POLICY FOR THE IMPLEMENTATION OF THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS 2000
Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000

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1. Purpose

All medical exposures in which a patient is exposed to ionising radiation must comply with the Ionising Radiation (Medical Exposure) Regulations 2000 (as amended 2006 and 2011) (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 2000 (as amended) (IRMER).

The duties of the employer as set out in IRMER are

i) Ensuring that appropriate written procedures, including those defined in Schedule 1, Regulation 7(8) (Clinical evaluation) and in Regulation 8 (Clinical Audit) of the IRMER are in place ((Regulation 4(1)), are subject to a quality assurance programme for document maintenance (Regulation 4(3)(b)), and are complied with by entitled Practitioners and Operators (Regulation 4(1)a).

ii) Ensuring that appropriate written protocols are in place for every type of standard radiological practice and equipment (Regulation 4(2).

iii) Establishing recommendations on ‘referral criteria’ for medical exposures and making these available to all entitled Referrers (Regulation 4(3)a).

iv) Establishing ‘diagnostic reference levels’ (DRLs) for radiodiagnostic examinations (Regulation 4(3)(c)), 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 (Regulation 4(6).

v) Establishing a procedure for the investigation of incidents resulting in overexposure of patients and for reporting such incidents to the appropriate authority (Regulation 4(5)).

vi) Establishing ‘dose constraints’ for biomedical and medical research programmes (Regulation 4(3)(d)).

vii) Keeping an up to date inventory of equipment (Regulation 10).

viii) Addressing the training needs of entitled Practitioners and Operators (Regulation 4(4)(b)) and keeping training records (Regulation 11(4)).

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).

3.2.2 The Executive Medical Director appoints the Medical Director for NHS Lothian Acute Services to act as ‘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. Copies of authorisations are provided to the appropriate Associate Medical Directors (AMD). 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 set out in section 4.7 of this document.

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.

3.2.4 The NHS Lothian Radiation Protection Committee provides a framework for the management of radiation protection for both ionising and non-ionising radiations in NHS Lothian. The Committee reports to the NHS Lothian Health & Safety Committee. The remit of the Committee is set out in NHS Lothian’s Radiation Protection Policy. The remit of the Committee 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 the Committee 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 Committee 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 the Committee is provided with an annual report on the implementation of this policy via the Clinical Audit Summary, at the summer meeting of the Committee.

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

4.1 Referrers

A Referrer is a registered health care professional (medical or dental practitioner or other healthcare professional) who is entitled by NHS Lothian to refer individuals to a Practitioner for a medical exposure.

Entitlement to act as a Referrer for medical exposures in NHS Lothian is restricted to members of professions regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002.

Referrers must be entitled by either the IRMER Policy Lead in the case of Medical and Dental Practitioners, or by Clinical Directors in the case of other registered Healthcare Professionals (non-medical Referrers) in accordance with an authorised written procedure, for a scope of referral that will be confined to procedures appropriate to their speciality.

Directorates/Departments must maintain a list of individuals or professional groups entitled to act as non-medical Referrers and of their scope of referral.

Entitlement to act as a Referrer may be extended to medically qualified persons not employed by NHS Lothian, for whom the same provisions for entitlement by the relevant Clinical Director for restriction on scope of entitlement must apply.

The Referrer must supply the Practitioner with sufficient clinical information relevant to the medical exposure requested, and with due regard to NHS Lothian’s authorised referral criteria, to enable a Practitioner to decide on whether there is justification for the exposure to proceed.
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Referral Criteria for Medical Exposures

Referrals must be made in accordance with referral criteria approved by NHS Lothian. Specifically, referrals for diagnostic radiology must comply with referral guidelines published by Royal College of Radiology: “iRefer Guidelines Making the Best Use of Clinical Radiology” The IRMER Policy Lead must ensure that the most recent version of the RCR referral guidelines is available on the NHS Lothian intranet.

For dental radiology, the "Guidelines for the use of radiographs in Clinical orthodontics" BOS 2008 and "Selection Criteria for Dental Radiography" FGDP (Royal College of Surgeons) 2013 apply. Clinical Directors of dental services must ensure that the Dental/BDA guidelines are available at all dental clinics.

4.2 Practitioners

A Practitioner is a registered medical or dental Practitioner or other health care professional who is entitled to justify and authorise individual medical exposures. The IRMER Policy Lead will authorise Clinical Directors to entitle Practitioners, in accordance with Directorate procedures and with section 4.7 of this policy.

Clinical Directors, or senior managers acting under the authorisation of the Clinical Director, must entitle each Practitioner for a scope of entitlement that will be confined to procedures appropriate to their speciality and in accordance with their training and competences. Each Clinical Director will ensure that a list of persons entitled to act as practitioners is kept and their scope of entitlement is properly recorded.

The primary function of the Practitioner is to undertake the justification of medical exposures, taking into account the risks and benefits while considering alternative investigations or procedures. The Practitioner must therefore have full knowledge of the potential benefit and detriment associated with the procedure under consideration.

As part of the justification process, the Practitioner must consider the potential diagnostic or therapeutic health benefits including the direct health benefits to the individual and, in the situation where there may be no direct benefit to the individual, the benefits to society if the exposure is carried out. There must be clear knowledge of the individual detriment the exposure may cause and information of the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation. This may include the use of alternative equipment or alternative technique where doses are an issue. To facilitate this, all Practitioners need to be adequately trained and regularly update their training to carry out this function effectively.

If the Practitioner is aware prior to the exposure that no clinical evaluation will occur, the exposure is not justified and cannot lawfully take place. For radiotherapy and for therapy nuclear medicine where the clinical outcome is not immediately apparent, such clinical evaluation may be restricted to confirmation that the exposure was carried out as prescribed.

A record of justification by a Practitioner having taken place shall be regarded as confirmation that the exposure has been authorised by the Practitioner in accordance with Regulation 6(1)(b). Where it is not practicable for a Practitioner to authorise the request, an Operator, if so entitled, may authorise an exposure in accordance with written guidelines provided by the Practitioner (Regulation 6(5)).

Practitioners or authorised operators must not justify or authorise requests if insufficient patient information or clinical data is provided by the Referrer. Clinical Directors must, in their written procedures, include a procedure for returning requests which do not satisfy these requirements.

4.3 Operators

An Operator is any person who is entitled to carry out practical aspects of a medical exposure which may affect the patient’s dose. The IRMER Policy Lead has authorised Clinical Directors to entitle Operators in accordance with Directorate procedures and with section 4.7. Only those staff who have received suitable and sufficient training for their roles as Operators may be entitled.

Clinical Directors, or senior managers acting under the authorisation of the Clinical Director, must entitle Operators for a scope of entitlement that will be confined to procedures appropriate to their speciality and in accordance with their training and competences. Each Clinical Director or authorised senior manager will keep a list of persons entitled to act as Operators, and of their scope of entitlement.

All Operators have a duty to ensure that, in their role, the radiation exposure to the patient is as low as achievable and compatible with the clinical purpose.

4.4 Medical Physics Experts
A Medical Physics Expert (MPE) is a person holding a science degree and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation. As a guide the Medical and Dental Guidance Notes (IPEM 2002) define an MPE as a HCPC registered clinical scientist with at least 6 years appropriate experience in the clinical specialty. The IRMER Policy Lead has authorised the Head of Oncology Physics and Head of Medical Physics to entitle medical physics experts in accordance with their respective Directorate procedures and in accordance with section 4.7 of this policy document. The head of Oncology Physics and Head of Medical Physics must keep a list of entitled MPEs and of their scope of entitlement.

4.5 ARSAC Certificate holders

The Medicines (Administration of Radioactive Substances) Regulations 1978 require that radioactive substances may only be administered under the direction of a doctor or dentist who holds a certificate issued by the Health Ministers. The certificate specifies the procedures and classes of radioactive products that may be administered by the holder. Certificates are issued by the Administration of Radioactive Substances Advisory Committee (ARSAC). Applicants are required to provide evidence of training and experience in the procedures for which the certificate applies.

For ARSAC certificate holders who are employed within the Directorates/Departments listed in the Clinical Governance/ Reporting Structure in Appendix 1, entitlement as Practitioner will be conferred by the relevant Clinical Director.

The scope of entitlement of ARSAC certificate holders must be limited to those nuclear medicine examinations or treatments that are included in their respective ARSAC certificates, but will not necessarily include all of these examinations or treatments.

An up to date ARSAC certificate may be considered as evidence of training, and it will be for the person conferring the entitlement to assess whether this constitutes sufficient training for entitlement. This assessment should take due regard of recent experience.

The Head of Nuclear Medicine receives copies of ARSAC certificates from ARSAC, via the Chief Executive office and maintains a copy of all certificates relating to this group of ARSAC certificate holders for reference by the IRMER Policy Lead.

4.6 Trainees

A trainee or student may undertake certain Operator duties whilst under the supervision of an appropriately trained Operator. The level of supervision will be determined according to Directorate procedures. Responsibility for duties undertaken by the trainee remains with the supervising Operator.

4.7 Entitlement of Duty Holders

The IRMER Policy Lead entitles doctors and dentists as Referrers for medical exposures in NHS Lothian and as Operators for the evaluation of exposures in accordance with a scope of entitlement that must be specified in the employer’s procedures (see Section 5 and Appendix 2).

The IRMER Policy Lead authorises Clinical Directors to entitle Practitioners, Operators, Referrers and Medical Physics Experts for those medical exposures carried out within their Directorate or Department in accordance with paragraph 3.2.3 of this policy.

Entitlement of any duty holder must be granted for a scope of entitlement (SoE) appropriate to the role of the duty holder and their level of competency and training. The SoE for each duty holder must be documented and each duty holder must be aware of their own SoE. The scope of entitlement for each duty holder will be defined by a competency record held within the directorate.

The SoE must also be supported by training records for each duty holder other than for Referrers. The training required and the form of the records is at the discretion of the Clinical Director but must as a minimum demonstrate that the duty holder has been appropriately trained with due regard to Schedule 2 of IRMER and as specified in Section 4.8 of this document.

Clinical Directors may authorise one or more senior managers to assess and assign competences for their own staff and to entitle them to a SoE evidenced by the competency record. The Clinical Director must confirm such authorisation in writing.

In those Directorates/Departments in which senior managers have been authorised to entitle duty holders, the Clinical Director must ensure that the entitlement process has been implemented as described above and must make regular audits of training and competency records.
For the avoidance of doubt, the Clinical Director must ensure that the following documentation is in place to support this process:

- Directorate entitlement procedure
- List(s) of competences against which duty holders will be assessed
- Competency records describing the SoE for each duty holder
- Training records to support the SoE.
- List of persons or groups entitled to refer for procedures with the Directorate
- List of Practitioners and Operators who hold duties within the Directorate

4.8 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 2000.

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. 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.

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.

4.9 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 and Level 2 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.

5. Documentation

Clinical Directors must ensure that copies of all IRMER procedures 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.

The IRMER Policy Lead and the Clinical Directors must ensure that the Level 1 and Level 2 written procedures comply with the requirements for the employer’s written procedures that are set out in Appendix 2 of this policy.
5.1 Employer’s written procedures

NHS Lothian’s Employers written procedures for medical exposures shall include:

- **Level 1 procedures** that apply to all areas to which this policy applies in NHS Lothian.
- **Level 2 procedures** that apply to specific Directorates or Departments.

The IRMER Policy Lead is responsible for the control, authorisation and issue of the Level 1 procedures. The IRMER Policy Lead must ensure that they are reviewed biennially by the IRMER Board. The outcome of the review must be recorded. The IRMER Policy Lead must authorise any changes that may be made as a result of the review.

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

Prior to initial authorisation by the respective Clinical Director, Level 2 procedures must be submitted to the Radiation Protection Committee for approval.

Clinical Directors must ensure that Level 2 procedures are reviewed biennially and must report the outcome of the review to the Radiation Protection Committee.

Clinical Directors do not have to seek Committee approval for changes made to the Level 2 procedures unless the changes made are significant.

The following written procedures (Level 1 and Level 2 as appropriate) are required by IRMER:-

- All those listed in Schedule 1 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

The Head of the Radiation Protection (RP) Service will retain the current electronic files of this policy and all Level 1 and Level 2 procedures through a document control management system, Qpulse. The procedures should comply with NHS Lothian document control systems. Separate quality control procedures exist in certain Directorates/Departments to comply with the requirements of externally audited quality systems. These should be used for Level 2 IRMER procedures in those particular Directorates/Departments.

The IRMER policy, Level 1 and Level 2 documentation are available on the NHS Lothian intranet.

5.2 Level 3 Documents

NHS Lothian Level 3 documentation can be utilised to manage departmental standard operating procedures (SOP) and departmental protocols.

Departmental leads will be responsible for the authorisation, control and issue of Level 3 documents
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: Senior 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
- Radiology (RAD)
- Medical Physics (DMP)
- Nuclear Medicine (NM)
- Combined Laboratories (LAB)

Head and Neck
Plastics (PRS)

Theatres, Anaesthetics and Critical Care
- Sentinel Node Procedures (SLNB)
  - Breast
  - Urology
  - Melanoma
  - Vulval
- Anaesthetics (ANA)

Unscheduled Care
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RIE
  o Cardiology (CAR)

WGH
  o Edinburgh Cancer Centre (ECC)
  o Acute Medicine (MED)
  o Breast Screening (BSP)
  o Urology (URO)

Primary Care
  o Oral Health Service (OHS)
APPENDIX 2: REQUIREMENTS FOR NHS LOTHIAN EMPLOYER’S WRITTEN PROCEDURES FOR IRMER

1. General requirements
The following general requirements apply:

- Procedures must be controlled documents that comply with the NHS Lothian Policy for policies and procedures.
- Procedure identifying numbers and titles as set out in Table A2-1 (for Level 1 procedures) and Table A2-2 (for Level 2 procedures) must be used.
- Each procedure must include objectives as set out in sections 2 and 3 below.
- Each procedure must include a list (by title or role) of those individuals who should read the procedure.
- Each set of Level 2 procedures must include a table of contents as set out in Table A2-2 below. Where applicable, the contents list should indicate any procedure which is not applicable to the Directorate.
- Each set of Level 2 procedures must include an introduction to indicate that the Level 2 procedures must be read in conjunction with NHS Lothian Level 1 procedures.

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

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Procedure Title</th>
<th>IRMER Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP1-01</td>
<td>Identification of medical and dental practitioners entitled to act as Referrer for diagnostic medical exposures and the establishment of referral criteria</td>
<td>Schedule 1(b) Reg 4(3)(a) Reg 5(5)</td>
</tr>
<tr>
<td>EP1-02</td>
<td>Identification of medical practitioners entitled to act as Operators for the evaluation of medical exposures</td>
<td>Schedule 1(b) Reg 7(8)</td>
</tr>
<tr>
<td>EP1-03</td>
<td>Establishing written protocols for standard radiological practices</td>
<td>Reg 4(2)</td>
</tr>
<tr>
<td>EP1-04</td>
<td>Quality assurance programmes</td>
<td>Schedule 1(e) Reg 4(3)(b)</td>
</tr>
<tr>
<td>EP1-05</td>
<td>The use of diagnostic reference levels (DRL)</td>
<td>Schedule 1(g) Reg 4(3)(c)</td>
</tr>
<tr>
<td>EP1-06</td>
<td>Special precautions for the exposure of patients voluntarily participating in biomedical and medical research programmes</td>
<td>Schedule 1(h) Reg 4(3)(d) Reg 6(2) Reg 7(4)</td>
</tr>
<tr>
<td>EP1-07</td>
<td>The recording and investigation of incidents in which a patient receives a dose that is greater than intended.</td>
<td>Reg 4(5)</td>
</tr>
<tr>
<td>EP1-08</td>
<td>Special precautions for medico-legal exposures</td>
<td>Schedule 1(c) Reg 6(3)(a) Reg 7(7)(a)</td>
</tr>
<tr>
<td>EP1-09</td>
<td>Provision of information and written instructions to patients having medical exposures involving the administration of radioactive medicinal products</td>
<td>Schedule 1(i) Reg 7(5)(a)</td>
</tr>
<tr>
<td>EP1-10</td>
<td>Provisions for clinical audit</td>
<td>Reg 8</td>
</tr>
<tr>
<td>EP1-11</td>
<td>The provision of expert advice</td>
<td>Reg 9</td>
</tr>
<tr>
<td>EP1-12</td>
<td>The keeping of inventories of equipment used for medical exposures</td>
<td>Reg (10)</td>
</tr>
<tr>
<td>EP1-13</td>
<td>The minimisation of the probability and magnitude of accidental or unintended doses to patients</td>
<td>Schedule 1(k)</td>
</tr>
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</table>
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Table A2-2: Index of NHS Lothian Level 2 IRMER Procedures

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Procedure Title</th>
<th>IRMER Ref.</th>
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<tbody>
<tr>
<td>EP2/XXX/01</td>
<td>Identification of non-medical or non-dental healthcare professionals entitled to act as Referrer</td>
<td>Schedule 1(b)</td>
</tr>
<tr>
<td>EP2/XXX/02</td>
<td>The identification of individuals entitled to act as Referrers for therapeutic exposures, and as Practitioners or Operators for all medical exposures</td>
<td>Schedule 1(b)</td>
</tr>
<tr>
<td>EP2/XXX/03</td>
<td>Training and training records of entitled Practitioners and Operators</td>
<td>Reg 4(4),(5), Reg 11</td>
</tr>
<tr>
<td>EP2/XXX/04</td>
<td>Justification and authorisation of medical exposures</td>
<td>Reg 5(4), Reg 6</td>
</tr>
<tr>
<td>EP2/XXX/05</td>
<td>The correct identification of individuals to be exposed to ionising radiation</td>
<td>Schedule 1(a)</td>
</tr>
<tr>
<td>EP2/XXX/06</td>
<td>Establishing whether female patients may be pregnant or breastfeeding</td>
<td>Schedule 1(d), Reg 6(3)(c)</td>
</tr>
<tr>
<td>EP2/XXX/07</td>
<td>Carrying out and recording an evaluation of medical exposures</td>
<td>Schedule 1(j), Reg 7(8)</td>
</tr>
<tr>
<td>EP2/XXX/08</td>
<td>Recording factors relevant to patient dose</td>
<td>Schedule 1(j), Reg 7(8)</td>
</tr>
<tr>
<td>EP2/XXX/09</td>
<td>Administration of radiopharmaceuticals</td>
<td>Schedule 1(f,k), Reg 4(1)</td>
</tr>
</tbody>
</table>

‘XXX’ is a two or three-letter code indicating the Directorate/Department to which the Level 2 procedures apply and these are shown for each Directorate in Appendix 1 of this policy.

2. Level 1 procedures

The objectives of the Level 1 written procedures are summarised below.

EP1-01: Identification of medical and dental practitioners entitled to act as Referrer for diagnostic medical exposures and the establishment of referral criteria

- To ensure that requests for medical exposures are issued by entitled Referrers
- To set out the scope of entitlement of all such Referrers
- To establish referral criteria for medical exposures
- To ensure that the information provided by entitled Referrers is adequate for the justification of the medical exposure and for the identification of the individual referred for the medical exposure.

EP1-02: Identification of medical or dental practitioners entitled to act as Operators for the evaluation of medical exposures prior to the receipt of a Radiological report

To identify individuals entitled to act as Operators for the evaluation of those medical exposures that are evaluated by individuals who are not entitled through the mechanisms established in Level 2 procedures.

EP1-03: Establishing written protocols for standard radiological practices

To ensure that:

- Written protocols are in place for every type of medical exposure and for all equipment used for medical exposures
- All such protocols and standard operating procedures are subject to a system of document control
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EP1-04: Quality assurance programmes
To ensure that quality assurance programmes are followed such that procedures and standard operating protocols for medical exposures are reviewed and revised in a timely manner in order to safely comply with agreed standards.

EP1-05: The use of diagnostic reference levels (DRL)
- To establish DRLs for radiodiagnostic examinations
- To provide a framework for assessing whether doses arising from medical exposures are kept as low as reasonably practicable consistent with the clinical objective
- To ensure that appropriate reviews and corrective action is taken whenever DRLs are consistently exceeded.

EP1-06: Special precautions for the exposure of patients voluntarily participating in Biomedical and Medical Research Programmes
To ensure that:
- All medical exposures carried out as part of a medical or biomedical research study are approved by an ethics committee
- Individuals participate voluntarily in any research programme
- Individuals are informed in advance about the risks of exposure
- Dose constraints are established for individuals for whom no direct benefit is expected from the research study and that there is adherence to these dose constraints.

EP1-07: The recording and investigation of incidents in which a patient receives a dose that is greater than intended
To ensure that:
- Incidents in which individuals having a medical exposure receive unintended doses of radiation are recorded
- All such incidents are investigated and appropriate action taken to minimise the likelihood of future occurrence
- The appropriate authority is notified of those incidents for which the dose was much greater than intended or likely to have been much greater than intended
- Arrangements are in place to inform patients as appropriate of radiation incidents that require notification.

EP1-08: Special precautions for medico-legal exposures
To ensure that special attention is paid to the justification of those medical exposures that are carried out in medico-legal grounds and that doses from those exposures are kept as low as reasonably practicable.

EP1-09: Provision of information and written instructions to patients having medical exposures involving the administration of radioactive medicinal products
- To describe those situations where the level of activity is sufficient to require information to be provided to the patient in order to ensure that the doses to individuals coming into contact with the patient following discharge from the Hospital or clinic can be kept as low as reasonably practicable.
- To ensure that the patient understands the precautions to be taken prior to the administration of the radioactive product.
- To ensure that the information is given and the precautions explained to an appropriate person in those circumstances that the patient lacks the capacity to consent to the treatment or diagnostic procedure.
- Where appropriate due to the high levels of dose, to set out the risks associated with ionising radiation
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EP1-10: Provisions for clinical audit
To ensure that arrangements are in place for carrying out clinical audit in relation to compliance with IRMER and with the principles of justification and optimisation underlying those Regulations.

EP1-11: The provision of expert advice
To ensure that a Medical Physics Expert is involved in every medical exposure. In particular that an MPE:

- Is closely involved in radiotherapy;
- Is available for standard therapies using unsealed radioactive sources;
- Is available for diagnostic nuclear medicine practices;
- Is consulted in regard to the optimisation of all other diagnostic uses of ionising radiations including patient dosimetry and quality assurance.

EP1-12: The keeping of inventories of equipment used for medical exposures
To ensure that:

- For each Directorate in which medical exposures are carried out, an inventory of equipment for medical exposures is drawn up and kept up-to-date
- The inventories are available for inspection if required by the Scottish Government's Inspector for IRMER.

EP1-13: The minimisation of the probability and magnitude of accidental or unintended doses to patients from medical exposures
To ensure that the risks and magnitude of unintended or unnecessary doses to patients or other individuals having a medical exposure are as low as reasonably practicable

3. Level 2 Procedures
Clinical Directors are responsible for ensuring that the Level 2 procedures for their respective Directorates/Departments are drawn up with regard to the objectives set out below. In addition, each procedure must consider the general requirements set out below. If any procedure is not applicable to the specific Directorate this should be clearly identified in the contents list for that particular Directorate.

EP2/XXX/01: The identification of non-medical or non-dental healthcare professionals entitled to act as Referrer
Objective

- To identify individual healthcare professionals or groups of healthcare professionals who are not doctors or dentists who are entitled to act as Referrers to the xxxxxx Directorate
- To establish the process by which they are entitled to act as a Referrer
- To set out the scope of entitlement for each such individual or group

General requirements
The procedure must consider those situations in which referrals for a medical exposure may be accepted from a healthcare professional who is not a medical or a dental practitioner. The procedure must set out the arrangements to ensure that the healthcare professional has sufficient clinical training to assess whether the patient's clinical situation complies with the relevant referral criteria.

For each Referrer entitled through this procedure there must be a scope of entitlement. The procedure must describe the arrangement in place to keep a register of Referrers, either by name or by job title, who are entitled to act as Referrer in accordance with the procedure. It must ensure that entitled Practitioners or Operators who are entitled to authorise requests have a copy of the register available to them.

EP2/XXX/02: The identification of individuals entitled to act as Referrers for therapeutic exposures, and as Practitioners or Operators for all medical exposures
Objective

- To identify those individuals who may be entitled to act as Referrer for therapeutic medical exposures carried out in the xxxxxx Directorate
To identify those individuals who may be entitled to act as Practitioner and/or Operator for the medical exposures carried out in the xxxxxx Directorate

To establish the process by which they may be entitled to act as Practitioner and/or Operator

To set out the scope of entitlement for Practitioners and Operators entitled in accordance with this procedure

**General requirements**

Entitlement to refer for diagnostic medical exposures must comply with Level 1 procedure EP1-1 for medical and dental practitioners and with Directorate specific Level 2 procedures (EP2/XXX/01) for other healthcare professionals. This procedure must set out the arrangements for the entitlement to act as Referrer for therapeutic exposures or any other medical exposure that is not within the scope of entitlement that is specified in EP1-1.

The procedure must set out the arrangements by which the Practitioners who justify referrals for medical exposures that are carried out within the Directorate and the Operators who carry out the practical aspects of those medical exposures are justified. The procedure must set out the arrangements by which a scope of entitlement for each of these duty holders is determined.

**EP2/XXX/03: Training and training records of entitled Practitioners and Operators**

**Objective**

To ensure that individuals entitled to act as Practitioners and Operators for those medical exposures that are carried out in the xxxxxx Directorate have had adequate training as specified in Schedule 2 of IRMER.

**General requirements**

The procedure must set out those arrangements to ensure that all individuals entitled to act as Practitioners and Operators for those medical exposures carried out in the Directorate are adequately trained and that records of training are maintained. This must include a requirement for newly appointed staff to provide proof of registration and copies of relevant qualifications and training certificates. The procedure should indicate how such records should be retained. The procedure must include arrangements for induction training. The extent and form of induction training should take account of the individuals’ previous experience.

**EP2/XXX/04: Justification and authorisation of medical exposures**

**Objectives**

To ensure that

- All requests for medical exposures carried out in the xxxxxx Directorate have been justified by an entitled Practitioner as showing sufficient net benefit taking account of the objectives of the exposure, the potential diagnostic or therapeutic benefits to the individual, the individual detriment that the exposure may cause, and the efficacy, benefits and risk of any available alternative technique.

- The Practitioner pays special attention to: exposures on medico–legal grounds; exposures that have no direct health benefit to the individual; the urgency of exposure in those cases where the patient may be pregnant or (in the case of nuclear medicine) is breastfeeding

- For any guidelines that may be used for the justification of medical exposure, the guidelines are clearly identified as the responsibility of a named, entitled Practitioner and that authorisation of an exposure made in accordance with these guidelines is by an Operator entitled to act for this

**General requirements**

The procedure must set out the arrangements by which the identity of the Practitioner is recorded for medical exposures. It should describe those circumstances in which a suitably entitled Operator is permitted to authorise the referral in accordance with generic justification guidelines provided by an entitled Practitioner. Where justification guidelines are used, the procedure must set out the arrangements for recording the identity of the Operator authorising the request. In addition the record should indicate that authorisation was made in accordance to justification guidelines.

**EP2/XXX/05: The correct identification of individuals to be exposed to ionising radiation**

**Objectives**

To ensure that the medical exposure is carried out on the individual for which it was intended.
Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000

General requirements

The procedure must require positive identification. The standard procedure should be as follows:

The Operator must ask the patient to state:

- Their first and last name
- Their date of birth
- Their address

This information should be checked against the data on the referral and if the information matches the medical exposure may go ahead.

The procedure must specify the way that the Operator is required to record that the patient has been correctly identified. It must provide for those situations in which the Operator initiating the exposure is not the same person as the Operator identifying the patient to ensure that evidence of the identity check having been carried out is passed to the Operator initiating the exposure.

The procedure must include arrangements for foreseeable situations in the specific Directorate such as:

- Patients with communication difficulties
- Children
- Medical emergencies
- Unconscious patients
- Anaesthetised patients
- The Referrer is present with the patient

The procedure should include action to be taken should the patient provide information that differs to a small extent from that which is on the referral request. It should define the extent to which the Operator may use their professional judgement in assessing whether those differences represent errors in the data provided. The procedure should set out the actions to be taken should it not be possible to confirm the identity of the patient.

**EP2/XXX/06: Establishing whether female patients may be pregnant or breastfeeding**

**Objectives**

To ensure that:

- Medical exposures are not justified and authorised for women for whom pregnancy cannot be excluded without due consideration of the possible detriment to both the woman and the unborn child
- Medical exposures involving the administration of a radioactive material are not justified and authorised for a woman who is breastfeeding without due consideration of the possible detriment to both the woman and the child.

**General requirements**

The procedure should apply to female patients in the age range of 12 to 55 who are having medical exposure for which the dose to the foetus of a pregnant patient could be greater than 0.1 mGy. In general this includes X-ray examinations, in which the beam includes regions below the diaphragm and above mid-femur, radionuclide imaging studies and therapies and external beam radiotherapy. In developing the procedure, advice should be sought on radiation dose from an appropriate MPE.

For diagnostic radiology including radionuclide imaging, foetal doses should be no greater than 50 mGy and the ‘28-day rule’ should be applied based on the advice of the HPA. The standard procedure should be:

Immediately prior to the medical exposure, ask the patient: “Are you or might you be pregnant”. The patient should sign a pre-printed form to confirm her response. If the answer is “no”, the examination may proceed. If the answer is “yes”, the medical exposure cannot proceed without the authorisation of an entitled Practitioner taking account of the possible detriment to both the patient and the child. If the patient states that she might be pregnant the patient should be asked for the date of her last period. If the period is overdue, the Operator should seek justification on the same basis as if the patient had stated that she was pregnant. If the LMP is less than 28 days the exposure may go ahead unless it is a high dose procedure in which it should only do so...

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Protection of the Pregnant Patient during Diagnostic Medical Exposures to Ionising Radiation, HPA 2009.
if it is less than 10 days. For those high dose procedures the decision whether to continue must be taken by an entitled Practitioner.

For the purpose of this procedure, high dose examinations are those that are associated with potential foetal doses in excess of 5 mGy and those examinations should be listed in the procedure.

For therapy examinations with potential doses in excess of 100 mGy, the procedure must include the use of pregnancy tests for those patients in whom pregnancy cannot be excluded. It must include arrangements to inform the patient of the risks of pregnancy prior to a course of treatment.

The procedure must include arrangements for those foreseeable situations in which the patient may not be able to understand or to answer the question regarding the possibility of pregnancy, in particular for children, patients with communication difficulties, and the unconscious or anaesthetised patient, in medical emergencies.

The procedure should set out the arrangements for the assessment of dose and risk for any incident of an inadvertent foetal exposure. The procedure should require the report of any such investigation to be sent to the clinician responsible for the patient’s care.

For those Directorates/Departments in which the medical exposures include nuclear medicine (diagnostic and therapeutic) the procedure must include arrangement for enquiring of female patients whether they may be breastfeeding. The procedure should set out those nuclear medicine exposures for which ARSAC notes for guidance recommend interruption in breast feeding. Prior to the administration of the radionuclide for the specified examinations or therapy, female patients in the age range 12 to 55 years should be asked if they are breastfeeding. Where appropriate, this information should be sought at the time of appointment. If interruption to breastfeeding is indicated, the patient should be provided with written instructions prior to attending for the medical exposure.

**EP2/XXX/07: Carrying out and recording an evaluation of medical exposures**

**Objectives**

To ensure that an evaluation is recorded for every medical exposure by an Operator entitled for that purpose.

**General requirements**

Every medical exposure must be evaluated by an Operator in accordance with their scope of entitlement. The procedures must set out the arrangements for evaluation of all medical exposures carried out within the specific Directorate. Those arrangements must include a description of how this is to be done by entitled Operators whose entitlement comes from the Clinical Director of that Directorate. It also must describe the arrangements in place for the recording of an evaluation by an Operator who is employed in another Directorate or by another employer and whose entitlement is not given by the specific Clinical Director.

For therapeutic exposures, the evaluation is of the delivery of the therapy and not its clinical outcome. It will confirm that the therapy was delivered in accordance with the protocol or prescription that was authorised by the Practitioner or will indicate the extent to which it may have differed from that protocol.

**EP2/XXX/08: Recording factors relevant to patient dose**

**Objectives**

- To ensure that for every medical exposure factors are recorded which are relevant to patient dose.
- To specify those situations for which the recording of factors relevant to patient dose do not require to be recorded for the individual patient due to the standardisation of the particular irradiation technique for which the dose is pre-determined by the relevant standard operating protocol.

**General requirements**

The procedure must set out the arrangements for recording factors relevant to patient dose. For every type of medical exposure the relevant factors to be recorded must be set out in the procedure and the form in which the record must be held, that is whether a paper record is required, whether the information can be held in the radiology information system or in some other electronic record, whether the information is recorded with the image on PACS. The procedure must specify whether a specific record must be held for each patient or whether it is sufficient to specify that the relevant dose factors are set out in the respective standard operating protocol and that this is sufficient information to derive dose for the individual patient.

**EP2/XXX/09: Administration of radiopharmaceuticals**

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Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources, ARSAC 2006.
Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000

Objectives

- To ensure that the correct dose and radiopharmaceutical is safely administered.

General requirements

Radiopharmaceuticals may only be administered by the ARSAC certificate holder acting in the role of the Operator or by those Operators authorised in writing to administer radiopharmaceuticals by the ARSAC certificate holder.

The procedure must set out the arrangements for measuring and recording the administered activity. The procedure should specify the mechanisms of checking the measured activity against the local DRL for diagnostic examinations and the prescription for therapeutic procedures. The administered activities should be reviewed periodically.