Policy on the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2017 in NHS Shetland

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NHS Shetland Document Development Coversheet*

Name of document	Policy on the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2017 in NHS Shetland		
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Proposed groups to present document to:		
CCPGC		

Date	Version	Group	Reason	Outcome
02/12/19	3.0	CCPGC	Final Approval	Approved

Examples of reasons for presenting to the group	**Examples of outcomes following meeting**
• Professional input required re: content (PI)	• Significant changes to content required – refer to Executive Lead for guidance (SC)
• Professional opinion on content (PO)	• To amend content & re-submit to group (AC&R)
• General comments/suggestions (C/S)	• For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
• For information only (FIO)	• Recommend proceeding to next stage (PRO)
• For proofing/formatting (PF)	• For upload to Intranet (INT)
• Final Approval (FA)	• Approved (A) or Not Approved, revisions required (NARR)

***To be attached to the document under development/review and presented to the relevant group**

Please record details of any changes made to the document in the table below

Date	Record of changes made to document
Nov 2019	Reflection of new IRMER Regulations 2017

Contents

Policy statement

This policy describes the provisions to be applied across NHS Shetland for implementation of the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) and as amended in 2018.

Overall responsibility for the safe use of ionising radiation with patients lies with the Shetland NHS Board's Chief Executive who has made the Medical Director responsible to him/her for ensuring that the provisions of the NHS Shetland Radiation Safety Policy and of this NHS Shetland IR(ME)R Policy are implemented.

All medical exposures to ionising radiation must be performed in accordance with NHS Shetland's employer's written policies and procedures. All duty holders under IR(ME)R must be identified in accordance with this policy and with the associated departmental written procedures.

Compliance with IR(ME)R in each relevant NHS Shetland Department (Medical Imaging and Dentistry) shall be monitored by the Departmental Responsible Person for IR(ME)R.

Any healthcare professional executing a practical aspect of an exposure to ionising radiation is responsible for ensuring it is in accordance with accepted practice so as to keep doses as low as practicable in order to achieve the required diagnostic purpose.

1. Arrangements for the management of the employer's responsibilities

1.1. Appointment of IR(ME)R responsible persons and their duties

The Medical Director, as Chair of the Radiation Safety Committee, will appoint in writing, for each department where medical exposures are carried out, a "Departmental Responsible Person for IR(ME)R (DRP).[1] The departments are identified as Medical Imaging and Dental Services. The duties of the DRP are:

- to entitle duty holders in accordance with Section 2 of this document;
- to provide, maintain and disseminate employer's written procedures and protocols as described in section 3;
- to arrange for the investigation of incidents, including near misses, that resulted or could have resulted in a radiation dose greater than intended to the patient in accordance with Section 12;
- to ensure that clinical audits are carried out and reported in accordance with Section 9;
- to ensure that a system is in place to audit radiation doses and compare them to local and national standards, as appropriate, in accordance with Section 11;
- to ensure an equipment inventory is maintained and that equipment QA tests are carried out in accordance with Section 10;
- to ensure that the provisions set out in Section 5 (Protection of the Patient) are adhered to in their department;
- to ensure that referral criteria are in place and that these are available to all entitled referrers (see EP2.); and
- to ensure that a procedure is in place for communicating radiation risk to patients (section 6).

2. Duty holders

2.1. General provisions.

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 his or her own SoE. A competency record held by the DRPs or by the Chair of the Radiation Safety Committee will define the scope of entitlement for each duty holder.

For the avoidance of doubt, the DRPs or the Chair of Radiation Safety Committee must ensure that the following documentation is in place to support this process:

- an Employer's Written Procedure for entitlement of duty holders;

[1] Note: "Departmental Responsible Person for IR(ME)R" will be referred to as "Departmental Responsible Person" or "DRP" throughout this document.

- 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 within the department;
- list of practitioners and operators who hold duties within the department.

2.2. Training of duty holders

All staff acting as practitioners, operators or non-medical referrers must have received appropriate training for their duties.

The level of training will be specified at departmental level (or, where appropriate, by the Chair of Radiation Safety Committee) 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 departmental procedures.

Training records must include evidence of:

- basic qualifications for the post;
- awareness of IR(ME)R;
- awareness of the departmental procedures;
- awareness of their personal roles and responsibilities;
- continuous professional development;
- training for new techniques;
- training for new equipment ;
- basic radiation protection (see EP6: Ionising Radiation Training Standard);
- training specific to the competences for which the duty holder is entitled.

2.3. Referrers

A **Referrer** is a registered health care professional who is entitled (in NHS Shetland) to refer individuals to a Practitioner for medical exposure.

Entitlement to act as a referrer for medical exposures in NHS Shetland shall be 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.

Medical and dental referrers will be entitled by the Chair of the Radiation Safety Committee, in accordance with NHS Shetland Procedure EP2.

DRPs may entitle non-medical/non-dental healthcare professionals to refer to their department(s) as referrers. Such entitlement shall be subject to completion and recording of appropriate training in IR(ME)R awareness and on the risks of ionising radiation. The DRPs shall authorise an Employer's Written Procedure outlining the means of conferring and

recording entitlement and the scope of entitlement for each group of non-medical referrers. This shall include provisions for assessing and recording adequacy of related training.

2.4. Practitioners

A **Practitioner** is a registered healthcare professional who is entitled to take responsibility for an individual exposure.

The Chair of Radiation Safety Committee has authorised Departmental Responsible Persons to entitle practitioners within their department. The DRPs shall authorise an Employer's Written Procedure outlining the means of conferring and recording entitlement and the scope of entitlement for each practitioner. This shall include provisions for assessing and recording adequacy of related training.

Practitioners will be entitled for a scope of entitlement that will be confined to procedures appropriate to their specialty. Each DRP will keep a list of persons entitled to act as practitioners, and of their scope of entitlement.

Justification of diagnostic medical examinations by entitled practitioners shall be in accordance with Departmental Employer's Written Procedures.

2.5. Operators

An **Operator** is any person who is entitled (in NHS Shetland) to carry out practical aspects of a medical exposure, which may affect the patient's dose.

The Chair of Radiation Safety Committee has authorised DRPs to entitle operators within their department. The DRPs shall authorise an Employer's Written Procedure outlining the means of conferring and recording entitlement and the scope of entitlement for each operator. This shall include provisions for assessing and recording adequacy of related training.

Operators will be entitled by the DRPs for a scope of entitlement that will be confined to procedures for which they have been suitably trained, including both general and system specific training. The DRP shall ensure that records, including training records and the scope of entitlement of persons entitled to act as operators, are kept within their departments.

Operators for clinical evaluation who fall outwith the management responsibility of the DRP will be entitled by the Chair of Radiation Safety Committee in accordance with procedure EP1.

2.6. Medical Physics Experts

A **Medical Physics Expert (MPE)** is a person having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure and who is listed on the MPE Register held by RPA2000. The Medical Director will appoint MPEs for Medical Imaging and Dental Services. The Medical Director will also authorise DRPs to entitle MPEs as operators for the practical aspects of their role directly relating to medical exposures.

An MPE must:

- be involved in high dose CT practices;
- be involved as appropriate for consultation on optimization of other radiological practices;

- give advice on dosimetry, quality assurance and physical measurements for the evaluation of dose delivered.

An MPE must contribute to the following:

- optimisation of radiological protection of patients and other individuals subject to exposures, including the application of diagnostic reference levels;
- the definition and performance of quality assurance of the equipment;
- acceptance testing of equipment;
- preparation of technical specifications for equipment and installation design;
- surveillance of medical radiological installations;
- analysis of events involving accidental or unintended exposures (see EP5);
- selection of equipment required to perform radiation protection measurements;
- training of practitioners and other staff in radiation protection (see EP6); and
- provision of advice to NHS Shetland relating to compliance with IR(ME)R17.

2.7. Trainees

A trainee or student may undertake certain operator duties whilst under the supervision of an appropriately trained and entitled operator. The level of supervision will be determined according to departmental Employer's Written Procedures. Responsibility for duties undertaken by the trainee remains with the supervising operator.

3. Employer's Written Procedures & Protocols

In addition to this IR(ME)R Policy Document, which is authorised by the Chair of Radiation Safety Committee, there shall be Departmental Employer's Written Procedures and Protocols. These will be authorised by the DRP. While it is recognised that the DRP may not be aware of the precise details of every written procedure in his/her department, they must ensure that all written procedures and protocols described in this section are provided, maintained and brought to the attention of all staff who may be affected by them.

3.1. Scope of written procedures

The following written procedures and documentation are required for each department:

- all those listed in Schedule 1 of the IR(ME)R, except where an NHSS wide procedure exists as listed in Appendix 1.
- a procedure describing the departmental entitlement, including provisions for keeping training records;
- a procedure describing equipment quality assurance provisions.

3.2. Written protocols for standard practice

There must be written protocols for every standard radiological practice for each piece of equipment. In radiology and dentistry exposure charts must be dated and displayed

appropriately. All anatomic or technique protocols stored electronically must be backed up electronically and in hard copy. These must be used by the persons operating equipment. Any errors in these protocols must be brought to the attention of the Departmental Responsible Person. Departmental Procedures for document quality control must include provisions to ensure that only current protocols are available and displayed.

3.3. Quality assurance of written procedures & protocols

Procedures for document quality control must include provisions to ensure that documents are reviewed, at least, on a 2 yearly basis.

Once approved by the appropriate DRP, all written procedures and protocols for standard practice are controlled documents. They will be available on the intranet. Requests for alterations to controlled documents will be made through the DRP.

Compliance with Procedures for document quality shall be audited by the DRP and the outcomes of this audit shall be reported to the Radiation Safety Committee as part of Clinical Audit (Section 9).

4. Reporting of clinical outcomes

A clinical evaluation of the outcome of each medical exposure (except an exposure to carers or comforters) must be carried out and recorded by an operator so entitled. Departmental procedures must set out how this is to be done and recorded. For the avoidance of doubt, any evaluation of a diagnostic image leading to a decision on clinical management shall be regarded as a clinical evaluation

If it is known prior to the exposure taking place that no clinical evaluation will occur, then the exposure cannot be justified and cannot lawfully take place.

5. Protection of the patient

All operators exposing patients to ionising radiation have the responsibility to ensure that the patient dose is the minimum compatible with the diagnostic intention, and that attention is given to the relevant diagnostic reference level (DRL). Special attention must be applied to:

- justifying doses to patients participating in a research programme;
- justifying non-medical imaging;
- justifying and optimising medical exposures of children;
- optimising exposures as part of a health screening programme;
- optimising high dose procedures;
- justifying and optimising exposures to females where pregnancy cannot be excluded;
- equipment quality assurance results.

For all health screening programs the national recommendations on quality control and audit must be followed.

Departmental written protocols shall include guidelines and best practice for optimising any exposures of paediatrics.

Each department will have a written procedure describing the process by which patients exposed to ionising radiation are identified. This must reflect the requirements of the NHS Shetland Patient Identification Policy. All operators must follow these procedures.

DRPs will authorise Departmental Employer's Written Procedures for ensuring that the practitioner and operator pay particular attention to the exposure of female patients of childbearing age.

6. Risk communication

DRPs will authorise a procedure for their department detailing how patients are informed of the benefits and risk associated with the radiation dose from the medical exposure they are to undergo.

7. Carers and comforters

The Chair of the RSC will authorise a procedure to establish justification and authorisation provisions, dose constraints and guidance for people who are exposed to ionising radiation whilst acting as a carer or comforter to a patient.

8. Research involving the use of ionising radiation

All research studies carried out in NHSS involving patients or volunteers being exposed to ionising radiation must be approved by an ethics committee. Employer's procedure RA10: Protection of individuals participating voluntarily in any medical research programme which involves exposure to ionising radiation, describes the procedures that must be followed for both research where NHSS is the lead organisation or where other institutions are the lead organisation.

9. Audits

All departments must participate in a program of regular audits to include audit of patient dose, clinical audit and audit of compliance with the provisions detailed in this policy.

Dose audits will be carried out according to departmental written procedures and section 11 of this policy. Clinical audit and compliance audits shall be carried out and recorded according to the provisions of EP3.

10. Radiation equipment

The DRP is responsible to the Shetland Health Board for ensuring that an up-to-date inventory of radiation equipment used in connection with medical exposures is maintained. The inventory must contain for each piece of equipment the name of the manufacturer, model number, serial number or other identifier, year of manufacture and year of installation.

The DRP must also ensure that a quality assurance program is implemented and maintained. The quality assurance program must include:

- appropriate preventative maintenance;
- performance testing at regular intervals including prior to its first clinical use and after any maintenance procedure which has the capacity to affect performance.

Any performance tests undertaken and their frequency will be determined by current guidance issued by professional bodies and on the advice of the MPE.

All equipment producing ionising radiation must be used in a manner that takes advantage of any dose reducing features whilst ensuring adequate image quality is maintained.

Any loan or hire equipment is subject to the same requirements outlined above.

11. Diagnostic Reference Levels

DRPs shall authorise a Departmental Employer's Written Procedure for monitoring patient doses, and comparing these with national Diagnostic Reference Levels (NDRLs). This procedure will require the DRP, in conjunction with the MPE, to review local DRLs at least every 2 years and report to the Radiation Safety Committee. Where DRLs are being exceeded the DRP shall ensure this is investigated and corrective action taken if appropriate.

RPAs, MPEs and RPSs, as appropriate, will review local diagnostic reference levels as new equipment and techniques are adopted.

Adequate information must be kept so that individual dose assessments can be made retrospectively.

12. Investigation and reporting of adverse events, incidents & near misses

All adverse events, incidents and near misses involving ionising radiation must be reported according to the provisions of the Learning from Adverse Events through Reporting and Review Policy.

Certain adverse events and incidents are reportable to external authorities. Employer's Procedure EP5 (Investigating and Reporting of Adverse Events, Incidents and Near Misses Involving Ionising Radiation) details the process for determining whether an adverse event or incident is externally reportable and to which authority.

The DRP shall ensure that a yearly report of all incidents and near misses is made to the Radiation Safety Committee.

13. Estimation of population doses

NHS Shetland will collect dose estimates from medical exposures for radiodiagnostic and interventional procedures and provide this data to the Secretary of State as requested.

Appendix 1 – Organisation-wide procedures

EP1 Entitlement of GMC registered medical staff (excluding radiologists) and GDC dental staff to interpret images

EP2 Entitlement and Responsibilities of Medical and Dental referrers for medical exposures

EP3 Departmental IR(ME)R audit and clinical audit

EP4 Procedure for ensuring Quality Assurance of documents relating to IR(ME)R Compliance

EP5 Procedure for Reporting Adverse Radiation Events and Near Misses

EP6 Radiation Protection Training Requirements

EP7 Procedures for establishing appropriate dose constraints and guidance for the exposure of carers and comforters