



Doncaster and Bassetlaw  
Teaching Hospitals  
NHS Foundation Trust

# IONISING RADIATIONS SAFETY POLICY (A)

This procedural document supersedes: CORP/HSFS 21 v.7 – Ionising And Non-Ionising Radiations Safety Policy



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### Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
Version 8	Dec 2024	Original document split into two policies for ease and understanding relevance, ionising and non-ionising radiation policies. Updates to document to include IR(ME)R amendment 2024. Other minor changes and updates to reflect current working. Radiation safety committee replaced with radiation safety group.	Sara Elliott/ Jane Davies/ Jen Harvey/ Giles Morrison
Version 7	Oct 2021	Minor amendments made to text throughout the document.	Sara Elliott
Version 6	21 Sept 2020	Substantial additions and alterations made in conjunction with STH advice and taking into consideration the new Trust Divisional organisation. Medical Imaging department is altered to Radiology.	Sara Elliott
Version 5	27 <sup>th</sup> April 2018	<p>Section 2 - "Purpose", Medico-legal exposures removed and replaced with Non-Medical imaging exposure. Definition included.</p> <p>Section 3 – "Duties and Responsibilities" 3.3 changed to Assistant Division Director. Changed to include – "authorize and approve the Ionising and Non-Ionising Radiations Safety Policy". 3.4 changed to Clinical Governance and Education Manager. 3.6 changed to IRR 2017 and reporting to the Chief Executive included. 3.8 changed to include requirement for MPE under IR(ME)R 2017 regulation 14. 3.12 changed to IRR17 Reg. 35.</p> <p>Section 4 – Changed and updated to allow for specific requirements and new terminology under regulation 17 of IR(ME)R 2017. Section 4.4 created to allow for IRR 2017 regulation 15 and the requirement for refresher training to be scheduled at regular intervals.</p> <p>Section 5 – Changed to reflect the new requirements under IR(ME)R 2017 regulation 15. i.e. see new sub-section 5.2</p> <p>Section 6 – Risk assessments changed to reflect IRR 2017 regulation 8.</p> <p>Section 7- Health Surveillance and Medical Examination changed to reflect IRR 2017 regulation 25 and the requirement for Medical Surveillance for classified workers.</p> <p>Appendix 1) - Changed to reflect update new Regulations.</p> <p>Appendix 2) - Changed to reflect update new Regulations.</p>	Peter Thompson

		<p>Appendix 3) - Changed to reflect changes in LPA role, now a purely advisory role, not responsible for implementation.</p> <p>Appendix 4) - Inserted for statement of MPE duties. Other Appendices numbers altered to allow for insertion</p> <p>Appendix 5) - Changed to reflect updated EPR 2016 Regulations</p> <p>Appendix 6) - Changed to reflect updated IRR and IR(ME)R 2017 Regulations</p> <p>Appendices 7) to 8) - Changed to reflect new management structure within Medical Imaging, including appointment of a new Chair and Vice Chair.</p> <p>Appendix 9) - Changed to reflect changes in LPA role, now a purely advisory role, not responsible for ORSC meetings and implementation of policy.</p> <p>Appendix 10) -New Management Framework within Medical imaging</p> <p>Appendix 11) -Updated Equality and Impact Assessment.</p>	
Version 4	8 <sup>th</sup> December 2015	<p>Updated policy with some changes and additions – New style and Trust format</p> <ul style="list-style-type: none"> <li>- Section 1, Updated and condensed ‘Introduction’</li> <li>- Section 2, ‘Purpose’ added</li> <li>- All paragraphs in Section 3 changed with new roles and titles defined to allow for the new Division management system and an additional paragraph added to allow for incident reporting using DATIX.</li> <li>- Section 4 expanded with more detail with the addition of paragraphs 4.1 to 4.3</li> <li>- Section 5, Incident Reporting, removed.</li> <li>- New Sections 5 to 7, added</li> <li>- Section 8, replacing Section 7 ‘Monitoring and audit’, much more detail and a table included as required by Trust’s new template.</li> <li>- Section 9, ‘Definitions’ added</li> <li>- Section 10, ‘Accountability framework’ - CGQ committee added and amendments made to reflect Division structure.</li> <li>- Section 11, ‘Equality and Diversity’</li> <li>- Sections 12 and 13 reformatted and references updated where required.</li> <li>- Appendix 9 added</li> </ul>	Peter Thompson
Version 3	September 2012	<p>4. Individual Responsibilities</p> <p>4.7 Changed to RWA from QE under new EPR10.</p> <p>4.10 Laser Protection Supervisor added.</p> <p>4.13 Optical Radiation Health &amp; Safety Committee added.</p> <p>Appendix 4.</p> <p>List of duties of an RWA under EPR10 replaces list of duties of QE under RS93.</p>	Peter Thompson

		<p>Appendix 7 altered Terms of Reference - Radiation Safety Committee Description of the Chair and the Vice Chair of the Committee Circulation of minutes and RPA reports Accountability framework amended to show the Trust's Board of Directors. Appendix 8 added. Term of Reference Optical Radiation Health &amp; Safety Committee.</p>	
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## 1 INTRODUCTION

The Trust uses ionising radiations and it will ensure, as far as is reasonably practicable, the safety of patients, members of the public (including the families of patients), employees and contractors working on its premises, who may be exposed to the hazards arising from the use of ionising radiations (e.g. X-ray, gamma rays etc.).

The ionising radiation safety policy sets out the general principles and processes that will be adopted by the Trust in order to comply with current legislation and best practice. It is supported by a number of subsidiary procedures, which give detailed instruction on the means whereby compliance with specific practices will be achieved.

The Trust is committed to a policy of keeping exposures to ionising radiation as low as reasonably practicable, social and economic factors being taken into account. It will maintain a Radiation Protection management structure to implement radiation safety requirements and will appoint suitable Radiation Protection Advisor (RPA), Radiation Waste Advisor (RWA), Medical Physics Expert (MPE) to advise on all matters concerning the safe use of ionising radiations. Radiation Protection Supervisors (RPS) will be appointed, where appropriate, to provide supervision in each department using ionising radiation to enable work with radiation to be carried out in a safe manner.

## 2 PURPOSE

To establish a framework to ensure compliance with the requirements of the Ionising Radiation Regulations 2017 (IRR 17), the Ionising Radiation (Medical Exposure) Regulations 2017 (IR[ME]R 2017), Ionising Radiation (Medical Exposure) Amendment Regulations 2024 (IR[ME]R 2024), the Environmental Permitting Regulations 2016 (EPR2016) and other relevant legislation.

To establish a framework to ensure compliance with the Management of Health and Safety at Work Regulations 1999.

Significant deliberate contravention of this policy or of the Local Rules and other Trust Controlled Policies will be considered subject to the Trust disciplinary procedure.

This policy does not apply to: Non-ionising radiation

## 3 DUTIES AND RESPONSIBILITIES

The Trust will implement this policy through the following organisational arrangements and responsibilities in order to effectively manage and control the risk from ionising radiation. The Chief Executive, as the employer, remains responsible in law for ensuring that these arrangements are in place.

The processes for managing radiation risks are defined within the Trust's Risk Identification, Assessment and Management Policy (CORP/RISK 30).

### 3.1 Clinical Specialities Division

The implementation of the policy will be the responsibility of the management team working within the Clinical Specialities Division who will liaise with the appropriate expert, (RPA/RWA/MPE/MRSE) regarding policy and procedures.

The following sections summarise the structure for the delivery of ionising radiations safety.

### 3.2 The Chief Executive

Although the Chief Executive retains overall responsibility for ensuring that systems are in place to manage risks arising out of the use of ionising radiations, they discharge this responsibility through designated individuals.

The Chief Executive, as the Accountable Officer, remains responsible in law for making sure these arrangements are in place. They will ensure that the Trust:

- Ensures that appropriate HSE notification, or registration has been made, or HSE consent obtained, prior to work in the Trust involving ionising radiation
- Appoints Radiation Protection Advisers (RPA), Radioactive Waste Advisers (RWA), Medical Physics Experts (MPE) with appropriate experience and qualifications, to advise on all matters concerning the use of ionising radiations.
- Must consult the RPAs on the matters detailed in Schedule 4, Ionising Radiation Regulations 2017 (IRR2017)

#### **SCHEDULE 4 Regulation 14(1)**

Matters in respect of which a radiation protection adviser must be consulted:

- The implementation of requirements as to controlled and supervised areas.
- The prior examination of plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design features, safety features and warning devices provided to restrict exposure to ionising radiation.
- The regular calibration of equipment provided for monitoring levels of ionising radiation and the regular checking that such equipment is serviceable and correctly used.
- The periodic examination and testing of engineering controls, design features, safety features and warning devices and regular checking of systems of work provided to restrict exposure to ionising radiation.

These are reflected in the annual reports to the Radiation Safety Steering Group.

- Must involve the MPEs on the matters detailed in Regulation 14, Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R2017), IR(ME)R (Amendment) 2024.
- Establishes an appropriate governance structure and resources to comply with relevant legislative requirements.
- Establishes Employer's Procedures as detailed in Schedule 2 of the Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) 2017 and related Standard Operating Procedures that meet the requirements of IR(ME)R 2017. Delegation of the task of preparing, reviewing and updating these documents will be clearly stated in the relevant IR(ME)R Procedure.



- The Employer will ensure that relevant licences to administer radioactive materials to patients are maintained at all sites where such activities take place. Individual practitioners who need to hold a 'practitioner' licence are responsible for ensuring this is in place and is renewed and updated as and when required. The Radiation Safety Group will make checks to ensure that all relevant licences are in place before carrying out administration of Radioactive Materials for diagnosis.
- Ensures there are sufficient Radiation Protection Supervisors appointed in areas where ionising radiation is used, that the RPSs receive training appropriate to their role and that there is a process in place for the appointment in writing of new Radiation Protection Supervisors.

### 3.3 Clinical Director

The Clinical Directors are responsible for ensuring that adequate monitoring and auditing arrangements are in place within their Divisions to assure the Trust that staff and facilities are compliant with this policy. They are also responsible for ensuring that the necessary responsibilities under this policy are included in staff job descriptions.

Ensures that the relevant Inspectorate or Agency and Chief Executive are notified of any incident involving ionising radiation as required and ensures that there are adequate arrangements in their absence.

### 3.4 Head of Medical Imaging / Divisional Nurse

Overall responsibility for safety by ensuring the provision of radiation protection, staff and patient dose monitoring and radiation equipment quality assurance programmes within each Division will lie with the Divisional Nurse.

These individuals will ensure that:

- radiation risk assessments, local rules and written systems of work have been drawn up with approval by the relevant specialist radiation adviser as appropriate and are reviewed annually
- all medical radiation exposures carried out in their Division will be carried out in accordance with the appropriate Procedures for the Ionising Radiation (Medical Exposure) Regulations [IR(ME)R] 2017 and Ionising Radiation (Medical Exposure) Regulations Amendment 2024.
- Relevant instruction and training is provided to all staff carrying out work with ionising radiation by their employing Division. This will include:
  - i. general training in the safe use of radiation facilities for staff entering radiation areas
  - ii. training for staff involved in the care and management of radioactive patients
  - iii. staff acting as referrers, operators or practitioners under IR(ME)R 2017 and IR(ME)R amendment 2024
  - iv. staff identified as non-medical referrers.
  - v. staff whose work involves the keeping and disposal of radioactive material
  - vi. staff who are required to respond to radiation incidents or emergencies.
- Records of this training are to be kept by Divisions.

- Incidents which may require notification to the relevant inspectorate or agency are reported in accordance with the Trust incident management policy CORP/RISK 33. Specialist Radiation Protection Advisor (RPA) involvement is likely to be required as part of the incident investigation process. It is essential the Chief Executive, as employer, is made aware of all externally reportable incidents via the Trust's Patient Safety Team and Quality Director for appropriate escalation.
- The appropriate specialist adviser is consulted at the planning stage when the department is considering using ionising radiation for the first time or will be implementing a change in practice which may affect radiation doses.
- after liaison with the supplier and the DBTH Medical Technical Services, following the Medical Devices Management and Training Policy CORP/PROC 04
- all instruments used for monitoring levels of ionising radiation in controlled and supervised areas are tested and examined annually
- an investigation is carried out whenever a member of staff receives a dose of ionising radiation exceeding the local investigation level set in the local rules
- Permits issued under the Environmental Permitting Regulations 2016 (EPR 2016) (formerly known as certificates of Authorisation and Registration and were issued Radioactive Substances Act 1993) are complied with

### **3.5 Operational Managers / Service Lead Radiographers**

The departmental managers will be responsible for ensuring that:

- Staff carrying out work with ionising radiation are appropriately trained or that training requirements are notified to the nominated responsible person.
- Work with ionising radiation is carried out in accordance with documented local rules and safe systems of work (under the supervision of the local supervisors) and staff are notified of any changes in these local rules/procedures.
- The necessary risk assessments are undertaken before carrying out work with ionising radiation.
- The risk assessments are reviewed every 2 years or sooner in response to an incident/changes to equipment.
- In conjunction with the local Head of Service any special measures required to restrict doses to staff, including pregnant staff, are implemented.
- Periodic audit of the arrangements for the management of work with ionising radiation within their department is undertaken, and a report is made to the Ionising Radiation Safety Group via the annual report, detailing the results of this audit.
- there are sufficient RPSs in the department to supervise the work. Additionally, they need to:

- i. Agree the Statement of Duties with the individual to be appointed.
  - ii. Ensure that the local RPS staff member is formally appointed to that modality area via the Radiology Head of Service
  - iii. Retain the signed letter of agreement from the RPS and the agreed Statement of Duties.
- implement procedures for cooperation with other employers where:
    - i. their staff work in Trust designated radiation areas; and,
    - ii. where Trust staff work in their designated radiation areas.

### 3.6 The Deputy Head of Medical Imaging – Radiology

The deputy head of medical imaging will chair the monthly radiation safety subgroup meetings and feed into the Head of Radiology via monthly 1 to 1 meetings any issues requiring escalation.

### 3.7 Director of Estates

In respect of the naturally occurring gas Radon, responsibility for the safety of occupants of affected buildings rests with the Director of Estates.

Planned preventative examination and maintenance of radiation safety engineering controls including radon mitigation and Environment Agency permitted disposal routes.

### 3.8 The Risk Manager

The Risk Manager will be invited to be a member of the Trust Radiation Safety Group (RSG). They will advise on general aspects of the risk management process.

### 3.9 Specialist Radiation Advisors

#### Radiation Protection Advisers (RPA)

These are independently accredited by HSE approved bodies. Appointed under the provisions of IRR2017 for the protection of staff and public from Trust use of ionising radiation

The RPA will undertake duties that are defined within the scope of the Ionising Radiation Regulations 2017, (IRR17). The relevant RPA will advise, as appropriate, on compliance with all legislation, which relates to the safe use of ionising radiations in relation to the Trust's activities. Radiation Protection Advisers report to the Chief Executive, via the Trust's Governance management framework.

The relevant RPA must be involved in the planning of all new radiation facilities and any changes to existing facilities that may affect radiation doses or require alterations to radiation protection arrangements.

The RPA will be appointed via an SLA agreement set up between the two organisations, this trust currently has appointed Sheffield Teaching Hospitals.

## Medical Physics Experts

Medical Physics Experts will advise, as appropriate, on all aspects of the justification and optimisation of medical exposures (i.e. the achievement of the desired outcome with the minimum patient dose), in both diagnostic radiology and nuclear medicine.

IR(ME)R 2017, IR(ME) (Amendments)R 2024 Regulation 14 requires the Trust to appoint a suitable Medical Physics Expert in relation to every type of exposure to which the Regulations apply.

A Medical Physics Expert must:-

- meet such criteria of competence as may from time to time be specified in guidance;
- be involved in practices including diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography;
- be involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning exposures, as required, in all other radiological practices.

See statement of duties of the MPE listed in Appendix 4.

### 3.10 Radioactive Waste Adviser (RWA)

The RWA will provide advice and supervision on matters concerning the holding, accumulation and disposal of radioactive substances as governed by the Environmental Permitting Regulations 2016, (EPR16) and the environmental permits for the site.

See statement of duties of the RWA listed in Appendix 5.

### 3.11 Radiation Protection Supervisors (RPS)

Radiation Protection Supervisors are appointed in writing by the Head of Medical Imaging and arrangements must be made to allocate the appropriate resources for them to carry out their functions. They must be familiar with the area where the radiation is being used and be able to confirm that people in the vicinity are working to the local rules on a regular basis.

The Radiation Protection Supervisor should also be familiar with the requirements of the local rules and relevant parts of the Ionising Radiation Regulations 2017 [IRR2017] and the Approved Code of Practice. The RPS assists the operational manager / modality lead radiographer in ensuring that the local rules are read, understood and, as far as possible, are followed by the relevant staff.

Responsibility remains with the operational manager / modality lead radiographer.

The RPS appointed to nuclear medicine whom use radioactive substances are in an ideal position to ensure that staff are competent in handling radioactive materials and to supervise the accumulation and disposal of radioactive waste. The RPSs must be familiar with EPR 2016 permits (previously issued as certificates under RSA93) and associated departmental procedures. There will be additional requirements for departments using sealed sources with which staff must be familiar.

The tasks that are carried out by the RPS are given in the Statement of Duties issued to them at their appointment. They include tasks relating specifically to the supervision of local rules and restriction of exposure as required by IRR2017 and additional management functions such as the issue of

dosemeters and the control of radioactive substances. Responsibility for these tasks remains with the modality lead.

### 3.12 Qualified Person

The qualified person (as defined within the Ionising Radiations Regulations 2017) is responsible for Supervising appropriate tests and examinations on radiation monitoring equipment. The Qualified person role is described in the Ionising Radiations Regulations 2017 as a person who provides managerial and scientific supervision of the examination and calibration of portable instruments used to make radiation safety measurements.

### 3.13 Employees' Responsibilities

It is the responsibility of every employee working with ionising radiation to be aware of the local rules and precautions necessary to carry out their work in a safe manner. It is their responsibility:

- not to expose themselves or any other person to radiation to a greater extent than is reasonably necessary for the purpose of their work,
- to report incidents or defects in equipment in accordance with the Trust's reporting procedure and
- to use any protective equipment that is provided and ensure that it is cleaned and stored correctly between use.
- to report any defects in protective equipment as soon as they are noted and removed from service until a repair is affected or a replacement obtained
- to wear all dosemeters issued to them appropriately and to return them at the end of the monitoring cycle in a timely manner
- To report loss or damage of personal dosimeters immediately to the RPS or line manager.
- to comply with relevant local rules and procedures
- to complete all necessary records as specified in local rules/procedures
- to immediately inform the local RPS and line manager about actual or suspected incidents e.g. overexposure of themselves or other persons to a source of ionising radiation or they become aware of the potential or actual loss of a source
- to co-operate with employers about dose measurements and assessments and if classified to complete medical surveillance and provide information to the relevant doctor as required
- to ensure the radiation passbook, where issued, is used appropriately and ensure that false information is not contained in it

### 3.14 Radiation Safety Group (RSG)

The Radiation Safety Group (RSG) has the remit of drafting Trust documentation, advising the Chief Executive and monitoring compliance with Trust policies and procedures in relation to ionising radiations. It is also responsible for the approval of this policy, (CORP/HSFS 21). The RSC will monitor the radiation protection programme, including a regular review of all occupational, medical and public exposure to radiation, as part of the management and communication framework for health and safety.

The Chair of the Radiation Safety Group is responsible for arranging for the RSC to meet at least twice a year. The RSC will formally review the radiation safety policy every 3 years. Members are expected to attend the meeting. In the event that this is not possible, they should send an appropriate representative to the meetings or alternatively submit a formal report to be tabled at the meeting. See Terms of Reference in Appendix 8.

### 3.15 DATIX – Incident Reporting

All incidents involving ionising radiation must be reported via the web-based DATIX system, using the Category Radiation and Sub-Category that corresponds to the legislation that may have been breached, with the relevant Incident Detail. Any Near-Misses can be filtered out by using the appropriate Sub- Category.

The head of the relevant department would normally instigate any investigation and involve the RPA, MPE, RWA, RPS or other manager as required. Reports and actions plans for incidents will be submitted to the monthly Radiation Subgroup Meeting and monitored. Any incidents logged involving radiation should also be linked through to the Radiation Protection Lead Radiographer who will review for themes and additional support requirements for individuals or teams.

## 4 ROLES AND RESPONSIBILITIES – MEDICAL EXPOSURES

IR(ME)R 2017 and IR(ME)(Amendment)R 2024, define certain duty holders associated with the process of carrying out medical exposures, and these are identified in the Employers Procedures. These are:

### 4.1 Employer

The Employer must establish a framework of procedures for medical exposures and ensure that they are complied with. The Employer may delegate these tasks but still retains the responsibility.

The Employer will ensure that written Employer's Procedures for medical exposures are produced and maintained as required by the Ionising Radiation (Medical Exposure) Regulations 2017, IR(ME)R 2017 (Amendment 2024) and that these are made available to all duty holders.

In this context Medical Exposures means exposure as defined in IR(ME)R Regulation 3.

The Employer's Procedures required as a minimum for compliance with Reg 6 IR(ME)R 2017 and listed in Schedule 2 are:

- a) identify correctly the individual to be exposed to ionising radiation;
- b) identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice;
- c) make enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding;
- d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;
- e) for the assessment of patient dose and administered activity;

- f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f);
- g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure;
- h) for the giving of information and written instructions as referred to in regulation 12(6);
- i) providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure;
- j) for the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose;
- k) to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable;
- l) to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure;
- m) to be observed in the case of non-medical imaging exposures;
- n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.
- o) for the carrying out of clinical audit, and for any appropriate action to be taken in accordance with regulation 7
- p) for making, amending and cancelling any referrals for exposure.

Employer's Procedures are provided specific to the following clinical areas:

- Diagnostic X-ray including dental
- Nuclear Medicine
- Radiosurgery

The Employer must identify those persons authorised to act as MPE, referrer, practitioner and operator (see below) and ensure that they are appropriately trained.

The Employer must establish referral criteria, QA programmes, diagnostic reference levels, dose constraints and must investigate any incidents which occur, reporting them where necessary to the appropriate authority.

## 4.2 Referrer

The referrer is a registered medical healthcare professional responsible for supplying the practitioner with sufficient clinical data to enable the practitioner to justify the exposure. The referrer must also provide sufficient demographic and other data to permit compliance with Employers Procedures.

#### 4.3 Non-Medical Referrer

Other non-medical healthcare professionals may be authorised to refer patients for certain investigations following application through the expanded scope of practice procedure and having received training.

#### 4.4 Practitioner

The practitioner is responsible for justifying the exposure and, within the extent of their involvement, keeping the dose to the patient as low as reasonably practicable consistent with the intended purpose.

#### 4.5 Operator

The operator is anyone who carries out practical aspects of the exposure. They are responsible for ensuring that, within the extent of their involvement, they keep the dose to the patient as low as reasonably practicable consistent with the intended purpose.

#### 4.6 Medical Physics Expert

The Trust will appoint suitable accredited Medical Physics Experts who will advise departments making medical exposures on the matters detailed in Regulation 14 of IR(ME)R 2017 and on those areas required in Schedule 3 of IR(ME)R. The medical physics expert carries out and gives advice (as appropriate) on topics such as patient dosimetry, dose optimisation, treatment planning, radiation protection, and quality assurance relating to the development and use of techniques and equipment for medical ionising radiation exposures. (See 4.6).

#### 4.7 Qualified Person

The qualified person (as defined within the Ionising Radiations Regulations 2017) is responsible for completing appropriate tests and examinations on radiation monitoring equipment. For DBTH, this service is provided by STH Radiation Protection services.

#### 4.8 Employees

It is the responsibility of every employee working with ionising or non-ionising radiation to be aware of the local rules and precautions necessary to carry out their work in a safe manner. It is their responsibility:

- not to expose themselves or any other person to radiation to a greater extent than is reasonably necessary for the purpose of their work,
- to report incidents or defects in equipment or personal protective equipment (PPE) and any divergence from or deficiencies in procedures, in accordance with the Trust's reporting procedure
- to immediately report any known or suspected overexposures of themselves or other persons to their employer



- to immediately report any spill, loss or theft of radioactive material to their employer
- to use any PPE and dosimeters that are provided and store PPE appropriately after use
- to comply with relevant local rules and procedures
- to complete all necessary records as specified in local rules/procedures.

Significant deliberate contravention of this policy or associated Trust Controlled Policies will be considered subject to the Trust disciplinary procedure.

## 5 TRAINING/SUPPORT

Specialist training where particular risks exist, will be the responsibility of the Clinical Governance Sub Group (Radiation) e.g. radiation safety training.

Under Regulation 17 of IR(ME)R 2017, IR(ME)(Amendment)R 2024 a practitioner or operator must not carry out any exposure or any practical aspect without having been adequately trained. A certificate issued by an institute or person competent to award degrees or diplomas can be used to provide other evidence of adequate training. The Trust must keep and have available for inspection by the CQC an up-to-date record of all relevant training undertaken by all practitioners and operators engaged by the employer to carry out any exposures or any practical aspect of such exposures, showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.

Training records for Radiology Staff will be kept and monitored by the Departments leads to ensure appropriate training is taking place. Training for non-Radiology staff on non-Radiology-owned equipment is the responsibility of the relevant department and managers within that department who must ensure records are kept. It is their responsibility to keep this record. An attendance sheet for the training event will be retained by the Radiology Department.

### 5.1 Ionising Radiation Safety - Training

With exception to radiographers and radiologists all new Operators must attend training specific to the equipment they will be using and relevant radiation safety training via the NHS Learning Hub. All new radiographers and radiologists will follow a suitable induction into new equipment prior to being signed off as competent to use that equipment without supervision.

All Non-Medical Referrers must undertake relevant radiology referral training as advised by the Radiology Department. Evidence of completion of that training must be retained by the relevant department and made available for inspection as required.

All Radiation Protection Supervisors must attend suitable RPS training which must be refreshed every 3 years. A list of available courses can be obtained from the Radiation Protection Advisers. No person will be appointed as RPS unless they know and understand the requirements of the Regulations the local rules and other procedures as they affect the work that they supervise. The prospective RPS must have undertaken appropriate specific RPS training before taking up the role.

### 5.2 Operator - Training

An **Approved User**, of ionising equipment, is an operator who has been approved to use a specific device. The relevant department will keep a list of Approved Users.

#### Ionising Operators

All IR(ME)R practitioners and operators must have received adequate training as required by the Ionising Radiation (Medical Exposure) Regulations 2017, IR(ME)(Amendment)R 2024. They must have received adequate instruction, including practical experience, in the techniques being used.

Both types of duty holders must maintain their knowledge with continuing professional development.

All operators must be able to demonstrate evidence of having attended operator training which is equipment specific. All staff involved in a medical exposure to Ionising Radiation must receive appropriate training. Evidence of completion of training, such as a certificate should be held within the department.

All operators will only operate equipment for which they have been trained and, where appropriate, hold qualifications. Users will receive training that will be organised by their line-manager and the department's nominated Training Co-ordinator.

### 5.3 Administration of Radiopharmaceuticals

The Trust will have certificates or an Employer's Licence covering all the exposures involving radioactive substances from the Administration of Radioactive Substances Advisory Committee (ARSAC). Only radiopharmaceuticals listed on the Employer's Licence may be administered within DBTH, irrespective of whether additional radiopharmaceuticals are listed on an individual's Practitioner Licence.

Staff acting as practitioners for the clinical administration of radiopharmaceuticals or the clinical use of sealed radioactive sources must have appropriate certification or hold a practitioner's licence from the Administration of Radioactive Substances Advisory Committee (ARSAC) as required by IR(ME)R2017, IR(ME) (Amendments)R 2024.

All staff administering radiopharmaceuticals to patients must do so under procedures endorsed by the ARSAC certificate holder covering the particular type of administration (examination or treatment).

### 5.4 Competency Training - The Role of the Lead Clinician

The **Lead Clinician**, identified by their divisional clinical director will have the responsibility for writing guidelines for use, training and supervision of junior clinical staff and assessing their competence, prior to performing diagnostics/treatments unsupervised. A written treatment protocol should be produced by the Lead Clinician which identifies the procedure that is being performed, that sets out the necessary checks and tests. The treatment protocol should be signed and dated. A separate treatment protocol should be in place for each investigation. Junior staff will work under the direct supervision of an appropriately trained and experienced registered user. Users will receive training that will be organised by their department's nominated Training Co-ordinator.

The training co-ordinator's role is to ensure that staff have been assessed against the equipment used or that might be used in their areas, and determine the most appropriate level of training required (if any).

### 5.5 Training and Information - IRR17 Regulation 15.

Those individuals who are engaged in work with ionising radiation will be given appropriate training in the field of radiation protection (currently recommendation is to undertake the relevant sections of eRADs (radiation safety for staff) via e-Learning for Health. This training will provide such information and instruction for staff to have sufficient knowledge regarding:

- the risks to health created by exposure to ionising radiation as a result of their work;
- the general and specific radiation protection procedures and precautions which should be taken in connection with the work with ionising radiation to which they may be assigned;
- the importance of complying with the medical, technical and administrative requirements of IRR2017.

All those involved in work or affected by work with ionising radiation, together with management and outside workers (including ancillary staff entering radiation areas, i.e. domestics, porters, maintenance staff), need to know how to work safely and reduce risk to their health.

Refresher training should be scheduled at regular intervals to maintain competence levels. In addition, employers should review employee's capabilities and provide additional or refresher training for employees as needed. If new equipment is brought in or working practices change, staff will require further training.

### 5.6 Outside Workers - IRR17 Regulation 16

IRR17 sets out the requirements for the training of classified and non-classified staff who are not employed by the Trust but who enter or work in designated ionising radiation areas. These staff require instruction on the nature of work and the hazards in the workplace, and the risks to their health that are associated with this work. These staff need to be informed of any procedures that they need to follow and where appropriate, arrangements for dose monitoring need to be agreed. This training needs to be refreshed at appropriate intervals and appropriate records maintained.

The Trust as the employer under IRR17 is required to seek the assurance from service suppliers that any of their staff required to enter a designated area controlled by the Trust do so having received suitable training and:

- under their own risk assessments and local rules (i.e. formal designated area handover); or,
- formally agree in writing to comply with Trust policies and procedures and supply evidence of appropriate training.

## 6 EQUIPMENT INVENTORY, MAINTENANCE AND QUALITY ASSURANCE

The Radiology department maintains a complete equipment list which is used to monitor the operational maintenance and provide a capital replacement plan which includes sources of Ionising radiation, MRI and Diagnostic Ultrasound. The replacement program is managed by the Medical

Equipment Group (MEG) after being agreed at Radiology Senior Management Team Meeting (RSMT). The replacement programme priorities will be based on risk assessment of performance factors including age, clinical performance, dose optimisation and other criteria deemed relevant.

The inventory must contain at least:

- name of manufacturer
- model number
- serial number or other unique identifier
- year of manufacture
- year of installation

And for equipment that is software—

- name of software company;
- brand name;
- current software version;
- year of original installation; and
- year of current software version installation in clinical use.

(Reg 15(2)&(3) IR(ME)R 2017 (Amendment 2024)

Expert support on radiation safety for equipment maintenance, replacement and new areas is afforded to the trust via an SLA with STH.

Maintenance of other devices purchased from outside of medical imaging are the responsibility of the purchasing departments via the Medical Technical Services Department for example the mini c arms used by orthopaedic surgery. Compliance with this policy is required and annual submission of compliance with this policy via the Radiation Safety Group is paramount.

## 6.1 Ionising Radiation – IR(ME)R17, (Amendment) 2024

The Trust must establish a quality assurance programme which gives assurance that equipment will satisfy the requirements of IR[ME]R 17(Amendment 2024) Regulation 15 that includes:-

- who has responsibility for organising the different elements;
- who will carry out testing or dose assessment;
- who has responsibility for acting on any adverse findings.

The assurance programme will set out the frequency of any testing and other measurements. It must also specify action levels, taking account of advice from relevant professional bodies. If these levels are exceeded, the employer must assess what remedial action is necessary, taking account of the risk arising from its continuing use.

Quality Control procedures will be created by an appropriately qualified state registered health care professional, in accordance with the manufacturer's instructions. Within medical imaging an adequately trained QA radiographer can then carry out procedures, with the results being formally documented for inspection by the relevant manager. Departments external to medical imaging are responsible for their own QA of ionising equipment and the compliance with this element of the document. It may be appropriate that they formally request radiology support via the radiation subgroup or that they adequately train a member of their own team. The reporting of any faults identified by the Quality control tests will be the responsibility of the QA radiographer or the

individual undertaking this testing in other departments, who will report to the Deputy Head of Medical Imaging via the monthly radiation subgroup meeting.

In accordance with the requirements of Regulations 32 of the Ionising Radiations Regulations 2017 (Amendment 2024), both the service engineer and the user will each carry out appropriate checks before returning equipment back to the user for routine use. A Radiation Controlled Area and Equipment Handover Form must be completed to transfer responsibility for a controlled area and equipment to the service engineer prior to the commencement of work. This will be used to identify any known hazards that exist with the equipment or environment (including non-radiation issues) such that the service company is able to perform the necessary risk assessments.

## 6.2 Requirements under IR(ME)R 2017 (Amendments 2024)

In addition, under Regulation 15 of IR(ME)R 2017 (Amendment 2024) the Trust must undertake adequate:-

- testing of any equipment before it is first used for a medical radiological purpose;
- performance testing at regular intervals;
- performance testing following a maintenance procedure which is capable of affecting the equipment's performance.

## 7 RISK ASSESSMENTS

The Trust is committed to ensuring the safety of patients, staff and the public through the integrated management of all aspects of governance and risk.

The Trust 'Risk Identification, Assessment and Management policy' CORP/RISK 30 is described in an "umbrella" document that defines the strategic direction for risk management in the Trust. It describes the framework and the method that the Trust will use to identify, manage and reduce the risks (actual or potential) which exist within the organisation. Before commencing a new work activity, radiation risk assessments are required that identify the radiation hazards present and evaluate the extent of the risks involved, i.e. IRR 2017 Regulation 8.

## 8 HEALTH SURVEILLANCE AND MEDICAL EXAMINATION

A medical examination will be made available to any patient or employee following a reported incident involving a suspected over-exposure and when an investigation shows that the employee has been exposed to predetermined levels of Ionising radiations. The individual's health record will be made and kept up to date and will contain a summary of the results of the medical examination. Continued Health Surveillance will be made available if appropriate.

Staff members exposed to ionising radiations as a result of work activities will be closely monitored. The radiation subgroup will decide when such an employee needs to be designated as a classified person (IRR 2017 Regulation 21). After the initial medical examination conducted before an individual's designation as a classified person (Regulation 25(2) and Regulation 25(3)), periodic reviews of health should take place at least once every year. The relevant doctor may specify a shorter period between reviews.

## 9 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

The implementation and effectiveness of this Policy will be monitored through the aforementioned groups and committees:

- The Radiology Department will implement procedures for the monitoring of staff and patient ionising radiation doses to ensure that adequate and effective controls are in place, management of which will be delegated to appropriate personnel for teams based outside of Radiology and working with non-radiology owned equipment
- The Clinical Governance Sub Group (Radiation) will performance manage the implementation of Trust/Divisions Governance Action Plans for ionising radiation, which will include risk issues;
- For significant risks (i.e., those risks with a score of 15 or more) the risk assessment and action plan will be escalated to the Management Board (via the Lead Nurse for the Division).

The RPA is responsible for providing the advice and information regarding any changes in legislation that is used during the periodic review of the policy. The Trust's Radiation Safety Group is responsible for the approval of this 'Ionising Radiation Safety Policy document'. Monitoring of this policy will be the responsibility of the members of the RSC.

Local rules and Risk Assessment will be reviewed at least every year by the RPS/ Department Operational Manager / Lead Radiographer. The assessor will be responsible for ensuring that the manager receives feedback so that any issues can be dealt with.

Risk Assessments referred to a department's management team will be reviewed, monitored and acted upon.

RSC meeting attendance (and non-attendance) will be recorded and monitored by an individual's line manager and discussed through the PDA system.

Training course attendance (and non-attendance) will be recorded and monitored by an individual's line-manager through the PDA system. The line manager of the recorded non attendees will be sent a letter informing them of the staff members failure to attend training and a further training date arranged.

In the event of persistent non-attendance the responsible manager will contact the staff member's line manager and develop an action plan to ensure this training takes place in a timely manner.

<b>What is being Monitored</b>	<b>Who will carry out the Monitoring</b>	<b>How often</b>	<b>How Reviewed/ Where Reported to</b>
<b>Current Legislation</b>	RPA/RWA/MPE etc.	Annually or when deemed appropriate by the RPA/LPA	Change in Policy reported to RSC Group

<b>Risk Assessments</b>	RPS/Manager/ RPA/	Annually or in response to a change in working practice	RPS/RPA Self- Assessment.  Actions reported to RSC and Service managers.
<b>Local Rules</b>	RPS	Annually or in response to a change in working practice.	RPS/RPA Self- Assessment and Service managers.
<b>RSC Meeting Attendance</b>	Chair of RSC through group secretary	Annually	Line Manager at PDA with reference to minutes from RSC meetings.
<b>RPS Update Training</b>	Manager/RPA	Every three years	Line Manager at PDA/RSC with reference to the minutes from RSC meeting

## 10 DEFINITIONS

CPD	Continuous Professional Development
DATIX	Web based system for reporting incidents.
EPR2016	Environmental Permitting Regulations 2016
IR(ME)R	Ionising Radiation [Medical Exposure] Regulations 2017
IR(ME)(Amendment)R 2024	Ionising Radiation [Medical Exposure] [Amendments] Regulations 2024
IR	ionising radiation (causes ionisation of atoms)
IRR17	Ionising Radiation Regulations 2017
MHSWR	Management of Health and Safety at Work Regulations 1999
MPE	Medical Physics Expert
PPE	Personal Protective Equipment
PDA	Performance Development Appraisal
RPA	Radiation Protection Adviser
RPS	Radiation Protection Supervisor
RSG	Radiation Safety Group

## 11 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 11).

## 12 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Equality Analysis Policy – CORP/EMP 27

Medical Devices Management Policy - CORP/PROC 4

Risk Identification, Assessment and Management Policy – CORP/RISK 30

Trust Policy for the Referral of Imaging Examinations by Qualified Non-Medical Healthcare Professional - PAT/T 1

## 13 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under ‘Current data protection legislation’ as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website:

<https://www.dbth.nhs.uk/about-us/our-publications/information-governance/>

## 14 REFERENCES

Environmental Permitting Regulations 2016

The Ionising Radiation [Medical Exposure] Regulations 2017

The Ionising Radiation [Medical Exposure] [Amendments] Regulations 2024

The Ionising Radiations Regulations 2017

The Personal Protective Equipment Regulations 2002

Management of Health and Safety at Work Regulations 1999



Medicines and Healthcare Products Regulatory Agency (MHRA) Safety Guidelines for Department of Constitutional Affairs Mental Capacity Act (2005): Code of Practice, 2007

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/497253/Mental-capacity-act-code-of-practice.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf)

## APPENDIX 1 – STATEMENT OF DUTIES OF THE EMPLOYER

While every attempt has been made to include as many of the employer's responsibilities as possible, the list in this Appendix is not necessarily exhaustive. Guidance has been issued jointly by the Health and Safety Executive, (HSE) and the Health Departments as *the Regulatory Requirements for Medical Exposure to Ionising Radiation: An Employer's Overview HSG22*.

The employer will need advice from the RPA from the issues contained in this appendix, although items 27-45 may lie in the domain of the MPE.

### **Before starting work with ionising radiation:**

1. Make a prior risk assessment before starting a new radiation activity; establish suitable dose constraints for the restriction of exposure of each category of person likely to be exposed.
2. Notify, register or obtain consent as appropriate from HSE for all radiation work undertaken at the site.
3. Notify the HSE before radiation work is undertaken for the first time, or if any material changes are made to a previous notification.
4. Obtain Permit under EPR 2016 or an exemption and conform to its conditions, if keeping, using or disposing of radioactive substances.
5. Prepare contingency plans and incorporate them in local rules if the risk assessment shows that an accident is reasonably foreseeable.

### **On commencing radiation work:**

6. Consult and appoint one or more suitable Radiation Protection advisers (RPA), providing adequate information and facilities for this function (Appendix 2).
7. Designate as appropriate the necessary controlled and supervised areas (to be described in local rules) with the necessary monitoring and controls (demarcation, signs, restricted access, systems of work, written arrangements, etc.) to provide adequate protection from external radiation and radioactive contamination, including washing and changing facilities as required.
8. Provide suitable and sufficient monitoring equipment and arrange for its maintenance and testing; ensure records of tests of monitoring equipment made by a qualified person are kept.
9. Ensure records of monitoring of designated areas are kept.
10. Obtain information from the manufacturer and installer about the proper use, testing and maintenance of radiation equipment after its critical examination, and involve the RPA.
11. Ensure the necessary steps are taken to restrict exposures to ionising radiation for staff, patients and others who may be exposed, setting investigation levels and providing written arrangements if necessary.
12. Demonstrate commitment to radiation protection through a written radiation safety policy, the establishment of a radiation protection group and by clear management lines, clear actions and the involvement of senior staff.
13. Provide sufficient engineering controls, design features, safety features and warning devices to restrict exposures as far as is reasonably practicable, and ensure that these are properly maintained and tested at suitable intervals.
14. Ensure personal protective equipment is provided, worn and maintained as appropriate, after all other measures have been considered.

15. Provide relevant local rules in compliance with the legislation, appointing radiation protection supervisors (RPS) as necessary to ensure the local rules are implemented and ensure that appropriate resources are given to them to undertake this role.
16. Ensure that all employees (including RPS) are given appropriate radiation protection training sufficient to understand the risks and precautions needed, including those who may be pregnant or breastfeeding.
17. Co-operate with other employers concerning exposure of others, as appropriate.
18. Designate classified persons, if necessary, and provide appropriate radiation monitoring and medical surveillance (health record); inform all persons when they are designated as classified persons.
19. Provide personal radiation monitoring and dosimetry records as necessary; ensure that the results of personal monitoring are kept under review (as low as reasonably practical; ALARP) and that any unusual results are investigated.
20. Ensure that dose limits are not exceeded, including those for pregnant and breastfeeding staff.
21. Investigate and notify to the HSE overexposures received by staff, respecting subsequent dose limitations, and medical exposures that are significantly greater than intended resulting from an equipment malfunction or defect.
22. Review procedures periodically, preferably with the support of the radiation safety group.

**On using radioactive substances:**

23. Ensure radioactive substances in use are sealed wherever practicable to prevent leakage. Where this is impracticable, the substance should be contained to prevent leakage in so far as is practicable, keeping records of appropriate leakage tests in both cases.
24. Account for and keep records of the quantity and location (including ultimate disposal) of all radioactive substances.
25. Ensure radioactive substances are suitably contained and stored when not in use.
26. Ensure radioactive substances are suitably contained and labelled when in transit.

**On making medical exposures:**

27. Determine locally those acting as duty holders under IR(ME)R 2017, IR(ME) (Amendments)R 2024, (referrer/practitioner/operator) within diagnostic radiology, diagnostic nuclear medicine, therapy nuclear medicine and external to Radiology where necessary.
28. Maintain records (available for inspection) of the training and continuing education of the above practitioners and operators, even when they are practising on contract at a site belonging to another radiation employer.
29. Ensure an MPE is available in diagnostic nuclear medicine.
30. Ensure an MPE is involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance (QA) and other radiation protection advice concerning medical exposure, in all other radiological practices not covered in paragraphs 30 and 31.
31. Ensure written protocols are in place for every type of standard radiological practice for each piece of equipment and a current inventory of equipment is kept for and at each radiological installation, ensuring the amount of equipment is limited to that necessary for the proper carrying out of medical exposures.
32. Establish QA programmes for standard operating procedures.
33. Establish recommendations concerning referral criteria for medical exposure, including radiation doses, and ensure these are available to the referrer.

34. Establish local diagnostic reference levels, undertake reviews and ensure corrective action is taken as necessary.
35. Establish dose constraints for research programmes where no direct medical benefit for the individual is expected from the exposure.
36. Ensure a clinical evaluation of the outcome of each medical exposure, including factors relevant to the patient dose, is recorded.
37. Ensure clinical audit is carried out in accordance with national procedures.
38. Implement written procedures (as specified in Schedule 2 of IR(ME)R [3], IR(ME) (Amendments)R 2024 and reproduced here) and ensure these are complied with by the IR(ME)R practitioners and operators:
  - (a) to identify correctly the individual to be exposed to ionising radiation;
  - (b) to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice;
  - (c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding;
  - (d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;
  - (e) for the assessment of patient dose and administered activity;
  - (f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations falling within Regulation 3(a), (b), (e) and (f);
  - (g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in Regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within Regulation 3(c) where no direct medical benefit for the individual is expected from the exposure;
  - (h) for the giving of information and written instructions as referred to in Regulation 12(6);
  - (i) providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure;
  - (j) for the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose;
  - (k) to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable;
  - (l) to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure;
  - (m) to be observed in the case of non-Radiology exposures;
  - (n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.
  - (o) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.
  - (p) for making, amending and cancelling any referrals for exposure
39. Make an investigation of any instance where exposure of staff or an over/unnecessary exposure of a patient, as defined in Significant accidental and unintended exposures (CSAUE)

CQC Guidance for employers and duty holders August 2024 (other than an incident resulting from an equipment malfunction (see paragraph 21) is suspected and notify the appropriate authority if the exposure has indeed occurred, with a detailed investigation.

40. Review procedures periodically, preferably with the support of a medical exposures group.

**On using equipment for medical exposure:**

41. Ensure that the equipment available for the range of examinations or treatments using ionising radiation is appropriate and is not used for procedures for which it is not suitable.
42. Ensure that the equipment is maintained in a manner consistent with the manufacturer's recommendations, to ensure that medical exposures are ALARP, and compatible with the intended clinical purpose or research objective.
43. Ensure that new or replacement diagnostic X-ray equipment is provided with a suitable means of indicating the quantity of radiation produced during a radiological procedure.
44. Draw up a suitable QA programme for all ionising radiation equipment, having consulted the RPA and MPE.
45. Identify, provide, maintain and calibrate appropriate test equipment as part of the QA programme.

## APPENDIX 2 - STATEMENT OF DUTIES OF THE RADIATION PROTECTION ADVISER (RPA)

The radiation protection adviser (RPA) is an individual or corporate body that meets the criteria of competence specified by the HSE and, for ongoing consultation, is appointed in writing by a radiation employer, IRR17 Regulation 14(1) – (3). The appointment includes the scope of the advice that is required as appropriate on the following matters (IRR 2017, Schedule 4). Where necessary an RPA will report directly to the Chief Executive's office.

The scope of advice is drawn up and agreed by the employer and RPA when making the appointment.

### **Matters in respect of which a radiation protection adviser must be consulted (IRR17 Schedule 4):**

1. The implementation of requirements as to controlled and supervised areas.
2. The prior examination of plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design features, safety features and warning devices provided to restrict exposure to ionising radiation.
3. The regular calibration of equipment provided for monitoring levels of ionising radiation and the regular checking that such equipment is serviceable and correctly used.
4. The periodic examination and testing of engineering controls, design features, safety features and warning devices

### **The RPA(s) will also be consulted on the following matters:**

5. Risk assessments, and contingency plans if necessary.
6. The form and content of local rules for each designated controlled or supervised area.
7. The conduct of investigations and subsequent reports as necessary.
8. Staff and public dose assessments and recording, including personal and area monitoring.
9. The selection and use of appropriate personal protective equipment.
10. Critical examinations of newly installed or repaired equipment and articles for work with ionising radiation.
11. Arrangements for outside workers.
12. Staff training as appropriate for classified persons, outside workers, those who enter controlled areas under written arrangements, other staff as necessary, safety representatives, radiation protection supervisors, staff undertaking monitoring, supervisors and managers with specific radiation responsibilities.
13. Information and instructions for pregnant and breastfeeding employees.
14. Training for emergencies.

## APPENDIX 3 – STATEMENT OF DUTIES OF THE MEDICAL PHYSICS EXPERT (MPE)

The Medical Physics Expert is an individual that meets the criteria of competence specified by the Department of Health and is appointed by the Trust. The appointment includes the scope of the advice that is required under Regulation 14 of IR(ME)R 2017, (Amendments 2024). The MPE must be available to contribute to the following issues.

A medical physics expert must—

- (a) be involved in practices including diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography;
- (b) be involved as appropriate for consultation on optimisation, in all other radiological practices not mentioned in sub-paragraphs (b) and (c); and
- (c) give advice on—
  - (i) dosimetry and quality assurance matters relating to radiation protection concerning exposures;
  - (ii) physical measurements for the evaluation of dose delivered;
  - (iii) medical radiological equipment.

A medical physics expert must also contribute to the following matters—

- (d) optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels;
- (e) the definition and performance of quality assurance of the equipment;
- (f) acceptance testing of equipment;
- (g) the preparation of technical specifications for equipment and installation design;
- (h) the surveillance of the medical radiological installations;
- (i) the analysis of events involving, or potentially involving, accidental or unintended exposures;
- (j) the selection of equipment required to perform radiation protection measurements;
- (k) the training of practitioners and other staff in relevant aspects of radiation protection;
- (l) the provision of advice to an employer relating to compliance with these Regulations.

## APPENDIX 4- STATEMENT OF DUTIES OF THE RADIOACTIVE WASTE ADVISER (RWA)

The Trust is required to have a management system, organisational structure and resources, which are sufficient to achieve compliance with the limitations and conditions specified in the Permits issued under the Environmental Permitting Regulations, (EPR16). The Radioactive Waste Adviser is a certified individual that meets the criteria of competence specified by the Environment agency, for ongoing consultation, is appointed in writing by the Trust. The appointment includes the scope of the advice that is required as appropriate on the following matters.

The scope of advice is drawn up and agreed by the employer and the RWA when making the appointment.

1. The use of Best Available Techniques (BAT) to minimise the amount of radioactive waste requiring disposal and reduce its radiological impact on the environment and members of the public.
2. The keeping and use of radioactive materials listed in the Trust's Permit issued under EPR16.
3. The accumulation and disposal of radioactive waste materials listed in the Trust's Permit issued under EPR16.

**The following list of duties will be supervised by the RWA:**

4. To provide a record that demonstrates the location of both open and closed sources whilst held on the premises.
5. To help the relevant RPS monitor and keep records of the date, quantity, route and activity of removal of radioactive waste from the premises.
6. To help the relevant RPS ensure that the total activity on the premises at any time is within the limits that are specified in the Trust's Permits.
7. To help the relevant RPS ensure that all sites acting under the conditional exemptions from the requirement to hold an environmental permit in respect of certain radioactive substances. This is to satisfy the conditions that must be met if they are to remain exempt from the requirement for a permit as listed in Section 7 of Schedule 23 within EPR16.
8. If required, to undertake radiological impact assessments prior to any application to the Environment agency for permission to use, hold, accumulate and dispose of radioactive materials. To specify and select and then justify the environmental consequences of the chosen routes for disposal.
9. To advise on the security and conditions under which the radioactive materials are stored are adequate and well maintained.
10. To provide an annual report to the Environment agency, for entry on to the Pollution Inventory Reporting, in respect of discharges of aqueous waste, transfer of solid waste for incineration and any other disposal route specified as part of the Trust's Permit.

**The following list of duties may be undertaken by a RPS who is responsible for the control of radioactive materials.**

11. The RPS has responsibility to duly complete and maintain clear and up to date records for compliance purposes in respect of all relevant limits and conditions.
12. The RPS will ensure records are adequately collated to represent activities on site as a whole, such that individual record keeping within departments does not result in a breach of an authorised limit once the records are totalled together as required for compliance purposes.



13. The RPS will immediately inform the RPA if any authorised limit has, or is about to be, exceeded. The RPA will initiate an urgent investigation to establish the facts before reporting to the relevant authorities without undue delay in the event that a statutory reporting requirement is necessary.
14. The RPS will present a written and verbal report to the RSC on an annual basis. In the event that the RPS is unable to attend the meeting, a duly briefed representative must be delegated to attend on their behalf and speak to the report.

## APPENDIX 5 - STATEMENT OF DUTIES OF A RADIATION PROTECTION SUPERVISOR (RPS)

### **Duties of an RPS under Regulation 18 IRR 2017**

To supervise the work with ionising radiation in the area to which the RPS appointment relates and ensure it is carried out in accordance with the local rules.

1. To specifically ensure any work instructions relevant to restriction of exposure or entrance to controlled areas are brought to the attention of persons who need to be advised.
2. To keep under review any supervised radiation areas and advise the radiation employer (through the RPA) should it be necessary to re-designate such areas.
3. To participate in rehearsals of contingency arrangements, where relevant.
4. To observe from time to time, all procedures involving exposure to ionising radiation in areas where the RPS has a supervisory role, to ensure working practices are consistent with any documented work instructions aimed at ensuring doses remain as low as reasonably practicable (ALARP).
5. To ensure that relevant sections of the local rules and the Trust Radiation Safety Policy are brought to the attention of those who may be affected.

### **Additional Duties under Regulation 5 of MHSWR 1999**

The following additional arrangements for supervision are necessary to comply with the general duty under Regulation 5) of the Management of Health and Safety of Work Regulations 1999, (MHSWR). These duties are indicative of those that may be undertaken by the RPS. Any RPS will be appointed by the Trust in writing, see the Approved Code of Practice, (ACOP) 18(5) and see paragraph 4.9.3 shown above. Any additional management duties will be delegated to the RPS by their line-manager.

1. To supervise the issue, wearing, collection and return of personal monitoring dose meters at the appropriate time, where relevant.
2. To assist the employer in performing risk assessments including those for pregnant and breast-feeding staff, where relevant. The risk assessment will normally be reviewed biannually or following a change in working practices or relevant legislation. An incident or near miss should also prompt a review of the risk assessment. The outcome of any review should be documented, even if no amendments were required at the time of the review.
3. To assist, in consultation with the Laboratory/Department /Section Manager and the RPA, in the production of Local Rules. The Local Rules should be subject to an annual review.

They should also be reviewed following changes in working practices, legislation or the risk assessment.

4. To assist the employer in the development of contingency plans and to ensure that all staff are able to implement them effectively.
5. To ensure that staff receive such information and training as is necessary for them to carry out their work in accordance with the Regulations, and that new employees read and understand the relevant sections of the Local Rules.
6. To attend and to arrange and encourage the attendance of other staff, on specific training lectures and/or courses relevant to the radiation protection aspects of their work.
7. To ensure that in consultation with the Laboratory / Section / Department Manager and the RPA, that all workers likely to be exposed to radiation are informed of the potential hazards.

8. To encourage staff to promptly inform the RPS or the employer if they are pregnant or breast feeding and to ensure that such staff are made aware of any necessary work restrictions.
9. To ensure that any investigations required under the Local rules, MHSAW Regulations or IR(ME)R 2017 (Amendment 2024) (as applicable) or as requested by the RPA, are completed and appropriately reported.
10. To notify the RPA of any significant changes in procedure, equipment, technique, the working environment, or new projects which could affect radiation safety.
11. Where relevant, to ensure that radionuclide stock is appropriately controlled, that radioactive waste is appropriately accumulated and removed from the laboratory, and that records of these activities are clear, legible and up to date.
12. Where relevant, to supervise the carrying out of contamination monitoring on a regular basis and the recording of the results, with due reference to any permissible contamination limits recommended for the working area. This requirement extends to the requirement for two yearly leak testing of sealed sources, where applicable.
13. Where relevant, as advised by the RPA, to maintain and keep available for inspection, records of: contamination monitoring, investigation reports, stock control, waste disposal, permit to work, personal monitoring records, transport consignment notes etc. as relevant.
14. To supply the RPA on request and at least annually, with a record of active waste disposals, as appropriate.
15. Where relevant, to ensure that all radiation monitors in the department are subject to an annual test and examination.
16. To ensure that any necessary action required by reports of the RPA/RWA or MPE is followed up.
17. To ensure any engineering or physical radiation control measures are appropriately supplied and functioning e.g. door interlocks, fume cupboards, warning lights/signs, PPE etc.
18. To play a role in equipment quality assurance in order to help maintain optimisation of exposures and to act in a timely manner to report any suspected equipment problem consistent with documented QA procedures.
19. To liaise with staff from other departments or outside workers/contractors where relevant, in respect of issue of permits to work, to ensure that they do not unknowingly put themselves at risk and are aware of relevant systems of work.
20. To make an appropriate entry into the radiation passbook of an Outside Classified Radiation Worker, where you have been appropriately trained.
21. To arrange for the monitoring of Controlled Areas before allowing cleaners or tradesmen to enter, in accordance with the system of work.
22. To supply the RWA on request and at least annually with a record of radionuclide use and waste disposal, in accordance with IRR 2017, and in conditions of Permits, under EPR 16.
23. To ensure that an effective QA programme is maintained for all the counting equipment held within the Nuclear Medicine Department, and that records of the QA are available for inspection by the Health and Safety Inspectors and IR(ME)R Inspectors.
24. To ensure that all radiation monitors in the department's care are regularly checked and calibrated annually, under the guidance of the RWA.

## APPENDIX 6 - CLINICAL GOVERNANCE SUB – GROUP (RADIATION)

### Terms of Reference

#### Frequency

The Clinical Governance Sub-Group (**Radiation**) (referred to as Radiation Group) will meet on a monthly basis. Exception updates will be discussed at the Radiology Senior Management Team (RSMT) meeting.

The Clinical Governance Sub-Group (Radiation) (incorporating Ionising Radiations (Medical Exposures) Regulations 2017 (Amendment 2024) and the Ionising Radiation Regulations (2017) will have the following membership:

#### Membership

The group shall comprise:

- Deputy Head of Service
- Radiation Protection Lead Radiographer
- Radiation Protection Advisers (by appropriate invitation dependant on agenda, minutes will be sent monthly to this group)
- Operational Managers
- QA Lead Radiographer
- Radiation Protection Supervisors – (Plain Film and Nuclear Medicine, Mammography, CT scanning and Interventional Radiology)
- Medical Physics Experts

The Deputy Head of Medical Imaging will act as Chair and the Radiation Protection Lead Radiographer as the Vice - Chair.

#### Meeting Arrangements

The Radiation Group will only be deemed quorate when the following requirements are met:

- The Chair and/or Vice-Chair are present. There are four members of the Group in attendance, including the Chair and/or Vice-Chair

It will be the responsibility of the Chair and/or Vice-Chair to declare the meeting void if it does not fulfil the above quorate arrangements. In their absence, the Elective and the Acute Operational Managers/Deputy Heads within Radiology will hold the responsibility.

### **Duties**

- The Radiation Group will be responsible for the continued implementation of the IR(ME)R 2017(Amendment 2024) Procedures and Protocols in line with current legislation, and provide guidance on training to referrers, practitioners and operators.
- The Radiation Group will be responsible for Quality Assurance documentation and setting, and standardisation of Local Dose Reference Levels across all imaging sites in the Trust.
- The Radiation Group will review and investigate untoward radiation incidents and near-misses and any examinations where Local Dose Reference Levels were exceeded without valid explanation. The relevant personnel will be informed as appropriate.
- The Radiation Group will be responsible for assessing all proposals from Non-Medical Referrers, PAT/T 1 - Trust policy for Referral for Imaging Examinations by Qualified Non-Medical Healthcare, including those relating to ultrasound and MRI.

### **Communication**

To ensure sharing of information with regards to all aspects of radiation safety, the agendas, minutes and supporting documentation will be circulated as follows:

- Radiology Clinical Governance Group
- Radiation Protection Adviser / Radioactive Waste Adviser/ Medical Physics Expert / Nuclear Medicine.
- Radiation Protection Adviser / Medical Physics Expert / Radiology

The Radiation Group will review the radiation awareness implications of future developments within the Directorate using guidance from:

- Ionising Radiation (Medical Exposure) Regulations 2017 (Amendment 2024)
- Ionising Radiations Regulations 2017
- The CQC
- The Health and Safety Executive
- The Environment Agency and National Counter Terrorism Security Office in respect of security of radioactive materials
- IPEM 91/IPEM 89

### **Accountability**

Accountability Framework for the Radiation Group is as follows:

- The Trust's Board of Directors
- The Trust's Clinical Governance and Quality Committee.
- Radiation Safety Group
- Radiology Senior Management Team
- Management Team
- Radiation Protection Supervisors – See Appendix 10.

## APPENDIX 7 - RADIATION SAFETY GROUP

### Terms of Reference

#### Statement of Scope and Purpose

As part of the management and communication framework for Health and Safety within the Trust, the Group shall assist the Chief Executive to comply with all relevant legislative requirements relating to the use of ionising and non-ionising radiations.

The Radiation Safety Group has responsibility for the following areas:

- Drawing up and ensuring implementation of systems for the safeguarding of radioactive materials, safe disposal of radioactive waste.
- Advising the Trust/other employees on appropriate radiation safety matters.
- Audit, inspect and perform such tests as necessary and issue an annual report.
- Ensuring radiation risk assessments are performed and reviewed and implemented.
- Ensuring policies and procedures relating to Radiation are in place and reviewed regularly.

#### Membership

The group shall comprise:

- Medical Director (Chair of Group)
- Clinical Director Radiology
- ARSAC Licence holder Nuclear Medicine
- General Manager for Division
- Head of Service, Radiology
- Radiation Protection Lead Radiographer
- Radiation Protection Supervisors
- Radiation Protection Advisers/Radioactive Waste Advisers
- Operational Managers, Radiology
- Radiation Protection Lead Radiographer
- QA Lead Radiographer
- Radiation Protection Supervisors – (Plain Film and Nuclear Medicine, Mammography, CT scanning, Interventional Radiology and Theatres)
- Medical Physics Experts
- Laser Protection Adviser appointed by the Trust
- Laser Protection Supervisors
- Magnetic Resonance Safety Expert
- Magnetic Resonance Responsible Person

and additional members as the Group may decide.

The Medical Director will act as the Chair and in their absence Head of Medical Imaging will act as Vice Chair.

#### Meeting Arrangements

#### Quorum

The Radiation Safety Group will only be deemed quorate when the following requirements are met:

- The Chair and/or Vice-Chair are present and there are five members of the Group in attendance, including the Chair and/or Vice Chair

It will be the responsibility of the Chair and/or Vice-Chair to declare the meeting void if it does not fulfil the above quorate arrangements.

### **Frequency**

The group shall meet twice a year at a place and time as decided by the group. The minutes of meetings and the RPA reports will be circulated to the Chief Executive and the Risk Manager.

### **Attendance**

In the event of foreseen but unavoidable absence from a meeting, the group member should identify and fully brief a competent member of the department to attend in his/her place.

### **Duties**

The following Core Duties will be undertaken by the group:

- to receive reports from the Radiation/Laser Protection Advisers/MPes/MRSE on any unsatisfactory conditions and to advise on measures to be used to remedy them,
- to receive reports from the RPS/MRRP and other supervisors on the implementation of Local Rules and on the disposal of radioactive substances,
- to consider the reports of Radiation Protection Advisers and Radiation Protection Supervisors and decide on appropriate action as necessary,
- to inform the Chief Executive when necessary, but at least once every 12 months, of measures to be taken to secure compliance with relevant legislation.
- as part of the Trust framework for the protection of patients, liaise on relevant topics with the Clinical Governance Standards Group.
- to receive a report regarding radiation incidents from the Radiation Protection Lead Radiographer.

### **Matters of Legislative Compliance**

Matters of legislative compliance that will be considered by the group will include but not be limited to:

- The designation of radiation controlled and supervised areas.
- The completion of prior risk assessments.
- The training and instruction of staff.
- The monitoring of staff doses and the designation of classified workers.
- The appointment of Radiation Protection Advisers and Radiation Protection Supervisors.
- Local rules, written systems of work and contingency plans.
- The safe use, security, safekeeping, disposal, movement and transport of unsealed and sealed radioactive substances.
- Written procedures for the protection of patients undergoing diagnostic and therapeutic procedures involving ionising and non-ionising radiation.

- The installation, maintenance, quality assurance and safe use of radiation generating equipment and equipment that can affect the exposure of patients to radiation.
- Diagnostic reference levels relating to patient radiation doses.
- The protection of members of the public exposed to radiation as a result of their contact with or support/care of patients.
- The annual return of disposal of radioactive waste
- Monitoring of ARSAC certificates
- Radiation incident reporting

**Accountability Framework:**

- The Trust's Board of Directors
- The Trust's Clinical Governance and Quality Committee.
- The Trust's Radiation Safety Group
- Radiation Protection Lead
- Departmental Service managers
- Radiation Protection Supervisors



## APPENDIX 8 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
CORP HSFS 21 v.8	CSS	Jane Davies	Existing Policy	31/12/2024
<b>1) Who is responsible for this policy?</b> Name of Division/Directorate: The CSS Division – Radiation Safety				
<b>2) Describe the purpose of the service / function / policy / project/ strategy?</b> Trust-Wide – all users of potentially hazardous Ionising/Non-ionising Radiations				
<b>3) Are there any associated objectives?</b> Yes				
<b>4) What factors contribute or detract from achieving intended outcomes?</b> None				
<b>5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief?</b> No				
<ul style="list-style-type: none"> <li>• <b>If yes, please describe current or planned activities to address the impact</b> [e.g. Monitoring, consultation] –</li> </ul>				
<b>6) Is there any scope for new measures which would promote equality?</b> [any actions to be taken]				
<b>7) Are any of the following groups adversely affected by the policy?</b>				
<b>Protected Characteristics</b>	<b>Affected?</b>	<b>Impact</b>		
a) Age	No			
b) Disability	No			
c) Gender	No			
d) Gender Reassignment	No			
e) Marriage/Civil Partnership	No			
f) Maternity/Pregnancy	No			
g) Race	No			
h) Religion/Belief	No			
i) Sexual Orientation	No			
<b>8) Provide the Equality Rating of the service / function / policy / project / strategy – tick (✓) outcome box</b>				
Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4	
<i>*If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a <b>Detailed Equality Analysis form</b> – see CORP/EMP 27.</i>				
<b>Date for next review:</b> December 2027				
<b>Checked by:</b> S Elliott		<b>Date:</b> 31.12.2024		