulfilled and that these persons are fully aware of the safety issues concerning MRI equipment.

MRI equipment must be formally handed over to the engineer by a Category A authorised person prior to commencement of works. Until formally handed back to a UHNM employee the engineer is responsible for the safe use of the equipment and jointly responsible with UHNM staff for control of access to the MR Environment. On completion of works the equipment must be formally handed back to a UHNM Category A authorised person.

Persons in this category may be provided with access cards / keys to the Controlled Access Areas including the MRI equipment rooms and shall have free access to the Controlled Access Areas and MR Environment.

Persons in this category should not admit other persons into the Controlled Access Area or MR Environment. If access to the Controlled Access Area is required outside of normal working hours, engineers must liaise with a Category A authorised person.

They must abide by their employer’s systems of work and MRI safety rules whilst working on UHNM premises.

Engineers working on live equipment or carrying out a cryogen fill must not work alone in the department.

8.8 Health and Safety at Work Act

In addition to the special rules given in this document, all staff are reminded of their duties under the Health and Safety at Work Act.

Each person entering the MRI unit has a duty to themselves and others to be diligent in the observation of the safety rules and also such verbal and written guidance as may be used to supplement these rules.

All staff have a duty to inform the MRI responsible person of any additional hazard not covered by these local rules, or covered in a way which is found to be inadequate.

There is a strict duty under the Health and Safety at Work Act to demonstrate due regard for the condition of apparatus used within the MRI unit and for its correct operation. Deficiencies in training or instruction should be drawn to the attention of the MRI responsible person at the earliest opportunity.

9 Scanning of Patients and Volunteers

9.1 General

MR imaging will be undertaken only by staff trained, and formally assessed as competent, in the safe clinical use of the MRI equipment. Scanning of human subjects can only be performed when a Category A authorised person (MRI operator) is present.

The ideal scan room temperature is 18-22ºC, and the ideal scan room humidity is 40-60%. If either temperature or humidity are outside of these ranges then safety procedure MR18/SAF/004 should be consulted as to whether scanning may continue. Particular care should be taken when scanning patients with impaired thermoregulatory response (neonates, infants, pregnant, febrile or elderly patients) or patients with implanted devices when operating outside of the ideal scan room temperature and humidity range.

The MRI operator (usually the scanning radiographer) is responsible for the patient during their MRI scan. The scanning radiographer must ensure the patient is carefully positioned in the scanner ensuring that:

- The patient must be fully changed into a metal free gown. If this is not possible, any clothing with metal must be removed, and the patient's dignity maintained by covering them with blankets or sheets. In the rare event that this is still not possible, padding that is at least 1cm thick must be positioned between the metal and the patient's skin.
- The patient's skin is not in contact with the scanner bore, use padding that is at least 1cm thick to avoid this where necessary.
- The patient's arms and legs are not touching.
- The patient's clothing is not wet.
- There is sufficient ventilation during examination.
- All peripheral equipment attached to patient is MR Safe or MR Conditional, and any conditions are followed appropriately.

- Cables do not form conductive loops.
- Patient's skin is not in contact with cables.
- Particular care should be taken when positioning and scanning patients who cannot report heating, e.g. sedated and anesthetised patients.
- Advice from senior clinical registered colleagues or MRI Physics must be sought if in any doubt.

The MR operator should ensure that when the patient / volunteer enters the scanner, any cables associated with the monitoring equipment or RF coils are kept well away from each other and from the patient and that there are no loops in any of these cables. Specific advice provided by the scanner manufacturer in the operator manual should be followed.

Patients requiring trolleys or wheelchairs should be transferred onto the MRI-conditional trolley or wheelchair provided within the MRI unit prior to entry to the MR Environment. On no account should any other trolley or wheelchair be taken into the MR Environment.

Wherever possible, MR unsafe wheelchairs should not be taken into the MR Controlled Access Area. When it is necessary for MR Unsafe wheelchairs to be brought into the department then the authorised member of staff who brings the equipment into the department must take responsibility for it and ensure it does not enter the MR environment. MR Unsafe wheelchairs should not be left unattended near to the entrance of the MR Environment, but could instead be stored in the control room or outside of the MR Controlled Access Area.

9.2 Patients Undergoing Sedation or General Anaesthesia

Orally sedated patients should be closely monitored for MR safety during scanning by the MR Operator, including frequent visual check by the video link and more frequent verbal communication with the patient.

Anaesthetic induction of the patient should take place in the preparation/recovery area where standard anaesthetic equipment and monitoring equipment may be used, and not in the MR Environment. The patient should be transferred to the MR Environment subsequently, where MRI Conditional monitoring and anaesthetic equipment is available. On no account must the standard anaesthetic and monitoring equipment be taken into the MR Environment.

Care should be taken to ensure that cables associated with the monitoring equipment are kept separate from the cables associated with RF coil of the MRI system and that there are no loops in any of these cables within the magnet. A Category A authorised person should check all ancillary equipment, including the ECG pads, are MR safe or MR Conditional before taking the patient into the MR environment.

Once the examination is completed, the patient should be transferred back to the preparation room prior to recovery.

MR Unsafe beds/trolleys must never be taken into the MR Environment. Any MR Unsafe beds/trolleys brought into the MR Controlled Access Area must have an MR Unsafe sign clearly displayed on them. All anaesthetised patients should ideally be removed from the scan room on the dockable table, and transferred onto a bed/trolley outside of the scan room.

Where this is not practicable, an MR Conditional trolley can be taken into the MRI scan room only under the direct supervision of the supervising radiographer or Consultant anaesthetist. No other staff members are authorised to bring an MR Conditional trolley into the scan room.

9.3 Control of Exposure and Monitoring Of Patients and Volunteers during MRI Examination

Patients and volunteers will be exposed to the static magnetic field. The MRI systems at University Hospitals of North Midlands have nominal magnetic field strengths (within the magnet bore) of 3.0 T or lower. This is lower than the recommended maximum exposure (4.0 T) for routine procedures specified by the HPA guidelines.

Patients and volunteers will be exposed to time varying magnetic fields generated in certain parts of the magnet bore by the rapid switching of the gradient magnetic fields.

Exposure to the radiofrequency field, expressed as the Specific Absorption Rate (SAR) is calculated by the MRI system prior to each scan and this calculation is based on the weight and height of the patient which must be entered by the operator at the beginning of the examination. The correct patient weight and height should always be entered at the start of each examination to ensure calculations are accurate. The scanner will also record the total energy deposited in the patient, this is the Specific Energy Dose (SED). The scanner will warn if the SED is approaching the limit. If an SED warning appears then radiographers must follow policy MR19/SWP/001.

The operator should be aware of the current national guidelines relating to the rate of gradient switching, SAR and SED limits and should seek to minimise these where practicable. The current guidelines and a list of the modes of operation are given in Appendix H. Care should be taken with the positioning of the patient and cables to minimise the risk of local heating.

The MR operator should observe the patient at all times for signs of distress, and maintain regular communication with the patient. Special consideration should be given to patients with implanted materials or devices that may increase their sensitivity to gradient switching or RF heating.

Operators must use their professional judgment when First level (Controlled) Mode is required for scanning, or when warnings of Peripheral Nerve Stimulation are displayed, to maintain SAR and gradient switching rates as low as reasonably practicable. When scanning patients with impaired thermoregulatory response (neonates, infants, and pregnant, febrile or elderly patients) or patients with implanted devices, the SAR and gradient switching rates shall be kept as low as reasonably practicable and, where possible, should not exceed Normal Mode unless there is a clinical imperative. Some implants may require more restrictive levels.

Patients and volunteers will be exposed to high levels of acoustic noise generated by the gradient magnetic fields. Patients and volunteers undergoing MRI examinations including those who are sedated or anaesthetised must wear appropriate ear protection throughout the duration of the examination. It is the responsibility of the Category A scanning radiographer to ensure that the ear protection has been fitted correctly.

9.4 Contrast Media and Drug Administration

Gadolinium based contrast agents used in MRI can present risks to particular groups of patients, including nephrogenic systemic fibrosis and the possibility of retention. All contrast agents must be administered in line with Trust policy and current local guidelines, and the procedures for identifying high risk patient groups must be followed.

All other medicines administered must also be administered only in line with Trust policy and the appropriate protocols and procedures.

9.5 Control of Exposure of Staff Entering the MR Environment

Authorised persons (e.g. radiographers) who regularly accompany patients into the MR environment are normally only exposed to a low level of static magnetic field in their normal working practice except in the immediate vicinity of the magnet bore.

Staff who remain in the magnet room during scanning must wear suitable ear protection.

Pregnant Staff

All staff are responsible for reporting changes to their screening form, such as pregnancy, to the MR Responsible Person at the earliest opportunity so that appropriate actions can be taken. Confidentiality will be maintained where reasonably practicable. A risk assessment must be performed for every pregnant member of staff.

In line with the MHRA guidelines (2021) pregnant staff must not remain in the scan room whilst scanning is underway in order to minimise foetal exposure to RF fields and acoustic noise.

The guidelines also make it clear that there is no known risk to a foetus attributable to the static magnetic field at field strengths less than 4T. However, where staff request to work at lower field strengths during pregnancy for their own peace of mind this will be accommodated whenever service needs allow, particularly within the first trimester. More information can be found in the MR Worker Pregnancy Guidance in the Health and Safety section of Sharepoint.

9.6 Control of Exposure of Escorts/Relatives Accompanying Patients into the MR environment

On occasion it is necessary for patients to be accompanied or escorted in the MR environment. Reasons might include close monitoring by clinical staff of acutely unwell patients, or psychological support by parents, relatives or friends for very young patients, or for anxious or claustrophobic patients. This list is not exhaustive and the MR Operator must use professional judgement to minimise unnecessary exposure.

Ear protection must be worn by any escort or relative who remains in the MR environment during the scan.

10 Emergency Procedures

In an emergency, unauthorised persons may not enter the Controlled Access Area until they have been verbally screened for the presence of a cardiac pacemaker or aneurysm clip. If necessary in an emergency, verbal assurance may be given in place of completing the screening from set out in Appendix E to obtain access to the MR Environment.

When an emergency occurs in the Controlled Access Area other Authorised Personnel can be alerted by pressing the patient alarm button.

10.1 Cardiac or Respiratory Arrest, Fire, or Quench

For instructions on what to do in the event of a cardiac or respiratory arrest, fire or magnet quench, please refer to the Emergency Action Cards in Appendix K.

These emergency action cards should be read in conjunction with the Trust's resuscitation policy (C09) and the Trust fire policy (EF01).

A magnet quench is accompanied by a rapid loss of cryogen gas through a vent pipe into the atmosphere and a rapid loss of the static magnetic field. This can be spontaneous or can be deliberately initiated by operator activation of the magnet quench button. The time taken for the magnetic field to fall to safe levels after this button is pushed is approximately 30 seconds.

The magnet emergency stop (quench) button should only be operated under the following conditions:

- Forces due to the magnetic field causing patient or personnel injury (see section 10.2).
- Fire or other unexpected occurrence that requires action and entry to the MR Environment by emergency personnel.

The decision to initiate a quench must be made by a Category A authorised person who should familiarise themselves with the location of the magnet stop button(s). The button is protected to prevent accidental activation.

10.2 Ferromagnetic Object within the Magnet Bore

A ferromagnetic object entering the magnet bore is likely to cause damage to persons in its pathway and the magnet structure. The following procedures should be followed if, despite all precautions, such an event occurs.

No Injuries

Evacuate all Unauthorised personnel from the MR Environment. The radiographer must seek advice from the most senior radiographer or physicist available. A Category A authorised person may remove the item only if it is small, light, easily removed and will not cause any further damage or injury to do so. Examples include a hair clip or coin.

If the object is heavy, large or might cause further injury or damage, do not attempt to remove the object. The object may try to twist to align with the field as it is removed, and can cause damage to wrists. Call the MRI manufacturer service desk, an engineer may need to come

and assess the best way to remove the object.

In all cases, urgently inform the MR Responsible Person, or deputy, and complete a DATIX.

Person injured, but NOT trapped

Remove the injured person from the MR Environment and obtain medical assistance.

Inform the MR Responsible Person, or their deputy, as soon as practically possible and complete a DATIX. Once the person has been removed the same process as above can be followed.

Person Injured and Trapped

Medical assistance should be obtained, ensuring that the **full verbal screening** procedure is followed.

If there is immediate danger to the person's life then a Category A authorised person should carry out a controlled quench following the procedure below.

Evacuate as many people as possible from the Controlled Access Area, keeping sufficient staff present to support the object and evacuate the patient in the event of a quench pipe failure. The object should be supported to prevent further injury when the magnetic field drops to zero. The injured should be given oxygen via piped gas during the magnet quench in case there is a failure of the quench pipe system and helium enters the scan room.

The injured person should be removed from the MR Environment for medical treatment.

As soon as practically possible inform the MR Responsible Person, MR Safety Expert and MRI manufacturer's service desk. Complete a DATIX

10.3 Ferromagnetic Object inside the MR Environment, but not in the bore.

A ferromagnetic object entering the MR Environment, has the potential to become a dangerous projectile. If a ferromagnetic object is discovered inside the MR Environment, all patients and staff should be evacuated from the room. Staff should seek support from senior colleagues (physicists or radiographers) to discuss how the item can be removed safely from the MR Environment. Appendix A shows the location of the 3mT projectile zone for each scanner, and may be helpful when planning how to remove the item safely. It is important that no-one is between the item and the scanner during its removal, in case it does become a projectile. If it is not clear whether the item can be removed safely then the scan room should be locked until either the MR Responsible Person or MR Safety Expert can advise further.

10.4 Loss of Electrical Power

In the event of a loss of electrical power, the backup generator should ensure that power to essential functions is returned quickly. Normal operation of the scanner is likely to be interrupted, and a scanner reboot may be needed.

Remove the patient from the bore. Contact Estates to report the power loss and establish expected time frames for return of mains power. Inform the MR Responsible Person, or their deputy, of the power loss.

Check whether the cold head is functioning correctly, by listening for the chirping sound in the scan room. If this is functioning non-contrast scanning may continue, providing that Estates confirm no imminent further power loss.

Switching of power from the backup generator to normal power supply is likely to interrupt normal operation of the scanner again, therefore no time sensitive (e.g. contrast scans with dynamics) should be performed until Estates have confirmed that the main electrical power has resumed to the scanner.

Whilst power is being supplied from the back-up generators contrast should not be administered to routine elective patients until normal power is restored. In the event the normal power supply is non-functioning for an extended period of time then at a radiologist's direction contrast may be given for urgent inpatient scans.

11 Records of Scanning and Contrast Media

11.1 Personnel Records

A list of authorised persons (category A/B/C) is kept within the department on Imaging SharePoint, together with a record of their training and certification as an authorised person. A list of MR Responsible Persons, MR Safety Experts and MR Clinical Safety Advisors should be kept.

11.2 Equipment Records

Records of the equipment status, including all updates, maintenance and modifications should be kept on Imaging SharePoint. This will most likely be obtained from the service record of the scanner.

11.3 Patient and Volunteer Records

For each patient the following information should be maintained: date of scan; subject's name or reference; sex and age; type of scan sequence; regions of the subject's body scanned; type of coil employed; approximate time spent by the patient in the magnet; and, where possible, the whole body SAR values for all scans. This information is available within the DICOM header and so it is important that all images are archived on PACS.

Details on the administration of contrast media including administrator, dose, and batch number should be recorded.

A record of volunteers who have been scanned must be maintained, similar to a patient's record described above, in accordance with the volunteer SOP (MR17/SOP/004).

11.4 Adverse Incident Records

Adverse incidents (any unexpected event that has the actual or potential detrimental effect on a patient, employee, member of public, or asset of the organisation) within the MRI unit should be reported according to the Trust's Policies and procedures, including the Trust *Health and Safety Policy* (HS01) and the *Organisation-wide Policy for the Management of Untoward Incidents Inc SUIs* (RM07).

All staff must report health and safety incidents using the Trust's Adverse Incident Report Form as soon after the incident as is practicable and no later than the end of a persons shift. If staff are in doubt whether to report the incident or not, it should be reported.

Managers should be informed of reported incidents. All managers must be aware of the Trust management arrangements to report, and where appropriate further investigate incidents.

RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995) incidents

SUI (Serious Untoward Incidents) and

PARS (Physical Assault Recording System) for violent incidents

If the MRI system or other equipment is involved in the incident: Where possible, record all system settings as they were at the time of the incident. Notify the MR Responsible Person and MR Safety Expert as soon as possible. They will be responsible for reporting any relevant equipment incidents to the MHRA. Any faulty equipment should be removed from use until it has been deemed safe to use.

12 Guidance Documents

Medicines and Healthcare products Regulatory Agency, MHRA (was Medical Devices Agency, MDA) guidelines:

Device Bulletin: *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*, DB2015, February 2021.

Health Protection Agency - Radiation Protection Division, HPA-RPD (was National Radiological Protection Board, NRPB) guidelines:

Health Protection Agency (HPA). *Protection of Patients and Volunteers Undergoing MRI Procedures.* RCE-7, August 2008.

National Radiological Protection Board (NRPB). *Advice on Limiting Exposure to Electromagnetic Fields (0–300 GHz).* Documents of the NRPB 15(2), 2004.

British Standard, BS EN 60601-2-33:2022 (same as International Electrotechnical Commission, IEC 60601-2-33:2022

International Electrotechnical Commission (IEC). *Medical electrical equipment: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.* IEC 60601-2-33:2022.

International Commission on Non-Ionising Radiation Protection, ICNIRP guidelines:

Statement on Medical Magnetic Resonance (MR) Procedures: Protection of Patients, Health Physics, 97(3):259-261; 2009

Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz), Health Physics 74(4):494-522, 1998.

Guidelines on Limits of Exposure to Static Magnetic Fields, Health physics 96(4):504-514; 2009

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 1Hz. Health physics 106(3):418-425; 2014

European Commission EMF Directive:

The Control of Electromagnetic Fields at Work Regulations 2016, SI 2016/588.

Guide to the Control of Electromagnetic Fields at Work Regulations 2016, Health and Safety Executive, HSG281

13 List of Appendices

A. Field Line Surveys

B. List of Responsible Persons and Authorised Personnel.

C. Controlled Access Area and MR Environment.

E. MRI Safety Screening Questionnaire

F. Patient Information: Magnetic Resonance Imaging in Pregnancy

G. Staff and Visitor Screening Questionnaire

H. MRI Scanner Normal and Controlled Modes of Operation

I. Supplementary Safety Form

J. Volunteer Info and Consent Form

K. Emergency Action Cards