University Hospitals of Leicester NHS
NHS Trust

Ionising Radiation Safety Policy

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REVIEWS

Version number	Changes made
5	This is a complete re-write. The aim to bring together the Radiation Safety Policy (B17/2008) and the Ionising Radiations (Medical Exposures) Policy (B13/2001). The sections on non-ionising radiation have been removed to be placed in a separate policy. The contents have been updated to include the requirements of the revised legislation to implement the requirements of the Basic Safety Standards 2013.
6	A large number of formatting changes were made to make responsibilities clearer and in line with current Trust practice. Updates were made inline with new guidance. Whilst the underlying processes are not changed the number of changes mean that it would not be possible to exhaustively list the changes. This review should been viewed as a re-write.
6.1	References to Schedule 3 Adequate training changed to Schedule 2. Amended the responsibilities section to reflect the change of responsibility for chairing the Radiation Safety Committee from the Deputy Director of Clinical Governance to the Deputy Medical Director.
7	References to schedule 3 incorrect and amended to schedule 2.

Key Words

Radiation
Protection
Safety
IRR
IR(ME)R
IRMER
X-ray
Nuclear Medicine

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trust's Policy and Procedures for the use of ionising radiation to ensure that radiation exposures are As Low As Reasonably Practicable (ALARP) and that they comply with current radiation regulations.

2 POLICY SCOPE

2.1 This policy includes all staff employed by UHL, including locum or agency staff. There are a number of education requirements that all staff must undertake and these are detailed further in the education and training section.

2.2 The policy also covers staff employed by other employers entering areas designated as Controlled or Supervised. These are referred to as outside workers.

2.3 The policy sets out the framework for working safely with radiation to ensure the safety of all staff, patients and the public.

2.4 This policy covers only ionisiong radiation and non-ionising radiation is covered by the Trust Non-Ionising Radiation Safety Policy (B25/2019).

3 DEFINITIONS AND ABBREVIATIONS

As Low As Reasonably Practicable (ALARP)	This means that the risk has been reduced to such a level that action to further reduce the risk is disproportionate to the benefits of risk reduction.
Administration of Radioactive Substances Advisery Committee (ARSAC)	ARSAC advises the licensing authorities on applications from practitioners; employers and researchers who want to use radioactive substances on people under IRMER17
Authorisation	Authorisation is the process by which a check is performed that justification has taken place and the procedures is approved to go ahead. This is an operator task.
Classified Radiation Worker	An employee who, because of the nature of the work that they undertake, has the potential to exceed an effective dose greater than 6mSv or an equivalent dose greater than 15mSv per year for the lens of the eye or greater than 150mSv per year for the skin or extremities.
Clinical Management Group (CMG) Managers	Those managerial responsible for the CMG.
Consultant Occupational Health Physician	A registered medical practitioner who has been appointed by the Trust to review and manage the occupational health requirements related to being a classified worker. Whilst this is no longer a legal requirement an appointed doctor will still be have this role at UHL.
Controlled Area	Areas designated under the Ionising Radiation Regulations (2017) where it is necessary for those entering the area to follow special procedures to restrict significant exposure to ionising radiation in that area or to limit the probability or magnitude of radiation accidents and their effects or any person in the area is likely to receive a dose that could lead to classification of the individual as a radiation worker (see 3.3)
Designated area	Either a controlled or supervised area under the Ionising Radiation Regulations 2017.
Dangerous Goods Safety Adviser (DGSA)	An appropriately trained person who is certified to advise on the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 as amended in 2011.
Area Manager	The person responsible for the day-to-day running of the department.
EPR (Environmental Permitting Regulations) 2016	The main piece of legislation that covers the retention and disposal of radioactive substances.

Ionising radiation	Defined by the Ionising Radiation Regulations 2017 as "the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less or a frequency of $3x10^15$ hertz or more capable of producing ions directly or indirectly." Practically, in the hospital this covers X-rays and gamma rays as well as beta and alpha particles.
HSE(Health and Safety Executive)	The inspectorate responsible for the enforcement of the Ionising Radiation Regulations 2017.
IRR (Ionising Radiations Regulations) 2017	The main piece of legislation which Covers the protection of people who work with radiation and the general public.
IRMER (Ionising Radiation (Medical Exposures) Regulations) 2017	The main piece of legislation covering the protection of patients undergoing medical exposure to ionising radiation and non-medical imaging exposures.
Justification	Justification is the considered thought process required to decide if there is an overall net benefit to the individual/society in carrying through with the proposed medical irradiation.
Local Rules	Written instructions that must be followed when entering radiation areas. They should detail all safety precautions required. These are rules produced locally in accordance with IRR17 and supervised by the Radiation Protection Supervisor.
LRSS(Leicester Radiation Safety Services)	Providing, under the direction of the Head of LRSS, advice on compliance with the legislation applicable to the use of ionising radiation.
Medical Exposures	Defined under IRMER17 as the exposure of patients to ionising radiation as part of their medical diagnosis/treatment; occupational health surveillance health screening or voluntary participation in medical research programs.
MPE (Medical Physics Expert)	Is defined under IRMER17 as an individual or a group of individuals having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State. MPE is a specific type of Qualified Person. Their duties are defined in Section 12
Non-medical Imaging Exposures	Any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed.
Non-Medical Referrer	A registered healthcare professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner.
Operator	Defined under IRMER17 as any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects related to medical exposures to ionising radiation except where they do so under the direct supervision of a person who is adequately trained.
Outside Worker	An outside worker is an individual who carries out services in the controlled area of another employer. Outside workers may or may not be classified.
PPE (Personal Protective Equipment)	Anything worn by the worker to protect against hazards in the environment. An example for use with ionising radiation is a lead apron.
Practitioner	Defined under IRMER17 is a registered health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure. Their main purpose is to provide adequate justification for an exposure.
Procedures	Defined under IRMER17 as a series of employer's written instructions that staff are obliged to follow in order to avoid legal liability under these regulations.
Protocol	This is defined by the IRMER17 as a validated exposure chart for performance of diagnostic x-rays or dosing chart for administration of radioactive materials.
Qualified Person	A person who has sufficient experience and qualifications to complete a specific task.
Specialist Radiation Adviser	A generic term to incorporate the DGSA, MPE, RPA, RWA and as required.
RPA (Radiation Protection Adviser)	A suitably qualified person appointed in accordance with IRR who should be consulted on matters detailed in Section 11 of this document.

RWA (Radioactive Waste Adviser)	The Radioactive Waste Adviser is a specialist in radioactive waste disposal and environmental radiation protection who has demonstrated competence in these areas who, in accordance with EPR, should be consulted on matters detailed in Section 13 of this document. The RWA is a specific type of Qualified Person.
RSC (Radiation Safety Committee)	Reports to the Trust Board on matters regarding radiation safety. The terms of reference for the RSC can be obtained from the Deputy Medical Director.
RPS (Radiation Protection Supervisor)	An individual appointed in writing for areas which use ionising radiation to supervise adherence to the local rules (produced in accordance with) and provide knowledge in an emergency situation.
Referrer	Defined under IRMER as a registered healthcare professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner. Their main responsibility is to ensure that the practitioner has adequate evidence to help with the justification process.
Specialty procedures	Local procedures produced within a CMG or Department to aid compliance with the regulations.
SOP(Standard Operating Procedure)	A written document used to thoroughly detail the commonly accepted method for performing a routine or repetitive task.
Supervised Area	An area where it is necessary to keep the conditions of the area under review to determine whether it should be controlled.

4 ROLES & RESPONSIBILITIES

4.1 Establishing responsibility

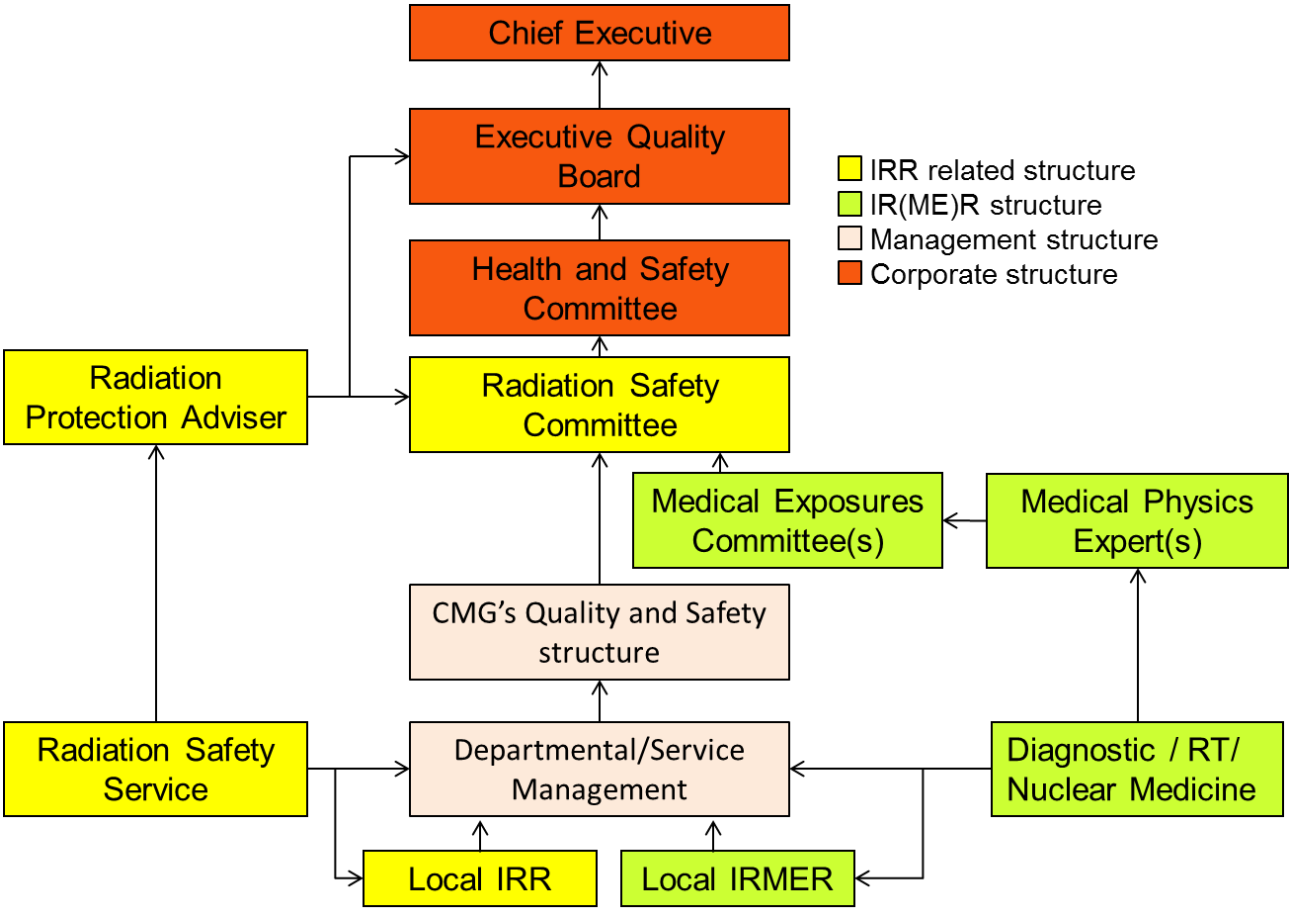


Figure 1: Governance structure for radiation safety across the Trust.

4.1.1 The section describes the roles and responsibilities throughout the Trust with respect to Radiation Safety. The overall governance framework for radiation safety can be found in Figure 1.

4.1.2 Throughout this document the responsibility for various tasks is indicated in the margin on the right hand side of the document.

4.1.3 It is possible for individuals to delegate tasks to other members of staff but the responsibility for ensuring that the task is complete remains with the individual identified in this policy. Therefore, it is important where tasks are delegated that there is written record of the delegation (for example, in an appointment letter such as an RPS appointment letter. All staff

4.1.4 Any individual delegating tasks must establish methods of gaining assurance that the task is being performed. An example would be the use of Assurance and Performance meetings or other local procedures. All staff

4.2 Roles

4.2.1 Chief Executive (CE)

The Chief Executive has overall responsibility for ensuring the health, safety and welfare of all persons who are, or may be affected by the Trust's business and for compliance with all ionising radiation regulations. The practicalities of ensuring these responsibilities are delegated as detailed below however the legal responsibility cannot be delegated. CE

The Chief Executive will:

- Ensure that sufficient resources including staff and finance are made available for compliance with this policy.
- Ensure that arrangements are in place to ensure the correct notification, registration or consents are in place with the HSE.
- Ensure that arrangements are in place to ensure the correct permits are in place with the EA.
- Ensure that the Trust appoints in writing the Specialist Radiation Adviser(s) required to ensure compliance. These written appointments should include their responsibilities and the scope of their role.
- Ensure systems are in place to monitor and escalate radiation safety issues where necessary.
- Ensure that the culture within the Trust is conducive to good radiation safety.
- Inform Leicester Radiation Safety Services of any changes effecting the details of the legal entity of University Hospitals of Leicester NHS Trust i.e. change of name or headquarters.
- Ensure all tasks indicated with CE in the margin of this policy are completed.

4.2.2 Deputy Medical Director (DMD) The Deputy Medical Director has delegated responsibility from the Chief Executive for practical implementation of the policy and compliance with the applicable regulations. They will: DMD

- Report directly to the Chief Executive and Trust Board on matters regarding radiation safety within the Trust.
- Be responsible for co-coordinating the implementation of risk management initiatives and policies.
- Chair the Trust Radiation Safety Committee.
- Act as the Executive Lead for Radiation Protection.
- Be responsible for co-ordinating the reporting of incidents under the relevant legislation to the relevant body. This responsibility may be further delegated to an individual that the Deputy Medical Director deems adequately trained.
- Take advice from the Specialist Radiation Advisers (Section 4.3) on matters of compliance.
- If the arrangements for provision of the Specialist Radiation Advisers change, it is the responsibility of the Deputy Medical Director to ensure resources are available for continuous cover for such services.
- Ensure that there are mechanisms in place such that when advised of issues with radiation safety within the Trust there is adequate redress.
- Ensure all tasks indicated with DMD in the margin of this policy are completed.

4.2.3 Health and Safety Manager (HSM): HSM

- Is responsible for ensuring that adequate radon monitoring and risk assessments are available for each site.
- Ensure all tasks indicated with HSM in the margin of this policy are completed.

4.2.4 Head of Facilities (HF): The Head of Facilities is responsible for: HF

- Appointing a DGSA for the responsibilities as detailed in Section 4.3.
- Ensuring that there is continuity of provision of the services of a Dangerous Goods Safety Adviser.
- Waste flows off site and will be contacted regarding any incorrect waste flows.
- Ensuring that the collection of solid radioactive waste from user departments and its transfer to a contractor for incineration is conducted as per any agreements with third parties.
- Notifying the RWA well in advance of any proposal to change arrangements for collection or disposal (including change of contractor) of waste. This will require notification to the Environment Agency and potentially a formal application for a variation to the Trust Authorisation.
- The Security Manager is responsible for ensuring that all security staff responds promptly to alarms in designated areas and security staff have been trained to follow a response procedure to keep themselves safe when they do so.
- Ensure all tasks indicated with HF in the margin of this policy are completed.

4.2.5 CMG Clinical Director (CMG): The CMG Clinical Directors are delegated to ensure that the Trust Radiation Safety Policy is implemented within their respective areas. They are responsible for ensuring: CMG

- Awareness of their own responsibilities and ensuring that Heads of Service / Areas Managers within their area are aware of their responsibilities under law and under this Policy and the carrying out of these responsibilities.
- That there are sufficient local mechanisms in place to ensure the prompt escalation of radiation issues.
- Ensure that there are appropriate mechanisms in place for escalation of radiation safety issues.
- Seek assurance from Heads of Service/Area Managers that radiation risks are adequately managed.
- That the advice of the Specialist Radiation Advisers is sought in the situations listed in Section 11, 12, 13.
- No radiation generating equipment or radioactive materials are requisitioned, loaned, moved or procured without consultation with the appropriate Specialist Radiation Advisers and, where applicable, the Radiation Protection Supervisors.
- Ensure adequate resources are provided to enable safe use of radiation.
- Ensure all tasks indicated with CMG in the margin of this policy are completed.

4.2.6 Head of Service (HoS) / Area Manager (AM): Where there is a radiation facility and / or activities are undertaken involving radiation the Head of Service / Area managers are responsible for ensuring that radiation safety and protection measures are carried out. AM

- Awareness of their own responsibilities and ensuring that staff within their area are aware of their responsibilities under law and under this Policy.
- All clinically used equipment will be covered by appropriate service agreements, and that routine quality control tests will be at the intervals required by national guidelines or determined locally.
- An inventory of equipment is kept as specified in the Guideline for the establishment of IRMER procedures (Section 15).
- Ensure that prior to any changes to the work carried out with radiation the advice of the relevant advisor is sought (Section 13, 11, 12)
- Adequate resources are provided to the areas both in terms of human resources and financial resources. This includes planned equipment replacements and supply of adequate PPE.
- Ensure that there are adequate training records in place.
- Ensure that there are appropriate mechanisms in place for escalation of radiation safety issues.
- Ensure that adequate numbers of Radiation Protection Supervisors are appointed, in writing, detailing the full extent of their responsibilities and any management responsibilities delegated to them.
- Seek assurance from managers/RPSs that radiation risks are adequately managed.
- Ensure that, if applicable, there are mechanisms in place to ensure compliance with the permit for the use of radioactive materials (See Section 5.5).
- Ensure that Radiation Risk Assessments are carried out, documented, and the findings implemented in line with this Policy. These must be reviewed on an annual basis.
- Ensure all tasks indicated with AM in the margin of this policy are completed to ensure compliance with the relevant legislation.

4.2.7 Radiation Protection Supervisor (RPS): Radiation Protection Supervisors (RPS) will be appointed in writing by the Trust for individual areas of work with ionising radiation following joint approval by the Head of Service / Area Manager. RPS will be allocated appropriate resources to carry out their functions. This appointment must detail their legal duties as well as any additional delegated duties identified as part of the appointment. The RPS must: RPS

- Supervise work with ionising radiation to ensure it is done in accordance with the local rules.
- They must be suitably trained to perform their role and have suitable authority to supervise work in the area they are appointed in.
- Be familiar with the requirements of the local rules, relevant parts of the Ionising Radiation Regulations 2017 and its Approved Code of Practice.

- Be aware of the local implementation of all parts of this policy.
- Routinely audit compliance with the local rules, to include correct wear of dosimeters.
- Escalate any issues with compliance in the area to the appropriate Head of Service (HoS), CMG Lead and Radiation Protection Adviser.
- Assist the Head of Service/ Area Manager with tasks specified in their appointment letter e.g. dose investigations.
- Ensure that they are adequately trained and have received update training every five years, when the legislation changes, or when advised by the RPA.
- Ensure all tasks indicated with RPS in the margin of this policy are completed.

4.2.8 Quality Control Leads (QC): Appointed in writing in each area to ensure compliance with the local Quality Control regime. They must ensure all tasks indicated with QC in the margin of this policy are completed and escalate any issues as required. QC

4.2.9 Personal Dosimetry Administrator (PD): Appointed by the Head of Service / Area manager to distribute and ensure the return of personal dosimeters. They must: PD

- Distribute and collect personal dosimeters in a timely manner
- Ensure all dosimeters are disinfected prior to return to Leicester Radiation Safety Service
- Return all collected dosimeters to Leicester Radiation Safety Service by the specified deadline
- Distribute spare dosimeters as required and make adequate records to allow assigned spare dosimeters to an individual's record;
- Advise staff how to wear dosimeters
- To inform their manager where they may be absent during change over periods
- Must inform LRSS of any circumstances which may affect recorded doses, for example:
  - When dosimeters have been lost, damaged or inadvertently exposed.
  - When dosimeters have been worn incorrectly, for incorrect period or by the incorrect individual
- Ensure all tasks indicated with PD in the margin of this policy are completed.

4.2.10 Consultant Occupational Health Physician (OH) : Responsible for performing the annual medical review and supervision of potential health effects on classified workers. and ensure all tasks indicated with OH in the margin of this policy are completed. OH

4.2.11 Classified Radiation Workers: Any worker that has to be classified as a radiation worker must: CW

- Present themselves during working hours, at the cost of their employer, to an initial medical check and provide the Consultant Occupational Health Physician with all information concerning their health as to which they may reasonably require.
- Attend an annual review going forwards every year for which they continue to be classified. Failure to comply will result in a warning letter, copied to the line manager and Deputy Medical Director. Failure to comply in a second instance will result in disciplinary action.
- Comply with all reasonable requirements imposed by the employer for monitoring doses. Therefore, failure to return a personal dosimeter, to take due care of a dosimeter or to wear one as required will result in a warning letter. Persistent non-compliance will result in disciplinary action.

Additionally, Classified workers must notify their manager and LRSS of any of the following circumstances : CW

- Leaving the Trust. A Termination Record of their dose to date will be produced;
- Intention to work for another employer to allow co-operation between employers;
- Intention to carry out services in a controlled area of any employer other than their own. Classified Outside Worker arrangements, including a radiation passbook, will be required;
- They are pregnant or breastfeeding. This should be notified as soon as possible to ensure any required changes to practice can be identified;
- Any incident which could lead to an increase in dose from that which is normally expected.
- Ensure all tasks indicated with CR in the margin of this policy are completed.

4.2.12 Operator : Has primary responsibility for all practical aspects that they undertake which could affect patient dose. Op

4.2.13 Practitioner: Has primary responsibility for justification and authorisation procedures (See Sections 5.4.7, 5.4.8). Pract

4.2.14 All staff: All staff have a responsibility for ensuring their safety and the safety of others that are impacted by their work. This includes escalating promptly and appropriately any concerns regrading safety, following the local rules, ensuring that they are adequately trained for any tasks they undertake, taking care of and wearing personal protective equipment as required by the local rules and complying with the requirements of this policy. All staff must inform their employer (via the area manager) in writing if they work for another employer or if they become pregnant so that an individual pregnancy risk assessment can be performed. All staff

4.3 Advisers

4.3.1 Dangerous Goods Safety Adviser (DGSA): The Dangerous Goods Safety Adviser is responsible for advising the Trust on issues concerning the transport of dangerous goods, including radioactive materials. This role is undertaken by an external contractor and is currently arranged through the Trust's Facilities provider. The contract with the external provider should state the extent of the advice required. They must ensure all tasks indicated with DGSA in the margin of this policy are completed. DGSA

4.3.2 Medical Physics Experts (MPE): The Medical Physics Experts will be appointed by the Trust in writing with their scope clearly defined. They will be available for consultation and support as detailed in Section 12. They must ensure all tasks indicated with MPE in the margin of this policy are completed. MPE

4.3.3 Radiation Protection Adviser (RPA): Is appointed in writing to provide items in Section 11. They must ensure all tasks indicated with RPA in the margin of this policy are completed RPA

4.3.4 Radioactive Waste Adviser (RWA): Is appointed in writing to provide advice in the areas described in Section 13. They must ensure all tasks indicated with RWA in the margin of this policy are completed. RWA

4.4 Committees

4.4.1 Radiation Safety Committee (RSC): The Radiation Safety Committee (RSC) reports through the Trust's Health and Safety Committee to the Trust Board. The RSC will implement and monitor compliance with the radiation safety regulations. There will be clearly defined Terms of Reference and the RSC will be chaired by an individual reporting directly to the Chief Executive. It must ensure that all tasks indicated with RSC in the margin of this policy are completed. RSC

4.4.2 Medical Exposure Committees (MECs): Medical Exposure Committees (MEC)s should be set up for each management area using ionising radiation unless it can be demonstrated by other means that optimisation is taking place. A MEC should be chaired by a Medical Lead and should: MEC

(a) review and document the approval of research involving radiation carried out within the area;
(b) implement and review local Diagnostic Reference Levels within the area;
(c) discuss and implement optimisation strategies.
(d) Ensure all tasks indicated with MEC in the margin of this policy are completed.

4.4.3 Task groups may be required to ensure that optimisation strategies are followed through. The Medical Physics Expert should be consulted regarding the set up . The MEC should be seen as a sub-committee of the RSC and as such should feed into the RSC. This should be reflected in the terms of reference of the group. MPE MEC

5 POLICY IMPLEMENTATION

5.1 Aims

5.1.1 The Trust will ensure, as far as is reasonably practicable, that appropriate measures are taken to secure the health and safety of its employees, patients, contractors working on its premises, and members of the public (including the families of patients) who may be exposed to the hazards arising from the use of ionising radiation.

5.1.2 The Trust is committed to a policy of restricting exposures to ionising radiation in accordance with the As Low As Reasonable Practicable (ALARP) principle, social and economic factors being taken into account. Such factors include a cost benefit analysis of providing additional protection and the effects steps taken may have on the dignity or privacy of a patient. To ensure this, the Trust will maintain a Radiation Safety management structure to implement radiation safety requirements.

5.2 Framework

5.2.1 The Trust will establish good communication and ensure co-operation between managers, Qualified Persons, and other interested parties.

5.2.2 Each Specialist Radiation Adviser will be given the power by the Trust to inspect and perform such tests as they may think appropriate and sufficient resources to carry out their duties and supporting work.

5.2.3 The Trust will give each Area Manager the responsibility for managing the radiation protection of all members of staff in their area. Action plans resulting from issues around radiation safety should be managed through local processes and escalated through the management chain as indicated in Figure 1.

5.2.4 The Trust will establish good communication and co-operation with those employers whose staff may be occupationally exposed by the Trust's radiation work.

5.2.5 Overall responsibility for ensuring that a radiation safety program is implemented and reviewed will lie with the Deputy Medical Director through a Radiation Safety Committee, as part of the management and communication framework for Health and Safety.

Appointments

5.2.1 The Trust will ensure that a process is in place for ensuring that appointments are made to all roles legally required and defined under this policy in line with the responsibilities defined by this policy.

5.3 Protection of staff and the public

5.3.1 Radiation Risk Assessment and Local Rules

5.3.1.1 The Area Manager is responsible for ensuring that no new activity with ionising radiation is performed without a prior risk assessment in place . New activity may include but is not limited to: AM

- Changes to equipment (new equipment of changes to existing equipment)
- Changes to techniques
- Changes to protocols
- Changes to the use of areas around radiation areas which result in changes to the occupancy levels.
- Any changes that could affect the integrity of the shielding

5.3.1.2 Ensure that the conditions of the notification, registration or consent, if applicable, are not breached. The RPA must be informed in advance of any organisational changes that may have any bearing on these conditions. AM, CMG

5.3.1.3 The Trust template for risk assessments must be used to ensure that all required elements are included. Any deviation from this template should be discussed with the RPA. AM

5.3.1.4 Risk assessments must cover all the foreseeable impacts of the activity including indirect impacts for example (but not limited to):

- Exposure of emergency service personnel attending an injury where the area is contaminated.
- Members of the public around the radiation source.
- Transport of radioactive samples or patients.
- Potential involvement of outside workers.

5.3.1.5 A risk reduction action plan must be developed from the risk assessment that is monitored and reviewed regularly. This action plan must: AM

- Prevent any identified radiation accidents where possible
- Limit the consequence of accidents which may occur.
- Identify the instruction, information and training to ensure that doses within the area are As Low as Reasonably Practicable.

5.3.1.6 Where a radiation risk assessment has identified that a controlled area is required, local rules must be drawn up based on the radiation risk assessment. AM

5.3.1.7 Local rules must be completed following the Trust template or another suitable alternative approved by the Trust Radiation Protection Adviser. AM

5.3.1.8 The area must have sufficient Radiation Protection Supervisors to implement the requirements of the Local Rules. AM

5.3.1.9 The area must implement version control such that only up-to-date copies are in use and an editable format of the local rules is available only to those that are permitted to amend them. AM

5.3.1.10 All material changes to the local rules must be distributed to all involved in work in the control area and a document signed to state that individuals have read and understood the local rules. AM

5.3.1.11 Individuals may only enter into a controlled area when they are following systems of work detailed within the Local Rules. AM, RPS, All staff

5.3.2 Contingency plans

5.3.2.1 Contingency plans are required for all radiation accidents identified within the associated risk assessment (Section 5.3.1. A radiation accident means any accident where immediate action is required to prevent or reduce the exposure to ionising radiation. There are situations where incidents may require actions to mitigate the effects of the incident but are not significant enough to constitute a radiation accident. In the local rules these are distinguished as “foreseeable incidents”. For example, a small amount of contamination in Nuclear Medicine may be expected and dealt with using normal decontamination procedures and would be defined as a foreseeable incident, however a large spill would require contingency plan enactment. It must be clear to all in the area which definition applies to different situations. AM

5.3.2.2 Actions identified as part of a contingency plan should be proportionate to the magnitude of the risk involved. For example, incidents that could not result in exposures of concern are not radiation accidents and do not require contingency plans. AM

5.3.2.3 Risk assessments must identify any foreseeable incidents and may wish to note these within their local rules but should be treated separately to contingency plans. AM

5.3.2.4 All contingency plans should be rehearsed periodically, with the period dependent upon the potential risk and complexity of the contingency plan. All contingency plan rehearsals must be documented. AM

5.3.2.5 Any enactment of contingency plans must be reported as per the Incident And Accident Reporting UHL Policy (A10/2002). The Datix report must include a completed copy of the contingency plan enactment record, which must be retained for at least 2 years. AM

5.3.3 Outside workers and co-operation of employers

5.3.3.1 Where work with ionising radiation undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer, the employers concerned are required to co-operate by the exchange of information or otherwise, to the extent necessary to ensure that each employer is enabled to comply with the requirements in the regulations. AM

5.3.3.2 For this purpose the Area Managers must cooperate with reasonable requests from other employers and provide information to support Outside Workers on UHL sites. AM

5.3.3.3 For external staff entering UHL’s controlled areas Section 5.3.4 must be followed.. AM

5.3.3.4 For UHL staff employed by another radiation employer Section 5.3.5 must be followed.. AM

5.3.3.5 For UHL staff entering another employer’s controlled area Section 5.3.6 must be followed. AM

5.3.4 External staff entering UHL's controlled area

5.3.4.1 Staff that are not employed by UHL shall not be permitted entry to UHL's radiation controlled areas unless the following conditions are met: RPS, AM

- The individual is **not** a classified worker . If they are a classified worker they must not enter the controlled area until the advice of the RPA (or a sufficiently qualified member of LRSS) has been obtained. RPS RPA
- The area can be made safe i.e. the source of radiation removed or disabled and the area can be designated as an uncontrolled area under the local rules. In this situation the individual may work without supervision. This is the preferred option where the individual is not working with radiation and cannot be directly supervised. RPS
- The AM has established a process for signing over control of the area to the external employer. All staff are aware of and follow this procedure to ensure that control of the area is signed over to the external employer. The external employee must then work under local rules and risk assessments provided by their employer. In this situation the AXREM Handover form or a similar locally developed , approved by the RPA , is used to sign over control of the area. The area must be signed back to UHL and appropriate quality control performed prior to the return of that equipment to use on patients. AM All staff RPA RPS, AM
- The individual works under UHL's local rules and risk assessment and is adequately supervised . If this is a regular occurrence a Co-operation of Employers Agreement must be completed by both employers and the advice of the RPA sought . If this is a unplanned visit and not a regular occurrence the Outside Worker Checklist should be completed. A copy should be retained by the area and a copy should be provided to the employer of the individual. AM, All staff AM RPA AM, RPS
- IN ALL INSTANCES The individual must be provided with information on the types of risks they are likely to encounter and how to ensure that those risks are minimised. The external employee should be monitored as staff working for UHL would be monitored in the area unless the risk assessment for the area does not require monitoring. If this requires additional dosimeters to be issued these can be obtained from Leicester Radiation Safety Service. AM, RPS AM

5.3.5 UHL staff employed by another radiation employer

5.3.5.1 There is a legal requirement for all staff to inform their Area Manager if they are employed by another employer working with radiation. This is to allow dose sharing procedures to be put into place by the Area Manager. All staff

5.3.5.2 The Area Manager must then inform Leicester Radiation Safety Service and must ensure that arrangements are made to share dose information with the other employer . In this instance the data can be shared with or without the individual's consent, as Health and Safety law takes precedence over Data Protection laws. AM AM

5.3.6 UHL staff entering another radiation employer's controlled area

All staff :

- The area manager should seek assurance about risks in the controlled area to ensure that the risks are not greater than those from working within UHL. AM
- The area manager should ensure that dosimetry provision by UHL is suitable for work carried out in an outside working capacity and cooperate with additional monitoring requests by the other employer. AM

5.3.6.1 **Classified** staff employed by UHL are not permitted to work in another employer's controlled area unless: CS, AM

- the requirements detailed in the previous section for all staff have been fulfilled. AM
- the advise of LRSS has been sought. AM, LRSS
- The area manager ensures that the classified member of staff has been issued with a passbook which is updated before they leave and an agreement has been obtained regarding who will be filling it in on behalf of the employer of the external designated area. AM

5.3.7 Dosimetry

5.3.7.1	Personal Dosimetry should be provided as indicated by Radiation Risk Assessments and the advice of the Radiation Protection Adviser . Dosimetry is mandatory for all classified staff and essential for demonstrating compliance for non-classified staff.	AM RPA
5.3.7.2	All individuals issued with a dosimeter are responsible for the wear of dosimeters at all times when they are within the area . This forms part of the health and safety requirements included in all contracts of employment. The RPS and AM must ensure that there are systems in place to ensure that this occurs, including periodic audit.	All staff RPS, AM
5.3.7.3	Periodic environmental monitoring based on the level of risk will be carried out on the advice the RPA . The area manager must ensure that staff are aware of these badges and make efforts to ensure that they are not tampered with in any way .	RPA AM
5.3.7.4	All individuals issued with a dosimeter are responsible for the prompt return of dosimeters at the end of the dosimetry period . TheAM must ensure that there are systems in place to ensure that this occurs and that all lost or damaged dosimeters are reported to LRSS.	All staff AM
5.3.7.5	The dosimetry results for all individuals must be checked against the dose investigation level when results are provided by the dosimetry providers. All results that are above the dose alert must be investigated and an Unusual Dose Investigation form completed AM and returned to LRSS. All results that are above the dose investigation level must be immediately escalated to LRSS.	AM
5.3.7.6	If it is suspected that an individual may have exceeded an applicable dose limit or may be approaching classification levels:	AM
	• The Head of LRSS or the RPA must be informed immediately	
	• The individual who received the dose if they are not already aware should be informed.	
	• The Clinical Lead, Operational Manager or Service lead must be informed immediately.	
	• A formal investigation commenced immediately.	AM, LRSS
	• The LRSS classification procedure should be followed or the HSE should be informed as soon as the veracity of the dose has been established.	LRSS

5.3.8 Classification of staff

5.3.8.1	Should a risk assessment show that it is likely, under routine or an accident conditions, for certain dose levels to be exceeded it is expected that all staff performing the associated role will be Classified.	AM
5.3.8.2	Notification of any such situations should be provided to LRSS and the Area Manager will be expected to work with LRSS to ensure that all the conditions for classification are met. Part of this process includes the issue of letters to the Area Manager and the classified individual further detailing the associated requirements.	AM, LRSS CS
5.3.8.3	If a classified member of staff is expected to act as an outside worker a passbook must be requested in advance.	AM
5.3.8.4	If a dosimeter is lost of damaged a dose estimate for the period covered should be provided by the area manager to LRSS to be entered into the individual's dose record.	AM, LRSS

5.3.9 Pregnant or breastfeeding staff working with radiation

5.3.9.1	Anyone working with ionising radiation who becomes pregnant must inform their manager in writing as soon as possible so that an individual risk assessment can be performed and a predicted dose undertaken.	All staff AM LRSS
5.3.9.2	It is necessary to ensure the radiation dose to the foetus will be as low as reasonably practicable and below 1mSv during the declared term of pregnancy. This risk assessment should also consider the risks involved in the use of PPE .	AM
5.3.9.3	During the declared term of pregnancy, the department manager will keep a record of any whole body dose recorded as a measure of the dose to the foetus. The manager must notify the RPA if the value approaches 1 mSv.	AM

5.3.9.4 Before returning to work with unsealed radioactive materials staff should inform their manager if they are intending to breastfeed their infant so that arrangements can be made to prevent significant bodily contamination of members of staff who are breastfeeding. All staff

5.3.10 Radon

5.3.10.1 Suitable radon risk assessments must be performed for all premises owned by the Trust. This must show either that the premises are not in radon affected areas using the UKHSA radon risk map or that there are not underground facilities in which people work. If the risk assessment shows that people do work underground or that any of the premises are in radon affected areas the results of radon in atmosphere measurements should be given. If these indicate levels exceed 300 Bqm^{-3} averaged over a year the remedial action that will be or has been taken should be stated . HAS

5.4 Protection of the patient

5.4.1 IRMER framework

5.4.1.1 The Trust will establish the necessary procedures and records as required by IR(ME)R 2017. CE

5.4.1.2 Written employer's procedures as detailed in (IR(ME)R 2017 Schedule 2. Guidance for developing these procedures and additional IRMER documentation is provided in Section 15.

5.4.1.3 Each radiation area must have a system to ensure that: AM

- IRMER procedures produced and ratified by the Trust Radiation safety Committee ; RSC
- Each area must maintain a matrix of the staff working in that area with signatures that they have read and understood all relevant documentation (particularly operators and practitioners). AM
- All Practitioners and Operators must be aware of and must follow Standard Operating Procedures and IRMER procedures , including full time, part time and temporary staff (e.g. bank or agency staff), and outside workers contracted to carry out Practitioner or Operator duties (e.g. service engineers) where the area has not been handed over to them. AM, All Staff

5.4.1.4 In addition to the Schedule 2 procedures (Section 15) procedures other local documents are required which include but are not limited to : AM

(a) Equipment inventory (Section 15.21)
(b) Equipment protocols (Section 15.20)
(c) Procedure for authorisation under protocol (Section 5.4.8)
(d) Referral criteria/protocol (Section 15.19)
(e) Training Records (Section 6)

5.4.2 Quality Assurance

5.4.2.1 All areas must have a thorough framework for Quality Assurance to ensure compliance with legislative requirements. AM

5.4.2.2 This framework should ensure:

- All equipment should be subject to a regular servicing contract as specified by the supplier. AM
- A schedule of audits, including clinical audits, to ensure compliance with IRMER procedures. AM
- Sufficient time and resource allocation to ensure that the quality assurance program can be followed AM
- That Quality Control tests are carried out following the recommendations of the Medical Physics Expert AM, MPE
- Quality Control Leads to be appointed in writing in each area to ensure compliance with the schedule of QC. QC lead AM

5.4.3 Selection, replacement and acceptance of radiation equipment

5.4.3.1	Requests for radiation equipment should be considered within the Trust's overall replacement program and the RPA should be notified as early in the process as possible .	AM
5.4.3.2	All equipment should be selected to ensure that the dose is As Low As Reasonably Practicable . Advice must be sought form the Medical Physics Expert on this prior to purchase of equipment.	AM, MPE
5.4.3.3	No new equipment should go into use which has not been subjected to a critical examination, acceptance testing and commissioning process approved by the Radiation Protection Adviser .	AM
5.4.3.4	All equipment must be subject to planned replacement and should be removed from service when advised by the MPE due to deterioration .	RPA AM MPE
5.4.3.5	Once in place the department is responsible for ensuring there is an on-going maintenance and quality control program .	AM
5.4.3.6	All equipment involved with the measurement of radiation hazards in connection with the Ionising Radiations Regulations 2017 will be tested annually under the supervision of the Qualified Person following appropriate national guidelines.	QP

5.4.4 Optimisation

5.4.4.1	Optimisation is a key principle of the radiation protection framework within IR(ME)R, the aim of which is to achieve the image quality required to answer the clinical question or successfully perform an intervention, using the lowest dose possible.	All
5.4.4.2	Particular attention must be given to optimising paediatric doses. Paediatric examinations should NOT be carried out by default using adult protocols .	AM
5.4.4.3	All optimisation must be recorded and discussed as a multi-disciplinary team coordinated by a local Medical Exposures Committee , with the input of an appropriate MPE.	AM MPE
5.4.4.4	This MEC must provide reports to the Radiation Safety Committee and must have an establish Terms of Reference .	AM
5.4.4.5	Adequate training of individuals is important to ensure optimisation. Records of equipment training must be maintained within the area .	AM

5.4.5 Diagnostic Reference Level (DRL)

5.4.5.1	Diagnostic Reference Levels must be established in line with procedures established according to the guidance for IRMER procedures (Section 15) and monitored by the appropriate Medical Exposures Committee.	MPE, AM
5.4.5.2	DRLs must be displayed within the clinical area and all staff must be aware of the values.	AM, All
5.4.5.3	Any exposure in excess of 10 x the DRL must be reported as a Datix regardless of whether there was an incident.	All
5.4.5.4	All local DRLs in excess of an applicable National DRL must be investigated, with details of the investigation recorded within the MEC minutes and if further optimisation is not possible this must be escalated to the Radiation Safety Committee.	AM

5.4.6 Therapeutic uses of radiation

5.4.6.1	The Trust will ensure that all radiation exposures of target volumes for therapeutic purposes are individually planned, taking into account that doses of non-target volumes and tissues shall be ALARP, consistent with the intended radio therapeutic purpose and the employers written procedures and protocols.	MPE
5.4.6.2	The employer's quality assurance programme must, in respect of radiotherapeutic practices, include a study of the risk of accidental or unintended exposures. This will usually take the form of a Failure Modes Effect Analysis (FMEA) .	AM

5.4.7 Justification by the Practitioner

Pract

5.4.7.1 Justification is the considered thought process required to decide if there is an overall net benefit to the individual/society in carrying through with the proposed medical irradiation. Justification is also required for carer and comforter exposures and must be documented in the same way as medical exposures.

Pract

5.4.7.2 In deciding whether the irradiation is Justified the following matters must be considered:

(a) the specific objectives of the exposure and the characteristics of the individual involved;

(b) the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to [the] society, of the exposure;

(c) the individual detriment that the exposure may cause;

(d) the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

Pract

5.4.7.3 In considering the weight to be given to the above matters the Practitioner must pay attention to the following:

(a) non-medical Imaging exposures;

(b) exposures that have no direct health benefit for the individual undergoing the exposure;

(c) and the urgency of the exposure in cases involving:

- where pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, taking into account the exposure both of the individual and of the unborn child; and
- an individual who is breast feeding, depending on the type of nuclear medicine exposure, taking into account the exposure of both the individual and the child.

5.4.8 Authorisation

5.4.8.4 Authorisation is the process by which a check is performed that justification has taken place, and the procedures is approved to go ahead. This is an operator task.

Pract

5.4.8.5 It is possible to separate the task of authorisation from the task of justifying the procedure. To enable this a procedure must be in place (Section 15) which:

(a) Details the groups of patients for whom a practitioner has deemed a particular exposure to be justified.

(b) Details of the staff who can authorise under the protocol adn the training required.

(c) A named individual who will act as the practitioner responsible for all imaging undertaken under that procedure.

(d) Details of the limitations under which the exam cannot be authorised, for example if a patient is pregnant.

Pract

5.4.8.6 For medical or biomedical research exposure, authorisation must be furnished by the approval of the Trust Research Ethics Committee.

5.5 Control of radioactive materials

The use of radioactive materials on Trust premises, and the disposal of radioactive waste arising from such use, is governed by permits from the Environment Agency (EA) under the Environmental Permitting Regulations 2016 (EPR16) as amended in 2018.

All

5.5.1 Permit compliance

Local managers of departments using radioactive materials are required to ensure that the terms of the Permits are complied with by. AM

5.5.1.1 Ensuring that receipts, transfers and disposals of radioactive materials are recorded in a timely manner, and such records are made available to the EA on request . AM

5.5.1.2 Reporting to the Radiation Waste Adviser as necessary on the disposal of radioactive waste made from Trust premises to enable reporting to the EA. AM

5.5.1.3 Keeping an inventory of sealed sources kept within their area, and undertaking “wipe testing” of those sources to confirm the integrity of their containment at intervals determined by risk assessment. AM

5.5.1.4 Ensuring that any breach of radiation safety regulations is reported by a Datix report and escalated appropriate to the severity of the breach. AM

5.5.1.5 Notifying the police and the EA Regulator if there is strong suspicion that a source has been lost or stolen, and carrying out a full investigation into each such occurrence. AM

5.5.1.6 As part of the radiation safety programme, the relevant manager must ensure that all relevant staff are appropriately trained and that security and contingency plans are regularly practised. AM

5.5.1.7 Where exposures involve the administration of a radioactive medicinal product (RMP) - a radiopharmaceutical - to a patient, responsibility for the administration lies with a medical practitioner holding licence as required under regulation 5 of IRMER 2017 . Pract

5.5.1.8 Area managers are responsible for ensuring that any procedure undertaken is covered by a valid ARSAC certificate. The Area Manager must also ensure that there is a valid employer licence in place.

5.5.2 Transport of radioactive materials

5.5.2.1 Departments that transport radioactive materials must develop a “Radiation Safety Programme” in conjunction with the Specialist Radiation Advisers . AM, DGSA, MPE, RPA, RWA

5.5.2.2 Staff transporting radioactive materials will comply with the relevant transport Regulations. A document management system must be established detailing these processes and audited by the DGSA . All

5.5.2.3 When the Trust acts as a carrier for the transport of radioactive material, it must comply with its duties under relevant legislation and international codes of practice. The responsibility for ensuring compliance rests with the manager of the department undertaking the transport. AM

5.6 Matters relating to all legislation

5.6.1 Incident Reporting

5.6.1.1 The Trust will ensure that all diagnostic examinations involving medical exposures are performed with the radiation dose to the patient being As Low As Reasonably Practicable (ALARP) to achieve the required clinical purpose, consistent with the employers written procedures and protocols. All

5.6.1.2 All incidents involving radiation should be reported according to the Trust incident reporting procedure and should be indicated as being a radiation incident using the tick box on Datix. All

5.6.1.3 The appropriate Specialist Radiation Adviser or an adequately trained representative will determine whether incidents are reportable to the relevant body and to whom they are reportable . RPA

5.6.2 Co-operation between employers

5.6.2.1 Where there are multiple employers or services providing a service for a patient it must be clear who is responsible for implementing each of the elements of IRMER . To ensure that this is in place a co-operation agreement is required. AM

5.6.2.2 Where agency staff are used, the Trust must ensure that they have training comparable to a member of staff directly employed by UHL and must have completed all applicable equipment and procedure competencies as well as general radiation safety training . AM

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 All areas carrying out work with radiation are responsible for maintaining records of their staff's training. This responsibility is at CMG level but actions can be delegated to Heads of Service. The following training is required by the legislation:

(a) Basic information, instruction and training to all employees that may be exposed to ionising radiation as a result of the work of the Trust. Demonstrated through the mandatory Health and Safety Training eLearning package on HELM and provision of local information at local induction. — AM

(b) Information, instruction and training to all employees that work with ionising radiation. This is demonstrated through the more detailed Ionising Radiation Regulations 2017 e-learning package. — AM

(c) Information, instruction and training for classified staff, this is provided by one-to-one discussion with the Head of Service based on the classification letter provided by Leicester Radiation Safety Service . — AM

LRSS

(d) All operators and practitioners as defined under IRMER must have adequate training for the task they undertake taking account of any professional guidance or accredited training courses provided elsewhere. This should be further detailed in the local IRMER procedure for the identification of practitioners, operators and referrers. See Section 15. — AM, Op

(e) Initial competency/equipment training will be provided to all Operators by the area in which they work and records should be kept in this area in such a way that it is easily demonstrable which members of staff are trained to undertake operator tasks. — Op, Pract

(f) On-going continuous professional development with respect to radiation must be undertaken by all operators and practitioners and this must be recorded in the area. Part of this must include the three yearly IRMER e-learning packages.

(g) Non-medical referrers must be a registered professional and have undergone Trust training to undertake the role. They must operate under a defined scope of practice produced by the area within which they intend to work and with the agreement of the CMG carrying out the exposure. — AM

(h) Radiation Protection Supervisors must complete an initial training course as detailed in HSE Ionising Radiation Protection Series 6 guidance. They must undertake update training every 5 years, whenever the legislation changes or it is advised by the RPA. — AM, RPS

(i) Drivers transporting radioactive materials must undertake initial training and 3 yearly update training. — AM

(j) All employees must co-operate with their employer to undertake training as deemed necessary to ensure compliance with the ionising radiation regulations. — All

(k) IRMER training records must be managed and maintained by individual Clinical Management Groups involved in the use of radiation and must be available to the Deputy Medical Director and the Head of Leicester Radiation Safety Service if required. — CMG, AM

(l) Areas must be able to demonstrate that there are records covering : — AM

i. individual identifiers;
ii. designation;
iii. area of specialisation/medical exposure (and any restrictions);
iv. IRMER status, e.g. Practitioner, Operator (or both);
v. Qualifications;
vi. registration details;
vii. basic training;
viii. continued education;
ix. Whether online IRMER update training has been undertaken.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 The Leicester Radiation Safety Service will periodically audit areas for compliance with the regulations and report these findings to the Area Manager, RPS and CMG leads. The CMG leads are required to provide assurance to the Trust that the advice provided in these reports is acted on. LRSS

7.2 Managers must perform regular safety walkabouts to ensure radiation safety is complied with. The frequency of these should be determined by the Area Manager based on the level of risk in the area. Records should be kept of the results of all walkabouts. AM, CMG

7.3 Area Managers must provide a regular manager's report to the Trust Radiation Safety Committee on compliance within their area. This should be escalated through local management structures as defined by the CMG leads. AM CMG

7.4 The Quality Assurance requirements detailed in Guideline for the establishment of IRMER procedures red(Section 15) and required under IRMER must be followed AM.

7.5 An annual Radiation Safety Service report will be produced and presented at the Trust Radiation Safety Committee. LRSS

Element to be monitored	Lead	Tool	Frequency	Reporting Arrangements
Compliance with the legislation	Specialist Radiation Advisers and staff working under their guidance	Audit tool established by the relevant adviser	Frequency as specified by the adviser within local management procedures	Radiation Safety Committee
Compliance with legislation	Area Managers	Submission of a manager's report on compliance with the legislation to the Trust Radiation Protection Committee	Upon request	Radiation Safety Committee.
Compliance with legislation	Manager area	Local compliance audits and safety walkabouts	Specified by the Specialist Radiation Advisers determined by level of risk	CMG Quality and Safety Boards
Compliance with training requirements	Departmental managers	Appraisal	Annual	Any deviations to dealt with through HR processes and reported through RSC where necessary
Performance of X- ray equipment	Leicester Radiation Safety Service	Quality Control surveys	Annual to 3 yearly as specified by the MPE based on IPEM Report 91.	Written reports sent to the area responsible for the equipment
Performance of X-ray equipment	Local area	Local Quality Control checks	As advised by the MPE	Records of the results to be retained for 10 years after decommissioning the equipment.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

9.1 Legislation

9.1.1 The carriage of Dangerous Goods Use of Transportable Pressure Equipment Regulations 2009 as amended 2011

9.1.2 The Environmental Permitting (England and Wales) (Amendment) (No. 2) Regulations 2018. SI No 428

9.1.3 The Environmental Permitting (England and Wales) (Amendment) Regulations 2018. SI No 110

9.1.4 The Environmental Permitting (England and Wales) Regulations 2016 SI No 1154 Health and Safety at Work etc. Act 1974

9.1.5 The Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018. SI No. 482

9.1.6 The Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018. SI No 430

9.1.7 The Ionising Radiation (Medical Exposure) Regulations 2017. SI No 1322.

9.1.8 The Ionising Radiations Regulations 2017. SI No 1075

9.1.9 The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018. SI No 121

9.2 Policy

9.2.1 Incident and Accident Reporting policy A10/2002

9.2.2 Interpreting and Translation Policy B30/2015

9.2.3 Trust Patient Information Policy B18/2002

9.2.4 Policy for the Use and Management of Diagnostic Display Monitors – Picture Archiving and Communication Systems (PACS) B10/2017

9.2.5 Safeguarding procedures B26/2011 and B1/2012

9.3 Guidance

9.3.1 Approved Code of Practice Guidance L121 2018

9.3.2 Medical and Dental Guidance Notes (IPEM)

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 The period of review for this document should be every 5 years or when the legislation changes.

10.2 The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system

Appendices

11 MATTERS ON WHICH THE RADIATION PROTECTION ADVISER MUST BE CONSULTED FOR ADVICE

There is a legal requirement for the employer to consult the RPA for advice on the following aspects. Responsibility for compliance lies with the employer:

11.1 The implementation of requirements as to controlled and supervised areas.

11.2 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.

11.3 The regular calibration of equipment provided for monitoring levels of ionising radiation and the regular checking that such equipment is serviceable and correctly used.

11.4 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.

11.5 The RPA may also be consulted other matters, including but not limited to:

- The radiation risk assessment;
- The designation of controlled and supervised areas as required by regulation 17, except where there is good reason to consider that such areas are not required, for example based on advice from the supplier of the radiation source or written guidance from an authoritative body;
- The handling of the various investigations required by the Regulations;
- The drawing up of contingency plans required by regulation 13;
- The dose assessment and recording required by regulation 22;
- Ensuring systems are in place to allow the testing and examination by a qualified person of instruments used for monitoring levels of ionising radiation in controlled and supervised areas

12 MATTERS ON WHICH A MEDICAL PHYSICS EXPERT MUST BE CONTACTED

The employer must ensure that a suitable Medical Physics Expert is appointed and involved, in accordance with the following:

12.1 Be closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;

12.2 Be involved in practices including standardised therapeutic nuclear medicine practices, diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography;

12.3 Be involved as appropriate for consultation on optimisation, in all other radiological practices;

12.4 Give advice on:

- Dosimetry and quality assurance matters relating to radiation protection concerning exposures;
- Physical measurements for the evaluation of dose delivered;
- The selection and acceptance of medical radiological equipment;

12.5 A medical physics expert must also contribute to the following matters:

- Optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels;
- The definition and performance of quality assurance of the equipment;
- Acceptance testing of equipment;
- The preparation of technical specifications for equipment and installation design;
- The surveillance of the medical radiological installations;
- The analysis of events involving, or potentially involving, accidental or unintended exposures;
- The selection of equipment required to perform radiation protection measurements;
- The training of practitioners and other staff in relevant aspects of radiation protection;
- The provision of advice to an employer relating to compliance with these Regulations;
- The Medical Physics Expert must, where appropriate, liaise with other Specialist Radiation Advisers

13 MATTERS ON WHICH THE RADIOACTIVE WASTE ADVISER MUST BE CONTACTED

A Radioactive Waste Adviser (RWA) is a specialist in radioactive waste disposal and environmental radiation protection who has demonstrated competence in these areas. The role of the RWA is Advisery; responsibility for compliance with radioactive waste legislation and permit conditions lies with the permit holder.The scope of advice given includes:

13.1 Achieving and maintaining an optimal level of protection of the environment and the population.

13.2 Checking the effectiveness of technical devices for protecting the environment and the population.

13.3 Accepting into service equipment and procedures for measuring and assessing exposure and radioactive contamination of the environment and the population.

13.4 Regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

13.5 In addition the RWA will advise on:

- Hazard and risk assessment including environmental impact;
- Control of releases;
- Record keeping (sources, doses, unusual occurrences etc.);
- Radioactive waste management;
- Radioactive waste disposal;
- Optimisation techniques – Best Achievable Technology (BAT) and Best Practicable Means (BPM);
- Environmental monitoring.

14 PROCEDURE FOR COMPLETION OF RADIATION RISK ASSESSMENTS AND LOCAL RULES

14.1 The Ionising Radiations Regulations 2017 require a suitable and sufficient assessment of the risk to any employee and other person before commencing a new activity involving work with ionising radiation. This Radiation Risk Assessment must identify the measures the employer needs to take to restrict the exposure of that employee or other person to ionising radiation. A new activity includes any new rooms where work with ionising radiation will occur, as well as changes to equipment or techniques within existing rooms.

14.2 Where there is significant risk of exposure to ionising radiation an area must be designated as a controlled or supervised radiation area. Local rules must be established to enable work with ionising radiation to be carried out in this designated area. The local rules must identify the main working instructions intended to restrict exposure in that area.

14.3 The Chief Executive is responsible for ensuring that Radiation Risk Assessments are completed and, where required, local rules established. The completion of these risk assessments can be delegated to any suitable individual. Where more than one employer works in a controlled area, each employer has a duty to prepare local rules.

14.4 Standard Radiation Risk Assessment Template and Local Rules Template are available from LRSS. These are generic templates and must be reviewed and adapted for your area. Guidance on how to complete sections are in red italics and should be removed during completion of the risk assessment. Any queries related to this risk assessment and development of local rules can be addressed by contacting the Leicester Radiation Safety Service (LRSS) for advice.

14.5 The risk assessment is divided into three stages to reflect the process:

- There is an initial discussion between LRSS, the staff working in the area and, if applicable, architects during room design. This will be used to complete Section A where the hazard will be defined, staff at risk identified and an assumed workload and room layout developed or recorded.
- The area will complete Section B to determine the appropriate systems of work, engineering controls and personal protective equipment required as well as performing an estimation of the risks. LRSS must be consulted in the development of this section. Any actions identified as part of this risk assessment are the responsibility of the manager for the area being risk assessed.
- Subsequent reviews of the risk assessment will be performed by managers of the area by completing Section C. This requires them to confirm that the assumptions made during the risk assessment are still true, that the precautions identified are in place and are sufficient to protect staff. Evidence of this review must be provided to LRSS for approval. Should there be concern or changes from the initial risk assessment then the risk assessment must be reviewed from the beginning.

Local rules should be developed based on the findings of the risk assessment.

15 GUIDANCE FOR THE ESTABLISHMENT OF LOCAL IRMER PROCEDURES

15.1 Introduction

15.1.1 The Ionising Radiation (Medical Exposure) Regulations (IRMER) came into force in 2017.

15.1.2 The Chief Executive must ensure that there is a framework in place to ensure that this legislation is effectively implemented. This guideline forms part of this framework.

15.1.3 IRMER 2017 Schedule 2 states that a number of employer's procedures must be established wherever medical or non-medical imaging is undertaken resulting in the exposure of a person to ionising radiation.

15.1.4 This applies to all types of procedure that result in a medical exposure of an individual to ionising radiation. Any such procedure can only be as a result of an exposure of:

- patients as part of their own medical diagnosis or treatment;
- individuals as part of occupational health surveillance;
- individuals as part of health screening programmes;
- patients and other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
- individuals as part of non-medical imaging;
- carers and comforters.

15.1.5 This guidance applies to all services within Clinical Management Groups who use ionising radiation as part of the patient pathway. This will include Radiology, Radiotherapy, Medical Physics and other specialities that use ionising radiation.

15.1.6 This applies to all staff including bank, agency and contract staff.

15.2 General Requirements

15.2.1 The principles and methods adopted in this document are fully recognised and endorsed by Trust management as the local method of implementing IR(M)ER 2017.

15.2.2 This Guideline details how the Trust implements the responsibilities set down in the Trust Ionising Radiation Safety Policy to establish the following procedures:

- written procedures covering a range of topics, including those specified in Schedule 2 of IR(ME)R 2017;
- written protocols for the practical arrangements for standard radiological practice with each piece of equipment;
- referral criteria for medical exposures;
- quality assurance programs;
- requirements for all Practitioners and Operators employed by the Trust;
- Justification of exposure (by Practitioners) and Optimisation of Exposure (by Operators);
- an inventory of radiation equipment;
- up to date records of all Trust Practitioners and Operators including training details.

15.2.3 Local implementation of the above procedures (Specialty procedures) must reflect the subtle variations in framework, procedures and protocols that occur for each irradiation specialty. The procedures must follow the format for category C procedures discussed in the Policy for Policies and be ratified by the Trust Radiation Safety Committee chaired by the Deputy Medical Director.

15.2.4 It is recognised that many of the written procedures referred to in IRMER are already in force, and are located among other quality assurance and policy frameworks. However in order to satisfy the requirements of IRMER they must be reproduced or paraphrased or referenced with the speciality IRMER documentation.

15.3 Procedure for Patient Identification (IRMER 17 Schedule 2 (a))

15.3.1 An inadvertent medical exposure of ionising radiation due to incorrect individual identification constitutes a serious but avoidable error. Employers must have written procedures for the verification of the identity of persons presenting for a medical exposure. The identification procedure can take the form of an annotated flow diagram.

15.3.2 The area must ensure that the following provisions are detailed:

(a) It must always be clear who is responsible for the identity check and this should be the operator pressing the initiation button or administering the radiopharmaceutical or contrast agent.

(b) Where the radiation exposure is a small part of the procedure, for example in theatres, this may be carried out by directly observing the identification check or other means specified in the local IRMER procedure. However, the operator remains responsible for ensuring that the identity of the patient has been adequately determined for the purposes of the radiation exposure.

(c) There must always be three independent points of identification actively confirmed usually name, date of birth and address.

(d) The ID check should require active statement of the points of ID rather than confirmation.

(e) Inpatients must have their wristband checked. Any discrepancies between the wristband and other details must be reported via the Trust incident reporting process and rectified prior to exposure.

(f) For invasive procedures a checklist of the WHO format may be used as long as it is ensured that there remain at least three independent points of identification.

(g) The procedure must consider and detail how the identity of children is confirmed and recorded.

(h) There must be provisions for emergency exposures where patients cannot be identified for example unconscious patients. However, there must be limitations on this such that the provisions do not compromise the integrity of the ID procedure. These will be individual to the area.

(i) Where translation is required the UHL Interpreting and Translation Policy (B30/2015) must be followed.

(j) When a family member or escort is required to supply corroborating details such as name, address, date of birth, wrist band ID, the details of the individual escorting the patient should be recorded in the patient record for example in CRIS.

(k) For the identification of, and communication with, persons with language or learning difficulties or with hearing or sensory impairment. If a patient is unable to speak but can write, this is acceptable.

(l) To ensure as far as practicably possible that the individual is embarking on the intended protocol (e.g. “pause and check” procedure)

(m) Pause and check lists such as the Society of Radiographers Operator checklist, referrer checklist or the WHO checklist should be made available to individuals within the area where appropriate.

(n) The steps to be taken if an inadvertent exposure does occur.

(o) If a patient refuses to divulge their details to the hospital a unique identifying number must be used, however it must be possible to link this to the original referral.

(p) If the address is incorrect, the patient should be asked for previous addresses. Details must be amended on both the relevant department systems (e.g. RIS) and the Hospital Information System.

(q) Where it is not possible to definitively identify the individual to be exposed the exposure should not go ahead and the incident should be reported following trust incident reporting procedures.

(r) Where it is noticed that two patients with the same (or similar) names are attending on the same day, then all relevant staff should be alerted. The person noticing the similarity (admin staff/ radiology manager/ radiographer/ Healthcare assistant) will take responsibility for marking the referral forms/day sheets in order to continue to alert staff to the potential for an error. This alert must be continued through all stages of the patient pathway, until the report and verification has been completed i.e by placing a ‘sticky note’ on the PACS image for the reporting Radiologist’s attention.

(s) Training on the correct identification procedure must be completed before the Operator can be entitled, and should be updated as part of the annual mandatory training cycle to ensure the operator is still competent to perform this task.

(t) The procedure must document how the completion of ID checks are recorded and audited.

(u) The procedure must detail the procedure to be undertaken if it is found that images have been associated with the incorrect patient or if the incorrect patient has been imaged.

15.4 Procedure for Identifying Referrers, Practitioners, and Operators (IRMER 17 Schedule 2 (b))

15.4.1 This procedure will identify the health professionals and other professionals who carry out the practical aspects of medical irradiation within the Specialty and their recruitment, retention and continued education.

15.4.2 The procedure must clearly define the roles of referrers, practitioners and operators as defined in IRMER 2017 and the Trust Ionising Radiation Safety Policy.

15.4.3 This procedure must ensure that for each patient image the associated practitioner, operator and referrer can be identified.

15.4.4 Each speciality must establish a specific process for checking that an individual is “adequately trained” before entitlement can be given to act as practitioner and / or operator.

15.4.5 The procedure should clearly state the scope of practice and duties of all entitled individuals or groups of individuals or individual entitlement agreements.

15.4.6 Examples of operator tasks include but are not limited to:

(a) Authorisation of exposures following practitioner approved protocols
(b) Quality control checks
(c) Patient identification and carrying out the ‘Pause and Check’
(d) Checking pregnancy status or breastfeeding status
(e) Optimisation and ensuring appropriate selection of equipment and technique, being mindful of type of examination and whether paediatric patient
(f) Contrast administration
(g) Initiating the exposure and operating the imaging equipment
(h) Image manipulation and archive
(i) Clinical evaluation

15.4.7 Third party service engineers should not be entitled Operators. Handover procedures must be in place and ensure that adequate QC is performed prior to returning the equipment to clinical use.

15.4.8 A named list of operators and practitioners mu be maintained by the Specialty with their registration details checked at regular intervals and recorded.

15.4.9 Any requirements for professional state registration must be adhered to and particular emphasis placed on the importance of ensuring that no lapsing in registration occurs.

15.4.10 It is the responsibility of the speciality to hold the training records that demonstrate adequate training for each role that is undertaken. These should be held in a form that enables easy checking of the tasks that an individual is trained and authorized to undertake. The method of maintaining these records along with the responsibilities should be detailed in the procedure.

15.4.11 It is suggested that the procedure includes a table containing the following:

- Staff group;
- Scope of practice (this may refer to other procedures in the case of non-medical referrers);
- Required level of training.

15.4.12 It should be clear that authorisation under protocol is an operator task and requires training but does not mean that the individual authorising is a practitioner. The contents of this protocol are detailed in 5.4.8.

15.4.13 If verbal referrals are accepted the limits and requirements for this to take place must be specified by the speciality.

15.4.14 Non-medical referrals are only accepted from registered individuals that have completed Trust approved training and are referring under an agreement approved by the relevant CMG or in conjunction with Imaging. A list of all non-medical referrers in an area should be kept and the methods of constraining referrals must be detailed including:

(a) Only registered individuals act as non-medical referrers.

(b) Non-medical referrals only occur within a defined scope of practice approved by imaging.

(c) Non-medical referrers undertake trust approved training every 5 years to ensure on-going competence.

(d) Audits are undertaken of any non-medical referrals on a regular basis to ensure quality and consistency with respect to the training and scope of practice of the individual (at a defined frequency based on risk).

15.4.15 The details of the scope of advice and names of the Medical Physics Experts as defined by IRMER.

15.4.16 Medical Physics Experts employed by the Trust will be based in the Medical Physics Department the Radiotherapy Department at University Hospitals of Leicester and must be registered members of the Institute of Physics and Engineering in Medicine (IPEM) and Heath and Care Professions Council (HCPC) registered.

15.5 Procedure for Checking Pregnancy Status (IRMER 17 Schedule 2 (c))

15.5.1 Because of the enhanced sensitivity of the developing foetus to external and internal irradiation, there may be special requirements (especially protocols) for the prospective management of the irradiation of individuals who are pregnant or are breast feeding. It is important, therefore, to have a clear, precise, written procedure to identify individuals who are definitely pregnant or breastfeeding. This should be based on current guidance such as that issued by the Royal College of Radiologists.

15.5.2 Whilst this does not preclude the imaging of patients that are pregnant the procedure should ensure that justification is always carried out by an IRMER practitioner. Authorisation under protocol is not sufficient in these situations. The practitioner, MPE and operator should work together to ensure that adequate optimisation for the individual and the feotus is carried out.

15.5.3 The procedure for each speciality must, where relevant, take the form of a simple flow diagram.

15.5.4 The procedure must:

(a) Identify the exams where the procedure is to be followed e.g for diagnostic radiology all exams between the knee and diaphragm.

(b) Contain details of how different age groups will be asked about their pregnancy status e.g. patients between the age of 10 and 55.

(c) Include a requirement for enacting Trust safeguarding procedures (B26/2011 and B1/2012) should a concern be identified.

(d) Include any requirements for future retrospective dose and risk estimates for suspected foetal irradiation in females where the overall procedure indicated no pregnancy at the time of irradiation.

(e) Follow the UHL Interpreting and Translation Policy (B30/2015) where translation is required.

(f) Include a procedure to follow if pregnancy status cannot be ascertained.

(g) Detail how records will be kept and audited to show that this procedure has been followed.

(h) Ensure that patients are made aware of the risk associated with exposure of the foetus and the importance of informing the operator prior to exposure taking place via suitable notices and information leaflets.

(i) Where the potential dose to the foetus or breastfeeding infant is high such as in certain Nuclear Medicine exposures, written informed consent will be required to ensure that patients are aware of the potential effects on any foetuses or breast feeding infants. This should follow the Trust's consent procedure. These considerations should be detailed in the local procedure.

(j) Clearly require that any exposures of the foetus should be reported as an incident following the Trust reporting procedure and Leicester Radiation Safety Service must be notified.

(k) Clearly detail whether pregnancy tests will be performed, in what situations and with what limitations.

15.6 Procedure for Quality Assurance Programs (IRMER 17 Schedule 2 (d))

15.6.1 Quality Assurance programs are a legal requirement and must not be sacrificed in favour of other aspects of service.

15.6.2 All specialities must have Quality Assurance programs in place that meet the following requirements. The procedure should require that:

(a) Compliance with all IRMER procedures must be checked by speciality management on a regular basis. Responsibility for this should be defined in the procedure.

(b) Audits must ascertain compliance of staff with these procedures and provide a feedback into redrafting procedures to reflect changed practices.

15.6.3 Common additional audits may include:

(a) The quality of referrals from non-medical referrers

(b) Reject rates

(c) The numbers of x-rays unreported

(d) Personal Dosimetry wear

(e) Quality of images.

15.6.4 The method of communicating and acting on the results obtained during these audits and checks must be specified in the speciality protocol.

15.6.5 Written records of audits must be kept to demonstrate the quality assurance procedures being followed.

15.6.6 The escalation process should be detailed. A report to the CMG Quality and Safety Committee should be submitted if there are persistent problems.

15.6.7 Reference should be made to the audits performed by Leicester Radiation Safety Service as part of monitoring compliance.

15.6.8 The speciality should identify any trends in procedural breakdown and act remedy the situation.

15.6.9 The method of ensuring that all IRMER procedures/protocols will be reviewed every three years should be detailed with the responsibility.

15.6.10 Safety walkabouts by management are a key part of ensuring compliance with the legislation and should be scheduled to occur regularly with responsibility defined in this procedure.

15.6.11 A method of ensuring document control must be detailed in this procedure.

15.6.12 Clinical audit is carried out. While the Trust must ensure that clinical audit is carried out, individual clinicians and professional bodies have a major role in ensuring that it is carried out appropriately. The Speciality must define or refer to documents that define the method of ensuring that this occurs.

15.6.13 Other areas that should be covered include:

(a) How equipment on loan will be put into use;

(b) How new techniques will be introduced;

(c) Servicing arrangements;

(d) The scope of work of the Medical Exposures Committee (if applicable);

(e) MPE approved Quality Control programs, based on national guidance;

(f) how equipment is returned to clinical use after a fault or service visit;

(g) Medical Physics Expert input.

15.7 Procedure for the Assessment of Patient Dose (IRMER 17 Schedule 2 (e))

15.7.1 For each medical exposure the dose of ionising radiation to the individual undergoing the exposure is to be kept as low as reasonably practicable (ALARP) and consistent with the intended diagnostic or therapeutic purpose. All relevant dose information for each patient exposure should be recorded and this information must be sufficient to allow individual dose assessments.

15.7.2 All procedures for the assessment of patient dose and administered activity must:

(a) Be based on accepted national guidelines using physical measurements traceable to national standards

(b) State that the operator is responsible for ensuring that a record of the patient dose is stored in the patients record.

(c) Clearly identify the dose descriptors and methodology for recording dose descriptors (e.g. Dose Area Product (DAP) to be recorded on CRIS system).

(d) Define how standard protocol charts or procedures are set up and how they will be reviewed regularly, clearly defining responsibility for this.

(e) Ensure protocol charts are formally signed off by the manager for the area and dated and have adequate practitioner input. The procedure must contain the method of doing this.

(f) Any incidents/near misses which may have led to a dose higher than intended should be reported as a radiation incident following the standard Trust reporting procedures (A10/2002).

15.8 Procedure for the Use and Review of Diagnostic Reference Levels (IRMER 17 Schedule 2 (f))

15.8.1 Diagnostic Reference Levels (DRLs) must be established for typical examinations for groups of standard-sized individuals or standard phantoms for broadly defined types of equipment.

15.8.2 The local procedure should ensure:

(a) There is a process for establishing local DRLs for all examinations. This should detail how the data is collected, broadly how it is processed and how it is communicated to individuals.

(b) Where appropriate, local DRLs are compared to national DRLs, European DRLs, or ARSAC data, and optimisation prioritised should local levels exceed these.

(c) The procedure details the process to be followed to ensure optimisation and the methods of escalation where a DRL is found that is in excess of the comparable data.

(d) Periodic patient dose assessments (or “Dose audits”) of a representative group of patients are performed and compared to local DRLs to ensure levels are still accurate.

(e) The process for establishing local DRLs must involve appropriate input from Medical Physics Experts.

(f) Where there is minimal or no control over the dose (e.g. DEXA or intra-oral equipment) the DRL should be determined based on appropriate output measurements.

(g) Particular focus should be given to establishing DRLs for paediatric examinations.

15.9 Procedure for Biomedical Research (IRMER 17 Schedule 2 (g))

15.9.1 This procedure aims to cover all requirements for medical research exposures required by IRMER. It is the responsibility of the local Principal Investigator to ensure the latest National Research Ethics Service (NRES) guidelines are followed.

15.9.2 Each speciality must have a procedure in place to ensure that all the following requirements are complied with

15.9.3 Prior to a trial starting all research programmes must have a completed IRAS (Integrated Research Application System) form and approval from the relevant Ethics Committee (EC) before commencing.

15.9.4 Prior to a trial starting within UHL:

(a) all research programmes within the Trust must be registered on with the Research and Innovation Team through Edge;

(b) the local MPE should ensure that where an ARSAC certificate for research is required it is obtained prior to approval of the study;

(c) for each research project involving exposure to individuals for whom no direct benefit is expected from the exposure the IRMER practitioner will approve a dose constraint on the advice of a suitable MPE. Where there is a direct benefit a target dose will be set. A dose constraint must not be exceeded, however a target dose should not be consistently exceeded but may be for the benefit of the individual patient. This will be detailed in the IRAS form and specialities must have procedures for ensuring that this dose constraint is never exceeded;

(d) these procedures should involve the escalation process should the dose constraint be exceeded. This should involve:

- immediate notification of the Research Department;
- immediate notification of the PI and Clinical Radiation Expert;
- notification of Leicester Radiation Safety Service;
- reporting of the incident according to Trust procedure (A10/2002);

(e) the speciality is responsible for ensuring that in the event that the research is part of a multi-centre trial being led by a Chief Investigator from another centre, there is a process in place to obtain approval from the local IRMER practitioner and MPE to demonstrate that the research protocol can be followed;

(f) the local IRMER Practitioner is responsible for reviewing the trial protocol and main Research Ethics Committee (REC) application and confirm in writing to the local Principal Investigator and Research Development (RD) office that the local site can adhere to the protocol, local patients are covered by the main REC (Ethical) submission, and any additional exposure is justified having regard to IRMER;

(g) similarly the local MPE is responsible for reviewing the trial protocol and main REC application to confirm to the local Principal Investigator that the estimated ranges of doses made by the Lead MPE for the research are reasonable. A local dose constraint or target dose should be established and this should be in line with the total research protocol dose estimated in the main REC application; concerns must be addressed with the Lead MPE for the research;

(h) The area must have assurance that the trial has been approved by the local IRMER practitioner and MPE prior to any research going ahead;

(i) Reference levels in Nuclear Medicine will be derived from Administration of Radioactive Substances Advisery Committee (ARSAC) data.

15.9.5 Before an individual is accepted onto a trial there must be provisions to ensure that:

(a) adults who lack the capacity to consent must be excluded as volunteers;

(b) pregnant women and children should not normally be accepted as volunteers unless the project concerns their population group specifically.

15.9.6 The IRMER Practitioner who authorises a research exposure must:

(a) satisfy themselves that the subjects participate voluntarily;

(b) ensure that the subjects are informed in advance about the risks of exposure using REC approved patient information;

(c) where no direct medical benefit for the individual is expected from the exposure, ensure that the employer's dose constraint is adhered to;

(d) where there is a direct benefit, plan a target for the dose to an individual volunteer;

(e) the operator must reconfirm that the individual has been informed of the risks of participating in the trial with respect to radiation.

15.9.7 For local trials or studies which are not part of multi-centre research programmes:

(a) the procedure outlined above should be followed, where the local principal investigator and MPE have the additional responsibilities of the Chief Investigator and Lead MPE respectively;

15.9.8 General requirements:

(a) all other IRMER procedures apply equally to research exposures;

(b) just as for standard medical radiation exposures, there should be a record of the exposure factors, to enable an estimate of the effective dose to the individual and to ensure compliance with the dose constraint.

15.10 Procedure for the giving of information and written instructions; (IRMER 17 Schedule 2 (h))

15.10.1 Instructions and information must be provided where radioactive medicinal products are administered to a patient. This information is to aid the consent process and should specify how doses resulting from the patients exposure can be restricted so as to protect persons in contact with the patient.

15.10.2 Procedures adopted by specialist departments must be based on national guidance referenced in documentation. The Medical Physics Expert must be involved in the development of these instructions. Where this procedure is not required a statement must be within the local procedures that it does not apply.

15.11 Procedure for providing risk information (IRMER 17 Schedule 2 (i))

15.11.1 Each speciality shall produce a framework for providing patients information regarding the risk of exposure to ionising radiation.

15.11.2 This framework should include patient information leaflets regarding the risks associated with radiation. There should also be comparible information available for provision to carers and comforters.

15.11.3 These leaflets should:

(a) Take into account national professional guidance where available;
(b) Present risks according to best practice guidelines;
(c) use national leaflets where possible;
(d) Should be approved by the patient information librarian and follow the Trust Patient Information Policy (B18/2002).
(e) In addition to information leaflets informational posters may be appropriate:
(f) In very low dose areas such as DEXA it would be sufficient to have a poster in the area indicating potential risk.
(g) For low dose such as plain film it is suggested that posters are used and information is made available either by patient information leaflets or on the internet.
(h) For higher dose areas such as cardiology, fluoroscopy, Nuclear Medicine and CT leaflets should be made available where possible and patients told that by proceeding with the imaging they are accepting the risk.
(i) In interventional radiology, cardiology and radiotherapy individual patient consent will be required and radiation risk should be part of the consent process. This consent should be obtained following Trust procedures (A16/2002).
(j) The information should cover a brief description of the justification process.

15.11.4 The area may want to consider referencing the website www.informedscan.com

15.11.5 The area may want to consider the appropriate method of converying information to patients based on the assocaited risk or the patient pathway.

15.12 Procedure for recording of an evaluation (IRMER 17 Schedule 2 (j))

15.12.1 A clinical evaluation of the outcome of each medical exposure must be recorded to prevent unnecessary exposures being undertaken. If an exposure is not to be evaluated then it cannot be justified and therefore should not be undertaken.

15.12.2 Local procedures must set out how and when this is to be done as well as methods of monitoring performance.

15.12.3 The procedure must ensure:

(a) that the responsibility for providing a clinical report is clearly defined;
(b) that primary reporting is carried out according to the Trust PACs policy;
(c) that every radiological exposure has a report associated with it that impacts the clinical treatment of the patient and that no image is undertaken where it is known in advance that this is the case;
(d) responsibility for regular review and audit of reports and the presence of reports is defined;
(e) where this process does not take place the Trust incident reporting procedure should be followed.

15.13 Procedure to minimise unintended or accidental doses (IRMER 17 Schedule 2 (k))

15.13.1 Speciality procedures must take steps to reduce the likelihood and magnitude of accidental or unintended exposures as much as reasonably practicable.

15.13.2 For therapeutic or diagnostic use of radiopharmaceuticals, this procedure must have the aim of ensuring the prescribed administered activity of the correct radioisotope, in the correct radiopharmaceutical form, is administered via the correct route. A risk assessment of the process must be undertaken. This should be in the form of Failure Mode and Effects Analysis.

15.13.3 Generally, major contributory factors to minimise the probability and magnitude of accidental or unintended doses include:-

(a) a clear and well understood policy on referral criteria;

(b) adherence to a thorough Justification procedure;

(c) clear and well understood IRMER procedures as detailed in this guideline;

(d) a properly functioning Quality Assurance Programme;

(e) all Operators suitably trained in protocols;

(f) vigilance during medical irradiation;

(g) efficient evaluation of medical irradiation;

(h) identification of shortfall, review and revision of procedure.

15.13.4 This procedure must detail how the area ensures (this may be through reference to another procedure):

(a) staff are adequately trained and how this training is recorded;

(b) the nature and recording of induction training;

(c) staff, bank staff, or other external staff demonstrate adequate training;

(d) adequate levels of supervision of trainees;

(e) that a new piece of equipment is introduced safely including the establishment of standard procedures and the sign off process;

(f) regular preventative maintenance and repairs are undertaken on each item of equipment involved in the imaging process;

(g) Equipment Handover procedures are in place;

(h) Quality Control procedures are in place, implemented and monitored;

(i) staff are made aware of their responsibility to identify equipment faults or procedural breakdowns which could lead to an accidental or unintended dose to a patient. These occurrences should be reported to their line manager to resolve. Lessons learnt will take place via staff meetings;

(j) there are clear processes to follow regarding concerns over the practice or training of individuals;

(k) how equivalence to training within the UK is established for oversees staff;

(l) reference to any cooperation of employers agreements within the area;

(m) how clinical audit as per regulation 7 of IRMER is carried out annually for each area and the records that are kept;

15.13.5 The following general approach is always taken and should be included in the procedure:

(a) patient identity checked, prior to any radiation exposure, by the operator;

(b) all equipment subject to regular preventative maintenance – to manufacturers and / or RPA advice;

(c) equipment Quality Assurance programme in place as outlined in IPEM 91 and advised by the RPA;

(d) equipment faults logged and reported to the senior staff for the area;

(e) equipment with known faults likely to cause patient overexposure must be taken out of use until repair by a service engineer. Written confirmation must be obtained that the unit is safe for clinical use.

(f) Alterations affecting patient dose must be checked by a relevant MPE, or individual working under an MPE's direction, and certified fit for clinical use prior to any patient exposures;

(g) all staff must undertake manufacturers or suitable in-house training before operating equipment for clinical use;

(h) all incidents must be reported using the DATIX system, with correct investigation and follow up procedures. Any suspected patient exposures 'much greater than intended' must be reported to Leicester Radiation Safety Service who will then decide whether the incident needs reporting to the appropriate authorities; incident investigation reports must be reviewed and appropriate action taken to minimise the risk of recurrence;

(i) when exposing patients to ionising radiation the most appropriate equipment available must be selected and operated in accordance with manufacturers' tolerances and Trust procedures.

15.14 Doses significantly different to intended

15.14.1 IRMER requires the local investigation of suspected or actual incidents in which a person undergoing medical exposure was exposed to radiation doses significantly different to intended than intended, otherwise than as a result of malfunction or defects in equipment. This portion may be a separate procedure or could be integrated into the previous procedure (IRMER 17 Schedule 2 (k)) depending on the set up of the area.

15.14.2 For actual incidents where it is shown that an overexposure has occurred, the appropriate authority must be notified and a further detailed investigation must be carried out of the circumstances of the exposure, including an assessment of the dose.

15.14.3 In deciding whether a dose greater than intended has been delivered the dose multiplying factors currently defined by the relevant regulatory authority must be adopted.

15.14.4 The detailed investigation must be aimed at:

(a) establishing what happened;

(b) identifying the failure;

(c) deciding on remedial action to minimise the chance of a similar failure occurring;

(d) estimating the doses involved;

(e) estimating additional risks to the patient.

15.14.5 This may be included in the minimising risk of accidents procedure or informing the patient of an incident procedure and does not necessarily need to be a separate procedure.

15.15 Equipment handover procedures

15.15.1 There must be a method of ensuring that equipment is effectively removed from service when there are issues with it's function. This may also be integrated into the IRMER 17 Schedule 2 (k) procedure depending on the area set up. This should include:

(a) ensuring there is a service contract in place;

(b) a statement that tests should never be undertaken on a live subject;

(c) method of escalating issues with equipment;

(d) method of ensuring that the equipment is not used until it is returned to a safe state;

(e) method of handing over the equipment to the service engineers (usually by use of the AXREM form) which should include a check that the company have a set of local rules and risk assessment covering the work and that the work to be carried out is not outside of the anticipated workload used to design the shielding;

(f) method of ensuring that adequate QC is carried out and recorded prior to first use;

(g) method of ensuring that equipment is safe to return to use including clear definition of the tests required with the approval of the MPE or the method of contacting the MPE;

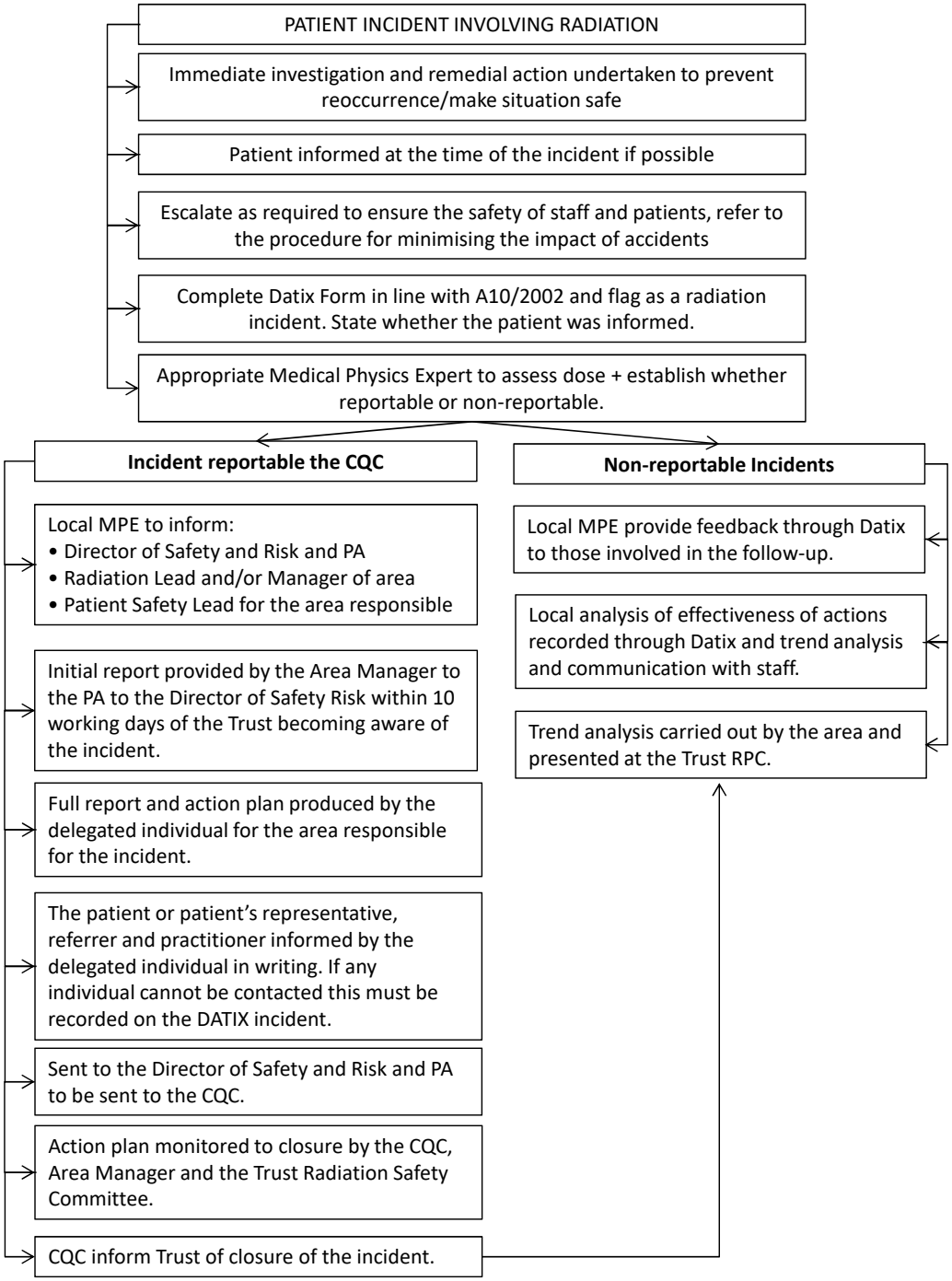
(h) method of ensuring that repeated faults are escalated and investigated.

15.15.2 In most cases the AXREM template for area handover is appropriate to record the handover process. Where local handover forms are developed these must be approved by the lead local MPE.

15.16 Procedure to ensure that individuals are informed of accidental exposures (IRMER 17 Schedule 2 (I))

15.16.1 Speciality procedures must ensure:

(a) the incident is reported through the Trust reporting procedure (A10/2002) and identified as a radiation incident to ensure that LRSS are aware of the incident. The flow chart below indicates the process to be implemented in each speciality;



(b) the IRMER procedure for each speciality should detail how the referrer, the practitioner and the individual exposed or their representative are informed of the occurrence and in which circumstances

these individuals must be contacted.

(c) The speciality must ensure that the definition of Clinically Significant Accidental and Unintended Incidents (CSAUE) and Significant Accidental Unintended Exposures (SAUE) are clearly defined in the procedure such that individuals are trained such that they are able to identify incidents that need to be reported.

(d) The method of escalation to the MPE must be defined.

(e) The method of contacting the patient, referrer and practitioner are clearly defined.

15.17 Procedure for non-medical imaging exposures (IRMER 17 Schedule 2 (m))

15.17.1 Non-medical imaging exposures include any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed.

15.17.2 This includes (but is not limited to):

(a) non-accidental injuries investigations;

(b) solicitors;

(c) insurance companies;

(d) some external medical services;

(e) police;

(f) courts;

(g) Customs and Excise –for imaging for suspected drug smuggling;

(h) sports performance related exams;

(i) screening of healthy individuals other than as part of screening programme.

15.17.3 This process must ensure:

(a) That non-medical imaging referrals will be identified as such.

(b) That exposures are justified by an IRMER practitioner who is working within a suitable scope of practice.

(c) That sufficient information is provided to allow justification.

(d) Patient records are checked to determine if any previous, relevant examinations have been performed to avoid unnecessary or repeat exposures.

(e) There are no alternative lower dose techniques.

(f) Exposures should follow all other standard procedures e.g. patient identification, assessment of patient dose, pregnancy checking.

(g) Sufficient information is provided to the referrer.

15.17.4 The images must be reported by the IRMER practitioner who justified the examination.

15.18 Procedure for carers and comforters (IRMER 17 Schedule 2 (n))

15.18.1 Carers and comforters are individuals who are knowingly and willingly exposed to ionising radiation through support and comfort of those undergoing exposure. The definition makes clear that individuals undertaking this role are not those doing so as part of their employment. Carers and comforters are commonly relatives or friends of those undergoing exposure.

15.18.2 Speciality areas are required to establish a procedure to ensure that carers and comforters are always subject to a dose constraint.

15.18.3 Pregnant individuals and individuals under the age of 18 should not act as carers and comforters.

15.18.4 The area may choose to use a “authorisation under protocol” methodology. Where this is used a practitioner must sign off the protocol.

15.18.5 The dose constraint must be determined based on the advice of the MPE for the area.

15.18.6 It is recommended that on occasions when a higher value may be appropriate, such as where the carer or comforter is supporting the treatment of a vulnerable individual, dose constraints should be assessed and agreed on a case-by-case basis, making clear to the carer and comforter the risks involved.

15.18.7 The speciality procedures must define:

(a) how information on the risks is made available to the carer and comforter;

(b) any precautions required to minimize the dose to the carer and comforter;

(c) whether Personal Dosimetry is required;

(d) the anticipated dose and the precautions required to ensure that the dose constraint is met.

(e) What will be done where communication is difficult.

15.19 Referral Process and Criteria

15.19.1 A referral is a request for an exposure to be performed and not a direction to undertake an exposure. Any referral for imaging or procedure involving ionising radiation must be made by an appropriately entitled registered healthcare professional acting as a referrer duty holder, as defined in these IR(ME)R schedules.

15.19.2 There must be a clear, precise written procedure explaining the referral criteria for each speciality. This must (where relevant) include:

(a) the range of radiation doses associated with procedures

(b) a requirement for the referrer must supply sufficient medical data for the practitioner, including relevant clinical history and information on pregnancy (where relevant and available), to be able to weigh up the benefit of the exposure against the risks.

(c) The referrer must also supply accurate, up to date information to enable the operator to correctly identify the individual to be exposed. The procedure should state the minimum dataset required for a referral to proceed.

(d) The procedure should state the procedure to follow if insufficient data is provided and how feedback is provided to the referrer.

(e) Reference must be made to any national referral guidance, e.g. i-Refer, NICE guidelines, Royal College of Radiologists guidelines

(f) There must be a method of disseminating referral criteria to referrers and this must be specified in the Speciality procedures.

(g) Details of the methods of control of access to referral systems should be provided and a specification of the frequency of audit of these measures.

(h) There must be a statement to the effect that it is a disciplinary offence to use someone else's login to initiate an electronic referral or to hold pre-signed blank request forms.

(i) All instances of suspected or confirmed misuse of referrals should be reported following the Trust's incident reporting system.

(j) The procedure should state any instances in which self-referrals will be accepted.

(k) The procedure should state how verbal requests will be handled.

(l) The procedure should state how cancellation of requests should be performed.

(m) Where there is a long gap between referral and imaging the practitioner or operator authorising the procedure should check that the procedure is still necessary.

(n) The procedure should make clear that although some of the receipt, processing, and onward transfer of referrals may fall to admin staff, they do not act or have responsibilities governed by IR(ME) as duty holders. Training should still be provided commensurate with the role.

(o) Referrers are responsible for ensuring that imaging results are reviewed and the results acted on and communicated in a timely manner.

15.20 Equipment Protocols

15.20.1 Each speciality must prepare written protocols containing information and instruction for standard radiological practice for each piece of equipment.

15.20.2 This will vary in content and complexity for each speciality; however these general guides must be followed and included in speciality documentation.

15.20.3 Protocols should be signed off by the lead for the area using radiation (usually a clinical lead, manager or clinical scientist) and should not be altered without following an approval process defined by the speciality.

15.21 Equipment Inventory

15.21.1 Each CMG must have established methods of ensuring that there is an equipment inventory for all radiation equipment and that this equipment inventory is kept up-to-date.

15.21.2 Requests for radiation equipment must be considered within the Trust's overall replacement programme.

15.21.3 There must be methods of ensuring that unused equipment is removed from service.

15.21.4 The equipment inventory must include:

(a) name of manufacturer;

(b) model number;

(c) serial number or other unique identifier;

(d) year of manufacture; and

(e) year of installation.