



# POLICY FOR THE IMPLEMENTATION OF THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS 2017

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# Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2017

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# **Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2017**

## **1. Purpose**

All medical exposures in which a patient is exposed to ionising radiation must comply with the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER). This policy provides a framework for the implementation of IRMER in NHS Lothian.

## **2. Scope**

The policy applies to all Directorates/ Departments in NHS Lothian in which ionising radiations are used for medical exposures. These are listed in Appendix 1.

## **3. Responsibilities**

### **3.1 Chief Executive, NHS Lothian**

The Chief Executive of NHS Lothian takes overall responsibility for compliance with the duties of the employer under the Ionising Radiation (Medical Exposures) Regulations 2017 (IRMER).

The duties of the employer as set out in IRMER are

- i) ensuring NHS Lothian holds a valid License, issued by the Licensing Authority, in respect of each radiological installation at which radioactive substances are to be administered for the purpose of diagnosis, treatment or research
- ii) ensuring that appropriate written Employers Procedures as defined in Schedule 2 are in place and any other matter within the Regulations which mandates written procedures
- iii) must take steps to ensure that any written procedures are complied with by the entitled referrers, practitioners and operators
- iv) ensure entitled Practitioners and Operators are adequately trained and undertake continuing education and training which is maintained via documented training records
- v) Ensuring that appropriate written protocols are in place for every type of standard radiological practice including practices involving non-medical imaging
- vi) Establishing recommendations on 'referral criteria' for medical exposures and making these available to all entitled Referrers
- vii) establish quality assurance programmes for written procedures and written protocols
- viii) Establishing 'diagnostic reference levels' (DRLs) for medical exposures involving ionising radiation and ensuring that there is a mechanism for assessment of compliance with these DRLs. Where DRLs are consistently exceeded, the employer shall set up a review, and shall ensure the corrective action is taken
- ix) Establishing dose constraints for 'carers and comforters' and 'biomedical and medical research' programmes
- x) must take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding
- xi) Provision for carrying out clinical audit
- xii) Establishing a procedure for recording and investigation accidental and unintended exposures of patients and for reporting such incidents to the appropriate authority
- xiii) Implement and maintain a quality assurance programme for radiation equipment which includes keeping an up to date equipment inventory and provisions to identify when equipment should be high priority for replacement

### **3.2 Management**

The arrangements for the management of the employer's duties under IRMER are set out below:

3.2.1 The Executive Medical Director of NHS Lothian is responsible to the Chief Executive for implementation of the provisions of this policy across the whole of Lothian NHS Board. This Policy is therefore authorised jointly by the Chief Executive (as his instruction on how the employer's duties shall be managed) and by the Executive Medical Director (to indicate acceptance of responsibility for providing and maintaining this Policy and for overseeing implementation of its provisions).

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- 3.2.2 The Executive Medical Director appoints the Medical Director for NHS Lothian Acute Services to act as the 'IRMER Policy Lead'.
- 3.2.3 The IRMER Policy Lead authorises, in writing, the Clinical Directors or Heads of Departments of those Directorates or Departments where medical exposures are carried out to discharge particular responsibilities in their respective Directorates or Departments. These Directorates and Departments are shown in Appendix 1 to this policy. For the purpose of this policy the title 'Clinical Director' is reserved for those individuals (Clinical Directors or Heads of Department) who have been authorised in accordance to this policy. The particular duties of the Clinical Directors are:
- i) To entitle duty holders as described in EP1.
  - ii) To provide, maintain and disseminate employer's written procedures as described in section 5.
  - iii) To arrange for investigation of incidents, including near misses, which resulted or could have resulted in a radiation dose greater than intended to the patient and to notify the relevant Inspectorate of incidents of patient doses much greater than intended.
  - iv) To ensure the annual clinical audit pro-forma is completed for each calendar year and returned to the IRMER policy lead in a timely fashion.
  - v) To ensure a system is in place to audit patient radiation doses and compare them to local and national standards as appropriate.
  - vi) To ensure an equipment inventory is maintained and that equipment QA tests are carried out.

Where appropriate, Clinical Directors can delegate, in writing, these duties to Responsible Managers within their service area to align with the operational needs of the service.

- 3.2.4 The NHS Lothian Radiation Protection Committee (LRPC) provides a framework for the management of radiation protection for both ionising and non-ionising radiations in NHS Lothian. LRPC reports to the NHS Lothian Health & Safety Committee. The remit of LRPC is set out in NHS Lothian's Radiation Protection Policy. The remit of LRPC includes the radiation protection of staff, public and patients and the implementation of the Radiation Protection Policy and of this Policy. The IRMER Policy Lead and the Clinical Directors (or their representatives) shall be members of the Committee.
- 3.2.5 The IRMER Policy Lead must advise LRPC of any changes to be made to this policy or any related provisions for the implementation of IRMER.
- 3.2.6 The IRMER Policy Lead must ensure that the LRPC is informed of any notifiable incidents involving breaches in employer's procedures or significant risk of harm to patients.
- 3.2.7 The IRMER Policy Lead must ensure LRPC is provided with an annual report on the implementation of this policy via the IRMER Audit Summary, at the Compliance meeting of LRPC.
- 3.2.8 The chairperson of the NHS Lothian Health and Safety Committee shall include this summary in the Health and Safety report that is presented annually to the Chief Executive via the December meeting of the Healthcare Governance Committee.

### **3.3 Authorisation of Policy**

- 3.3.1 This policy is authorised jointly by the Chief Executive as the instruction on how the employers duties shall be managed and by the Executive Medical Director in order to indicate acceptance of responsibility for providing and maintaining this policy and for overseeing implementation of its provisions.

## **4. Organisational Arrangements**

Duty Holders under IRMER are Referrers, Practitioners, Operators and Medical Physics Experts and are defined in EP1.

### **4.1 Training of Duty Holders**

All staff entitled as Practitioners or Operators must have received appropriate training for their duties in accordance with the Ionising Radiations (Medical Exposure) Regulations 2017.

All Practitioners and Operators must be able to satisfy the training requirements necessary for carrying out their duties. The level of training will be specified at Directorate level for the duties to be undertaken and will refer to the adequate training requirements laid down in Schedule 3 of IRMER. Records of such training must be kept and must be available for inspection. Arrangements for keeping and updating training records must be specified in Directorate procedures.

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The training should include, as appropriate:

- Basic qualifications for the post
- Awareness of IRMER
- Awareness of the Directorate procedures
- Awareness of their personal roles and responsibilities
- Continuous professional development
- Training for new techniques
- Training for new equipment
- Basic radiation protection
- Training specific to the competences for which the duty holder is entitled.

### **4.2 IRMER Board**

The IRMER Board is appointed by the IRMER Policy Lead to provide reassurance on compliance on the implementation of IRMER in NHS Lothian. The purpose of the IRMER board is:

1. To approve Level 1 Employers procedures
2. To improve all aspects of IRMER compliance at directorate and departmental level
3. To improve the corporate management of IRMER
4. To establish effective IRMER management controls
5. To demonstrate compliance with IRMER at formal inspections required by regulatory and statutory bodies

IRMER board is chaired by the IRMER Policy Lead. The Board will meet at least twice a year with additional meetings being called as required. The IRMER Policy Lead will ensure NHSL Radiation Protection Committee is provided with an annual compliance report.

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## **5. Documentation – Employers written procedures**

NHS Lothian's IRMER documentation is categorised as follows:

- **Level 1 Documents: Employers Procedures** that apply to all areas within NHS Lothian where ionising radiation is used for medical exposures. Areas are listed in Appendix 1
- **Level 2 Documents: Standard Operating Procedures** that apply to specific Directorates or Departments.

Departments may include further sublevels (Level 3 etc) to reflect local departmental protocols and forms that apply to specific staff groups or to reflect supporting documentation.

### **5.1 NHS Lothian Employers Procedures (EPs) – Level 1**

The following Employers Procedures are required by IRMER:-

- All those listed in Schedule 2 of the IRMER;
- A procedure describing the entitlement of duty holders;
- A procedure describing arrangements for incident reporting;
- A procedure describing document quality control;
- A procedure for Clinical Audit
- A procedure for maintaining an inventory of equipment used for medical exposures

Appendix 2 lists the NHS Lothian Employers Procedures required by IRMER 2017.

The IRMER Policy Lead, in consultation with the Lead MPE, is responsible for the control, authorisation and issue of the NHS Lothian Employers Procedures (Level 1).

The IRMER Policy Lead must ensure that the EPs are reviewed biennially by IRMER Board. The outcome of this review must be recorded.

The Lead MPE (Head of Radiation Protection) will retain the current electronic files of this Policy and all Level 1 Employers Procedures through a document control management system.

The IRMER Policy and NHS Lothian EPs (Level 1) are available on the NHS Lothian IRMER intranet page.

### **5.2 Level 2 Documents**

Clinical Directors are responsible for ensuring Level 2 documents for their respective Directorates/Departments are drawn up with regard to the Employers Procedures set out in Appendix 2.

Clinical Directors are responsible to the IRMER Policy Lead for the authorisation, control and issue of Level 2 documents for their respective service area or directorates.

Level 2 procedures must include an introduction to indicate that the Level 2 documents must be read in conjunction with NHS Lothian Level 1 procedures

Clinical Directors must ensure that Level 2 documents are reviewed biennially and must report the outcome of the review to IRMER Board.

Clinical Directors do not have to seek IRMER Board approval for changes made to the Level 2 documents unless the changes made are significant.

Clinical Directors must ensure that copies of all IRMER documents that apply to their Directorate (Level 1, Level 2 and Level 3) are available to all staff in the Directorate. They must take steps to ensure that Practitioners and Operators in their Directorate carry out their duties in accordance with these procedures.

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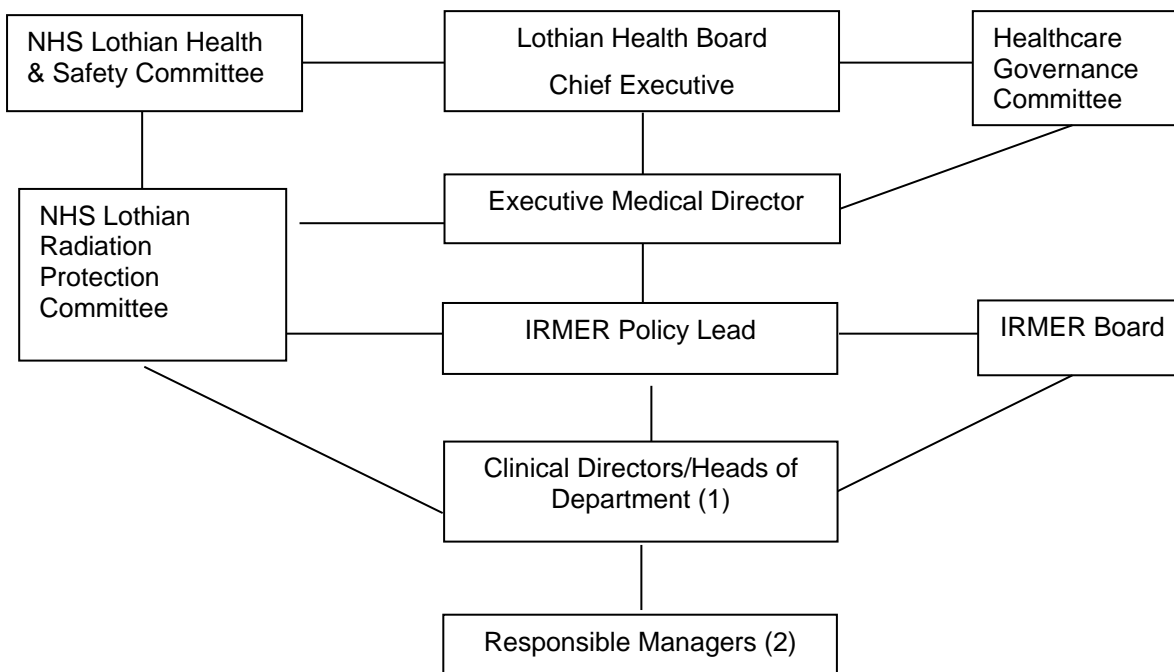
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**APPENDIX 1: Clinical Governance and Reporting Structure for IRMER in NHS Lothian**

The solid lines represent reporting routes in respect of this policy.

Dashed lines indicate membership of the Radiation Protection Committee



**Note 1:** Clinical Directors (or Heads of Department) are responsible for the implementation of Policy in those areas in which Medical Exposures are carried out and to discharge the responsibilities set out in paragraph 3.2.3 of this Policy. The relevant areas/ departments are listed below under their respective service groups. The two or three letter coding for each group is used as an identifier for the relevant Level 2 procedures.

**Note 2:** Responsible Managers may be authorised by the relevant Clinical Director to assess competences of individuals and to entitle duty holders on his or her behalf in accordance with Section 4 of this Policy.

**Scheduled Care**

**Diagnostic Services**

- o Radiology (RAD)
- o Medical Physics (DMP)
- o DEXA (DEXA)
- o Diagnostic Nuclear Medicine (NM)
- o EI (QMRI) (EIQ)

**Head and Neck**

Plastics (PRS)

**Theatres, Anaesthetics and Critical Care**

- o Sentinel Node Procedures (SLNB)
  - o Breast
  - o Urology
  - o Melanoma
  - o Vulval

**Unscheduled Care**

**RIE**

- o Cardiology (CAR)

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- o Pharmacy (PHM)

### **WGH**

- o Edinburgh Cancer Centre (ECC)
- o Acute Medicine (MED)
- o Breast Screening (BSP)

### **Primary Care**

- o Oral Health Service (OHS)

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## APPENDIX 2: NHS Lothian EMPLOYER'S WRITTEN PROCEDURES FOR IRMER

Table A2-1: Index of NHS Lothian Level 1 IRMER Procedures

Ref No	Procedure Title
EP1	Entitlement of Duty Holders for Medical Exposures
EP2	The identification of individuals entitled to act as Referrers, Practitioners and Operators.
EP3	Referral Procedure and Referral Criteria
EP4	Justification and Authorisation of Medical Exposures
EP5	Patient Identification
EP6	Establishing whether female patients may be pregnant or breast-feeding
EP7	Clinical Evaluation
EP8	Provision of information relating to the benefits and risks of an exposure
EP9	Diagnostic Reference Levels
EP10	Assessment of Patient Dose and Administered Activity
EP11	Recording and Investigating Accidental and Unintended Exposures
EP12	The minimisation of the probability and magnitude of accidental or unintended doses to patients from medical exposures
EP13	The provision of expert advice
EP14	Provisions for IRMER Audit
EP15	Quality Assurance of Written Procedures and Protocols
EP16	Equipment Inventory
EP17	Biomedical and Medical research programmes involving ionising radiation
EP18	Non-medical exposures
EP19	The provision of information to patients undergoing treatment or diagnosis with Radioactive medicinal products
EP20	Written Protocols for Standard Practice
EP21	Carers and Comforters
EP22	Equipment Quality Assurance programme
EP23	Licensing Arrangements

### General requirements

The following general requirements apply:

- o Procedures must be controlled documents and part of a managed document control system.
- o Each procedure must include objectives.
- o Each procedure must include a list (by title or role) of those individuals who should read the procedure.
- o Each procedure must include a list of responsibilities where relevant.

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