NHS Lothian Magnetic Resonance Imaging (MRI) Safety Policy



Title:

NHS Lothian Magnetic Resonance Imaging (MRI) Safety Policy

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NHS Lothian Magnetic Resonance Imaging (MRI) Safety Policy



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Oct 2023	Lead MRI Physicist, Medical Physics Head of Imaging Physics, Medical Physics	v0.1-2	New policy, using reviewed content previously contained within NHS Lothian Radiation Protection Policy v2
Dec 2023	Lead MRI Physicist, Medical Physics Head of Imaging Physics, Medical Physics	v1.0	Approved by the Policy Approval Group

Executive Summary

NHS Lothian will ensure, as far as reasonably practicable, the health and safety of members of the public, of its employees and of outside workers working on the premises who may be exposed to the hazards arising from the use of Magnetic Resonance Imaging (MRI) Equipment.

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1.0 Purpose

NHS Lothian (The Board) aims to ensure that:

- there is a robust framework in place for the management of MRI safety in NHS Lothian;
- the necessary standards for the protection of staff, patients and the public from the hazards associated with the use of MRI are implemented and maintained;
- NHS Lothian meets its obligation to protect staff, patients and the public, as far as is reasonably practicable, from the hazards associated with the use of MRI;
- all staff are aware of their roles and responsibilities in relation to managing MRI safety, and to ensure these risks are managed effectively, consistently and supportively.

2.0 Policy statement

The policy ensures that NHS Lothian will follow the recommendations from national guidance documents and relevant legislation associated with the use of MRI.

3.0 Scope

This policy sets out the framework to oversee health and safety relating to all uses of MRI on NHS Lothian property and contracted services for MRI of NHS Lothian patients.

Compliance with the policy is mandatory for all Board staff, external contractors, students and agency staff in all NHS Lothian locations.

Adherence to the following guidance and legislation, in relation to the use of MRI equipment for clinical use on NHS Lothian property, is included within the scope of this policy:

- MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use
- The Health and Safety at Work etc Act 1974
- The Management of Health and Safety at Work Regulations 1999
- The Control of Electromagnetic Fields at Work Regulations 2016
- The Control of Noise at Work Regulations 2005
- The Pressure Equipment Regulations 1999

4.0 Definitions

MR Controlled Access Area (MR CAA) – is a locally defined area of such a size to contain the MR ENVIRONMENT. Access shall be restricted and suitable warning signs should be displayed at all entrances. Free access to the MR CONTROLLED ACCESS AREA should be

given only to MR AUTHORISED PERSONNEL. For practical purposes the MR Environment shall be considered the MRI Scanner room.

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

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

MR Authorised Person (Supervisor) - An MR AUTHORISED PERSON who is authorised to supervise directly others within the MR CONTROLLED ACCESS AREA and MR ENVIRONMENT.

MR Responsible Person (MRRP) – has day-to-day responsibility for MR Safety in a given MRI department. The duties and required competencies required of MRRPs in NHS Lothian are defined in Radiology QPulse documents MRI/4, MRI/5. Each MR RESPONSIBLE PERSON should be in full consultation with an MR SAFETY EXPERT. The MR RESPONSIBLE PERSON should not take on the role of MR SAFETY EXPERT.

MR Safety Expert (MRSE) — a designated professional (usually a physicist with expertise in MRI) with adequate training, knowledge and experience of MRI equipment, its uses and associated requirements. The MR SAFETY EXPERT will have an advanced knowledge of MRI techniques and an appropriate understanding of the clinical applications of MRI. Clinical units should appoint an MR SAFETY EXPERT who acts according to recognised standards (e.g. HCPC registered). The MR SAFETY EXPERT should be in a position to adequately advise on the necessary engineering, scientific and administrative aspects of the safe clinical use of the MR devices including site planning, development of a safety framework, advising on monitoring the effectiveness of local safety procedures, procurement, adverse incident investigation and advising on specific patient examinations. Their knowledge of MR physics should enable them to advise on the risks associated with individual procedures and on methods to mitigate these risks.

Quench Pipe - In the event of a scanner fault/emergency, the quench pipe vents the large volume of cryogenic helium gas from the superconducting magnet safely to the building exterior. If a quench pipe is blocked there is a risk that, in the event of a scanner malfunction or an emergency in which the quench button is pressed, cryogenic helium will escape into the scan room with resulting risk to patients & staff of cold burns, asphyxiation and death. Risks to staff/contractors working in the vicinity of the quench pipe also include cold burns, asphyxiation, or death.

5.0 Implementation roles and responsibilities

All directorates or departments working with MRI shall have a set of Local Rules, Standard Operating Procedures and Risk Assessments detailing Safe Systems of Work.

Responsibility for the protection of staff, patients and visitors from the risks associated with MRI arising from their use by NHS Lothian rests with the Chief Executive of the Board.

It is the responsibility of Clinical Directors and Heads of Service to ensure that MRI equipment is used in a manner that complies with these policies and procedures.

They must appoint MR Responsible Persons (MRRPs) for each MRI department with defined areas of responsibility to assist with implementing these procedures. Each MRRP must be a MR Authorised Person (Supervisor). Their role is fully described in the MRRP duties and competencies documents, and they must be given sufficient time and resources to fulfil their responsibilities.

Local Rules for each MRI department must be available on QPulse and read and acknowledged by all staff required to access the MRI department as part of their duties.

All staff working with MRI are required to adhere to the Local Rules and to ensure that their actions do not cause any unnecessary risk to themselves, patients, other staff or members of the public. They are required report to their MRRP any deficiencies in the arrangements for MRI safety.

The MRRP is required to ensure there is a system in place to provide appropriate MRI safety training to new staff, to update training as required and to keep a record of training, in line with the MRI Safety Training Policy (available on QPulse) (please note that although currently named a policy, in practice it is a procedure for staff to follow to gain and maintain MR Authorisation status). The level of training should be appropriate and relevant to their role.

5.1 Staff roles and responsibilities

5.1.1 Chief Executive

It is the responsibility of the chief executive to ensure delegation of the day-to-day responsibility for MR safety to a specified MR RESPONSIBLE PERSON for each MRI department.

It is ultimately the responsibility of the chief executive of the institution to ensure that:

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

It is the responsibility of the chief executive to ensure appropriate appointment of MRRPs who will inform, as appropriate, all heads of departments and senior medical staff, who may have personnel that will be involved with MRI equipment, of the formal procedures for training and authorisation.

5.1.2 MR Safety Experts

Each MR RESPONSIBLE PERSON should be in full consultation with an MR SAFETY EXPERT (see Section 4 - Definitions). NHS Lothian appoints MR Safety Experts (MRSEs) to advise the Board on compliance relating to the safe use of MRI.

The Responsibilities of the MR SAFETY EXPERT include providing advice on:

 The development and continuing evaluation of a safety framework for the MR Environment

- The development of local rules and procedures to ensure the safe use of MR equipment
- The modification of MR protocols including diagnostic effectiveness linked to safety
- Safety regarding MR procedures for individual subjects and specific subject groups regarding implanted devices, metallic foreign bodies and similar issues.
- MR safety training programs
- MR Quality Assurance Programs
- Procurement, siting, and installation of MR Equipment
- Acceptance testing

Local assessment of experience to act as MRSE in NHS Lothian is required and will be assessed using the NHS Lothian MRI Physics Competency Matrix.

Once the required competencies have been achieved, MRSE appointments are approved by the Head of Medical Physics and Medical Director and confirmed with a formal letter of appointment.

Once appointed as MRSE, continual review will be undertaken as part of ongoing PDPR to ensure that the professional and competence requirements of the role continue to be met.

The competencies required of the MRSE can be found <u>here</u> (available on QPulse).

5.1.3 MR Responsible Person

The Chief Executive delegates the day-to-day responsibility for MR safety to a specified MR RESPONSIBLE PERSON (MRRP). An MR Responsible Person will be appointed for each MRI Controlled Access Area. The MRRP must be present within the MR CAA on a daily basis.

The role of the MRRP is to act as the focal point for all MRI safety matters arising on a day-to-day basis and is responsible for ensuring work is carried out in accordance with the Local Rules and any other control measures identified in the risk assessment.

The MRRP will appoint one or more deputies who will assist the MRRP and will assume the responsibilities of MRRP when the MRRP is not available.

Once the required MRRP training has been completed, the staff member must be formally appointed as the MRRP on behalf of the Chief Executive by the relevant Radiology Sector Manager by issue of a formal letter of appointment.

Once appointed as MRRP, continual review will be undertaken as part of ongoing PDPR to ensure that the professional and competence requirements of the role continue to be met.

The duties and required competencies of the MRRP can be found here (on QPulse):

- MR Responsible Person Duties and Responsibilities
- NHS Lothian+Fife MRRP Competency Requirements

5.1.4 MR Authorised Person (MR Environment)

A MR Authorised Person (MR Environment) is authorised to enter the MR Environment but is <u>not</u> authorised to supervise others in the MR Environment. They may supervise others in other areas of the MR Controlled Access Area.

5.1.5 MR Authorised Person (non-MR Environment)

An MR Authorised Person (Non-MR Environment) is authorised to enter the MR Controlled Access Area but <u>not</u> to enter the MR Environment.

5.1.6 MR Authorised Person (Supervisor)

An MR Authorised Person (Supervisor) is authorised to have free access to the MR Environment and to supervise others in the MR Environment.

5.1.7 All staff

All staff required to work within the MRI Department are responsible for following the Local Rules and safety procedures and training materials established by the Employer and must follow instruction to them by an MR Authorised Person (Supervisor) while in the MR Controlled Access Area.

All staff are responsible for alerting their MRRP or line manager of any potentially hazardous equipment being brought into the MRI department, and for reporting all incidents or nearmisses.

5.2 Governance

The Board needs to be both assured of compliance and informed of any deficiencies in MRI safety that require action.

To advise the Board on the safe use of MRI and on compliance with the relevant legislation, NHS Lothian appoints MR Safety Experts (MRSEs).

5.2.1 MR Safety Committee

The MR Safety Committee meets a minimum of 3 times a year and invites all staff members working in MRI, primarily from Radiology and the Department of Medical Physics, to attend the regular MR Safety Committee meetings chaired by the clinical director of Radiology. The purpose of this meeting is to ensure that the necessary responsibilities, defined by the MHRA safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, are locally established and carried out across NHS Lothian and NHS Fife.

5.2.2 Radiation Protection Committee (RPC)

The Lead MR Safety Expert and the Chair of the MR Safety Committee will attend the three annual meetings of the NHS Lothian RPC or will nominate a deputy to attend in their place. The RPC receives an annual report from the Chair of the MR Safety Committee and the Lead MR Safety Expert.

The NHS Lothian RPC considers a separate element of safety reporting from each discipline at each of its three meetings; compliance audits, annual reports and clinical user feedback. However, any matter of MRI safety concern can be reported at any meeting of this committee throughout the year. The RPC sits above the MRI Safety Committee in the Health and Safety governance structure. The overarching aim of the Radiation Protection Committee is to ensure that gaps in safety are identified and acted upon in an acceptable timescale.

The Medical Director, or another person appointed by the Medical Director, will act as Chairperson and the membership is drawn from Directorates using radiation.

The Board RPC reports to the NHS Lothian Health & Safety Committee. The Radiation Protection Committee is required to produce annual reports to the Health and Safety Committee.

5.3 Training

Guidance on the organisational structure of an MRI department and appropriate levels of MR Safety training for different staff groups is provided by the 'Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical use' Medicines and Healthcare Regulatory Agency (MHRA), February 2021. Hereafter, this publication is referred to as the MHRA guidelines.

The MHRA guidelines define 4 categories of staff:

- Category A a staff member authorised to operate the MRI scanner and also to supervise others in the MR Environment (e.g. MR Radiographer, MRI physicist).
- Category B a staff member required to enter the MR Environment to provide clinical care to a patient (e.g. nursing staff or clinician).
- Category C a staff member required to enter the MR Environment when scanning is not taking place (domestic staff member).
- Category D a staff member required to enter the MR Controlled Access Area but does not enter the MR Environment (e.g. administrative staff).

The training requirements for each category of MRI staff within NHS Lothian are set out in the NHS Lothian MRI Safety training policy.

- This policy sets out the required training of staff to enable them to protect themselves and others from risks arising from the use of Magnetic Resonance Imaging (MRI) in NHS Lothian hospitals.
- Training is adapted appropriately to staff group depending on their level of involvement with MRI.
- Training must be delivered initially before staff work in the MRI department and refreshed at regular intervals thereafter.
- Only the MR Responsible Person can assign MR Authorised Person status to staff, following confirmation that an appropriate level of training has been completed and maintained.

- The MRRP will maintain a training record for each member of staff that has been designated as being MR Authorised
- All staff required to work in MRI departments must have a safety presentation from an MRI physicist. The delivery and frequency of presentation will be appropriate to role

5.4 MR Controlled Access Area management

The MR Controlled Access Area (MR CAA) is demarcated by appropriate warning signs relating to the high magnetic field and is entered through self-locking doors. Means to access these areas (via card or fob access) are only made available to MR Authorised members of staff who will have successfully completed MR safety training and screening. MR Safety screening of MR Authorised staff must be updated annually. The individual must make the MRRP or supervising MR OPERATOR aware of any changes in their MR safety status in the intervening time.

Unauthorised staff, visitors and patients can only enter the MR CAA following screening by and under the supervision of an MR Authorised Person (Supervisor).

The MR Responsible Person is responsible for approving members of staff as MR Authorised and for maintaining records of staff who are authorised to work within the MR CAA. These records must be made available to the supervising MR Operator in each department so they can check whether an individual is authorised to enter the MR CAA.

Faults to the MR CAA door must be immediately reported to the MRRP who must ensure that work is undertaken to promptly resolve the fault.

All items entering the MR CAA must first undergo MR Safety checking and labelling. Only MR Safe and MR Conditional items can be taken into the scanner room (the MR Environment) by an MR Authorised Person.

Only items intended for use in the MR CAA or in the MR Environment must be kept within the MR CAA. The MR CAA must not be used as a storage space for MR Unsafe items or items that are not required to be used in the MR CAA.

5.5 Risk Assessment

The Management of Health and Safety at Work Regulations 1999 require employers to carry out risk assessments covering all risks in the workplace. This includes the risks associated with MRI. The Control of Electromagnetic Fields at Work (CEMFAW) Regulations 2016 also requires employers to assess exposure to electromagnetic fields and then assess the resulting risks to their staff.

The core MRI risk assessments (i.e. those listed on the website of the British Institute of Radiology website: Risk Assessments - British Institute of Radiology (bir.org.uk)) are required for all NHS Lothian MRI departments. These must be reviewed annually and updated as required. Additional risk assessments will likely be required for specific services and tasks carried out for individual MRI departments (e.g. Use of General Anaesthesia in MRI departments, Intraoperative MRI service, Cardiac Implantable Electronic Devices MR service).

Exposure to the hazards associated with MRI shall be managed within the framework of the Management of Health and Safety at Work Regulations. This includes the requirement to complete risk assessments and regularly review them.

The legal responsibility for undertaking the risk assessment lies with the Employer. In practice however, the MRRPs will usually carry out risk assessments in conjunction with the MRSE, with additional assistance from manufacturers or other expert input where required.

Many of the hazards associated with MRI in Lothian are common across all MRI Departments. A series of generic risk assessments will be maintained, stored & distributed on QPulse, and reviewed regularly, including: Static and time-varying fields, Acoustic noise, Cryogens and staff with implanted devices.

Any new risk assessments will be approved by the MR Safety Committee.

In particular, it is a requirement of the Control of Electromagnetic Fields at Work (CEMFAW) Regulations that risks are assessed, and exposures kept as low as low as reasonably practicable.

A specific risk assessment will be carried out for any staff member working in MRI who is pregnant.

Risk assessments will be reviewed every two years, or sooner if there has been a change in equipment or work practice.

It is the responsibility of the MRRP to inform the MRSE of any planned changes to equipment or working practices to allow sufficient time for the risk assessment to be reviewed and updated as appropriate.

5.6 MR Safety audits and reviews

5.6.1 Annual MR Safety audits

Annual MR Safety audit will be carried out for each MRI department in NHS Lothian. This will be conducted by an MRI Physicist/MR Safety Expert and the MR Responsible Person for that site. The Radiology manager for that site will also be invited to attend.

The annual audits will formally review the following areas: Health Board Governance, MRI Governance, Implant safety, Training records and MR Authorisation list, MR Quality Assurance, MR safety control measures, Incidents and near misses. Evidence may need to be made available as part of this review.

MRI physics will produce a report on the MR safety audit and they will then work with the MRRP and Radiology management to implement any recommendations.

5.6.2 Bi-annual review of department MR Safety signage

The MR Safety signage of each MR department will be formally reviewed by MR Physics twice per year. One of these occasions will coincide with the annual MR safety audit for the department. If any members of staff notice any issues with existing signage (e.g. damage to signs or missing signage) then they must make the MR responsible Person and the MR Safety Expert aware of this immediately.

5.6.3 Review of MR safety labelling of ancillary equipment

Immediate MR safety checks must take place of all ancillary equipment before it is taken into the MR Controlled Access Area. Checks are carried out using a hand-held magnet in accordance with the MR Safety equipment checking and labelling Procedure (available on QPulse).

In addition, reviews will be carried out every 2 months of MR safety labelling of ancillary equipment and updated as required. These checks will be carried out by the MRRP or their deputy and must be recorded.

5.6.4 Audit of specific services

Specific MR services that require the implementation of a separate Standard operating Procedure to ensure MR safety is adhered to, must be subject to regular audit by the MRRP and MRI physics/MRSE. Examples of such services are given below:

- General Anaesthetic MRI sessions The MRRP and MR physics/MRSE to audit GA
 MRI sessions on a quarterly basis. This is primarily to ensure designation of a single
 lead MR Authorised Person (Supervisor) who takes responsibility for all aspects of
 MR safety during the GA session. The completion of the MR safety checklists and the
 modified WHO checklists will also be audited.
- Cardiac Implantable Electronic Devices (CIEDs) MR services MRRP and MR
 physics/MRSE to audit the CIED MR services on a quarterly basis. This is primarily to
 ensure that all the multi-disciplinary checks are carried out and recorded on the
 appropriate forms. This audit will also assess what percentage of patients referred to
 MRI with an implanted CIED have been considered for an 'off-label' scan.

5.7 MR Safety queries

Anyone (staff, patient or visitor) who has reason to enter the MR Controlled Access Area of any NHS Lothian MRI department must first undergo MR safety screening by a member of staff designated as an MR Authorised Person (Supervisor). This is to ensure that it is safe for them to enter the MR Controlled Access Area, where high magnetic fields could adversely affect implants and implanted devices. Please see departmental MR local rules for more details.

If MR safety screening reveals that a patient has an implant or implanted device then it is important to identify the make/model of that implant/device and determine whether the manufacturer has classified it as MR Safe, MR Unsafe or MR Conditional. Even if there is evidence that a patient with an implant has had a previous MRI scan, the MR Operator must check for up-to-date MR safety information on that implant. If the implant/device is classified as MR Safe then the MRI scan can proceed without any restrictions. If a device is designated as MR Conditional then you must know how to meet the required MR conditions set out by the implant manufacturer before scanning the patient. If you are unsure of how to meet the necessary scanning conditions then please ask MR Physics for assistance. If the device is MR Unsafe then the scan must not proceed. In other cases, MRI physics can investigate and subsequently issue an MR Safety letter which would be uploaded to the patient's notes on TRAK.

In certain circumstances, when the type of implant is known but the exact manufacturer/model is not known, the use of locally approved Generic Implant Safety Procedures (GISP) can be used to determine whether MR scanning can safely proceed.

Where there is any doubt about the MRI safety of a patient's implanted device or whether a GISP can be safely applied in a particular case, then please contact the MRI physics team for further advice.

On rare occasions there may be significant clinical need for an MRI scan despite it not being possible to meet manufacturer MR Conditions for a particular implant or despite a device being designated as MR Unsafe i.e. 'off-label'. In such cases a risk assessment must be prepared by MRI physics in collaboration with a Consultant Radiologist. The risks and potential mitigations would then be discussed with the clinical team who would use this in making their final clinical risk-benefit decision on whether the MRI scan should proceed. The patient must be informed of the risk-benefit decision and the scan can only proceed if the patient provides informed consent.

5.8 Incidents

5.8.1 Reporting an incident on DATIX:

Anyone can report an incident or a near miss on the Datix system. This can be in relation to any aspect of our work environment, not just about those that occur in an MRI department. The Datix form can be found through the Applications list on the intranet. The summary of the incident must not include identifiable information about any patients or staff involved in the incident. It is this summary that will be distributed to the contact email list.

Examples of types of MR incidents to be reported on DATIX include the following.

- Projectile incident
- Near miss
- Burns
- Discomfort from heating reported by patient
- Any abnormal sensation relating to an implant or implanted device reported by a patient
- Anything relating to breach of local rules (e.g. unauthorised access to the MR CAA, equipment that has not been MR safety checked or labelled being brought into MR CAA)
- Patient implants/devices undeclared at MRI referral

Please note that this is certainly not an exhaustive list. If there is any doubt about whether an incident should be reported on DATIX then discuss it with your MRRP or the MR Safety Expert.

It is ultimately the responsibility of the MRRP to ensure that incidents or near misses occurring in the MR department are formally reported on DATIX. It is important that all incidents or near misses are reported so that trends can be evaluated, and MR safety

practices can be assessed and improved if any gaps in safety are identified. The MRRP and MRSE must have the opportunity to provide formal feedback on the incident on the DATIX system.

5.8.2 Reviewing an incident on DATIX:

Incidents occurring in the MRI department will be investigated in the first instance by the MRRP. If the incident relates to an incident or near miss incident in the MR Environment then this must also be discussed with MRI Physics, who will then provide a separate MRI Physics incident investigation report. This report will be uploaded and attached to the DATIX report. The report will detail recommended actions to minimise the probability of a particular incident being repeated in the future. The MRRP must work with the MR Safety Expert to ensure that the recommendations are applied.

Where an MRI referral has been made for a patient who is subsequently found to have an undeclared implant or implanted device then a letter must be sent to the referrer making them aware of this. A template letter is available and can be found on QPulse. Usually, it would be the MRRP that would send this letter to referrers, but this can be carried out by MRI Physics where the MRRP does not feel able to carry this out.

MRI Physics will provide a quarterly report to the MR Safety Committee summarising DATIX incidents reported across the different MRI departments in NHS Lothian. This gives members of the MR Safety Committee the opportunity to discuss the reported incidents, compare MR safety practice across the different sites and ensure that learning is shared across all MR departments.

5.9 External Providers

It is the responsibility of the Radiology Manager planning to procure MRI scanning services from an external provider to inform the MRSE at an early stage. When an external provider is contracted to provide MRI scanning service for NHS Lothian, there must be a written agreement in place summarising the division of MR Safety responsibilities and signed by both parties. The following documentation must be supplied by the service provider in advance of finalising the contract:

- Local Rules
- Risk assessments
- Procedure for investigating and scanning implanted devices
- Procedure for reporting and managing adverse incidents.
- Confirmation of compliance with MHRA Guidelines

The following documentation must be available on request.

- Staff training records
- Equipment quality assurance and servicing records

5.10 Mobile scanners

The procuring manager must inform the MRSE at an early stage of the intention to bring a mobile scanner onto NHS Lothian property in order to allow a risk assessment to be completed.

There must be a visit by the service provider to the hospital site in advance to agree respective safety responsibilities and plan the location of the van with local MR Safety Expert involved at an early stage. Consideration must be given to stray magnetic fields, acoustic noise, quench pipe vent location and appropriate safety warning signage. Contour plots of the fringe magnetic field in all directions must be provided. The MRSE will measure fringe fields when a mobile scanner is brought to site to ensure these are at a safe level, or otherwise that suitable access restrictions are put in place.

5.11 Documentation

5.11.1 Local rules

Each department must have a written set of MRI local Rules that describes the processes that must be carried out in the MRI department to ensure the safety and wellbeing of patients, staff and visitors when they are in the MRI Department.

5.11.2 Use of QPulse

All relevant documentation relating to each NHS Lothian MRI department must be stored on QPulse. This is the Quality Management Information System that is used by NHS Lothian. This ensures that documents are stored securely and are version controlled, ensuring that staff have access to the most up-to-date version of the document. It also allows staff to electronically acknowledge reading the document. The manager responsible for the document can issue an alert to all staff that are required to read and acknowledge the document.

5.11.3 Harmonisation of MR safety documentation across all NHSL sites

Where possible, a 'once for Lothian and Fife' approach will be taken to documentation such that safety documentation is harmonised, utilising generic documentation and risk assessments where possible. A function of the MR Safety Committee is to ensure a consistent approach to MR Safety documentation across the region. Any generic policies, procedures or risk assessments will be tabled at the MR Safety Committee, and if appropriate the Radiation Protection Committee, for discussion and approval.

5.12 Equipment Maintenance

- It is the responsibility of the Radiology Manager to ensure that MRI equipment in their area is regularly calibrated, serviced and maintained to a defined scheduled based on the manufacturer's recommendations.
- All MRI scanners must have appropriate service contracts in place.

- The MRSE can act as technical reviewer of proposed service contracts and advise the service of their suitability.
- It is the responsibility of the MRRP to co-ordinate with clinical users and service engineers to ensure the equipment is made available for maintenance when required.
- The NHS Lothian MRI equipment handover form must be used during and following maintenance or repair visits by service personnel. Responsibility for permitting access to the MRI Controlled Access Area must never be handed over to the servicing engineer i.e. they must never be considered a MR Authorised Person (Supervisor).
- The MRI equipment should only be put back into clinical use if the service engineer
 has indicated on the handover form it is safe to do so and that appropriate local QC
 checks have been carried out. If they are unsure what local checks should be carried
 out, then the radiographer should contact MRI Physics for assistance. The NHS
 Lothian equipment MRI handover procedure can be found on QPulse.
- Maintenance reports for all MRI equipment, including ancillary equipment (e.g. power injectors, MRI Conditional Monitoring equipment, MR Conditional Anaesthetic equipment), should be retained by NHS Lothian. The MRRP must retain a copy of scanner maintenance records.

5.12.1 Quench pipes

- As per MHRA guidelines, quench vent pipes must be inspected once per year. The
 primary purpose of inspection is to ensure that this outlet is not blocked, that an
 appropriate exclusion zone is indicated around the quench pipe exhaust outlet, and
 that there is appropriate cold cryogen discharge hazard warning signage in place.
- Overall responsibility for ensuring that a contract is in place and that regular quench pipe inspections take place lies with the relevant Radiology Manager. The MRRP is responsible for ensuring that appropriately time is scheduled to allow access to the MRI scan room for these checks.
- The contractor will inspect according to a written protocol, prepared by Medical Physics in consultation with MRI vendors.
- The external provider will provide the services of a Competent Person under the Pressure Systems Safety Regulations (PSSR)
- For areas inaccessible to contractor (e.g. RIE roof) Radiology must arrange for Estates/Building management to provide photographs of quench exit vent, taken according to a protocol written by a MR Safety Expert, for the Contractor to review and compile with report.
- The contractor must compile a report for each quench pipe according to the inspection format provided by Medical Physics.

5.12.2 MR Controlled Area Access doors

- The MR Controlled Access Area (MR CAA) doors are a key checkpoint controlling flow of people and/or objects into the vicinity of the MRI scanners and therefore must be considered as a crucial safety device. The doors must be of a self-closing, self-locking design.
- It is essential that the MR CAA doors are maintained in good working order. It is the responsibility of the MRRP to report any failure or fault of these doors immediately to Estates/Building management.
- It is the responsibility of the relevant Radiology Manager to liaise with Estates/Building management to ensure appropriate response times are in place to effect MR CAA door repairs.

5.12.3 Quality Assurance

The MRRP must ensure that regular MR scanner quality control checks are carried out according to recommendations by the relevant scanner manufacturer.

Radiology Managers must provide access to the MRI scanners for MRI Physics to carry out a detailed annual MRI quality assurance program.

5.13 Induction/training for contractors

- Any contractors required to work in the MR CAA or in the vicinity of a quench pipe must undergo appropriate site induction including safety briefing relating to the hazards from MRI equipment.
- It is the responsibility of the MRRP for the relevant MRI department to ensure that a safety induction has taken place before any contractor begins work.

5.14 Getting help

- The MRRP is identified in the Local Rules for each MRI Department, which can be found on Radiology QPulse
 - DCN MRI Local Rules
 - IntraopMRI Local Rules
 - RHCYP MRI Local rules
 - RIE MRI local rules
 - SJH MRI Local Rules
 - WGH MRI local rules

The MRSE and MR Physics team can be contacted for any safety queries via email on loth.mriphysics@nhslothian.scot.nhs.uk

6.0 Associated materials

NHS Lothian Radiation Protection Policy, approved by the Policy Approval Group, June 2023

Terms of Reference of MR Safety Committee, approved by MR Safety Committee, 20/08/2019

NHS Lothian Radiation Protection Committees – Terms of Reference, (including Terms of Reference for the NHS Lothian Radiation Protection Committee, X-Ray Radiation Protection Committee, Cancer Services Radiation Protection Committee, and the Radionuclide Radiation Committee), approved by the Radiation Protection Committee, March 2023

MR Responsible Person – Duties and Responsibilities, approved by MRSE/MRRP Committees 10/10/2023 (available on QPulse)

NHS Lothian+Fife MRRP Competency Requirements, approved by MRSE/MRRP forum, 10/10/2023 (available on QPulse)

Duties of the MRSE, in MRI Physics Training Policy, approved by Lead MRSE & Head of Imaging Physics, 25/01/2023 (available on QPulse)

NHS Lothian MRI Safety Training Policy, approved by MR Safety Committee, 5/12/2022 (please note that although this was named a Policy when uploaded to QPulse, it is a procedure for gaining and maintaining MR Authorisation status).

NHS Lothian MRI Handover form and procedure, approved by Head of Imaging Physics, 29/04/2016

Local Rules for each MRI Department, which can be found on Radiology QPulse

- DCN MRI Local Rules
- IntraopMRI Local Rules
- RHCYP MRI Local rules
- RIE MRI local rules
- SJH MRI Local Rules
- WGH MRI local rules

7.0 Evidence Base

MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, Medicines and Healthcare Products Regulatory Agency, February 2021

The Health and Safety at Work etc Act 1974, HMSO, 1974

<u>The Management of Health and Safety at Work Regulations 1999</u>, Statutory Instrument 1999 No. 3242

<u>The Control of Electromagnetic Fields at Work Regulations 2016</u>, Statutory Instruments 2016 No. 588

The Control of Noise at Work Regulations 2005, Statutory Instrument 2005 No. 1643

The Pressure Equipment Regulations 1999, Statutory Instrument 1999 No. 2001

8.0 Stakeholder consultation

The departments of Radiology and Medical Physics have been consulted during the development of this document. Radiologists, Radiographers, Medical Physicists in addition to Clinicians who frequently refer patients for MRI scans have been given the opportunity to review and comment on the document.

This document is subject to approval at NHS Lothian MR Safety Committee, NHS Lothian Radiation Protection Committee and NHS Lothian Policy Approval Group.

9.0 Monitoring and Review

The MR Safety Committee reports to the NHS Lothian Radiation Protection Committee, which in turn reports into the NHS Lothian Health and Safety Committee.

This policy will be reviewed, as a minimum, every three years, but may be subject to earlier review in the event of changes in best practice, guidance or legislation, results from performance reviews and audits, or any other factors that may render the policy in need of review.

As required by national MR safety guidelines, each department has a set of MRI Local Rules which describes the operation of the MR department in keeping with the information provided in this policy. Each MR department in NHS Lothian is subject to annual audit against their MRI Local Rules, and hence against this policy. Any breaches of the MRI Local Rules would also constitute a breach of this policy and would be subject to reporting on the DATIX system. Compliance with the policy is also reviewed in an annual report submitted by the Lead MRSE to the NHS Lothian Radiation Protection Committee. Any failures to adhere to the policy can be escalated to the NHSL Radiation Protection Committee by any staff member at any time throughout the year.

The effectiveness of this policy may also be monitored and evaluated using the outputs from:

- SAE reviews
- DATIX investigations
- Complaint investigations/improvement plans
- Health and Safety Quarterly Reports (compliance with relevant policies/risk assessments)