Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

Procedure for Medical Exposures

Issue Date	Review Date	Version
Feb 2021	Feb 2023	5

Purpose

The Trust uses ionising radiations produced by X-ray and Radiotherapy equipment, and from radioactive substances for patient diagnosis and treatment. In doing so it must comply with relevant legislations concerning such medical exposures and implement written procedures as required by the "Ionising Radiation (Medical Exposure) Regulations 2017".

This procedure will apply to all medical exposures carried out within the Trust or on behalf of the Trust.

Who should read this document?

All **managers** whose are responsible for the provision of clinical services utilising ionising radiations for patient diagnosis, intervention or treatment, health screening programmes, research exposures, exposures of carers and comforters, exposure of asymptomatic individuals, and exposures of individuals undergoing non-medical imaging.

All **staff** who conduct any part of the medical exposure process, including referral for medical exposure, justification of medical exposure, any practical aspect associated with a medical exposure, or evaluating the outcome of any medical exposure.

Key messages

Service Line Directors and **Managers** are responsible for safe care of any patient undergoing a medical exposure within their service line, or where they are responsible for the referral or clinical evaluation. They must ensure appropriate written procedures and protocols are in place as detailed in this procedure, and that staff undertaking designated roles are suitably trained to do so, and are authorised to do so.

Any **employee (including honorary contract holders)** who are required to undertake any duty associated with any medical exposure must do so in accordance with the written procedures and must ensure that they are adequately trained and competent to undertake the role.

The Trust will ensure that medical exposures performed are carried out in accordance with the requirements of the regulations, and are subject to monitoring and review.

Core Accountabilities

Owner	Nick Rowles/Ivor Jones
Review	Radiation Safety Committee
Ratification	Director of Healthcare Science & Technology – Peter Wright
Dissemination (Raising Awareness)	Radiation Safety Committee
Compliance	Radiation Safety Committee

Links to other policies and procedures

Trust Policy 218 Ionising Radiation Safety Policy

Version History

1	February 2001	Approved by Radiation Protection Committee
2	2 April 2013	Reviewed and approved by RPC

2	April 2015	Extended by the Medical Director to August 2015
2	January 2016	Extended by Director of Corporate Business to January 2017
3	November 2016	Review & approved by Radiation Safety Committee
4	November 2017	Review for Ionising Radiations Regulations 2017
5	February 2021	Review & approved by Radiation Safety Committee

The Trust is committed to creating a fully inclusive and accessible service. By making equality and diversity an integral part of the business, it will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on the Trust Documents Network Share Folder (G:\TrustDocuments). Larger text, Braille and Audio versions can be made available upon request.

Contents

1 Introduction

1.1 The Trust uses ionising radiations produced by X-ray and Radiotherapy equipment, and from radioactive substances for patient diagnosis and treatment. In doing so it must comply with relevant legislations concerning such medical exposures and implement written procedures as required by the "Ionising Radiation (Medical Exposure) Regulations 2017".

2 Purpose, including legal or regulatory background

2.1 This procedure is designed to ensure the Trust's compliance with the Ionising Radiations (Medical Exposures) Regulations 2017 (hereafter referred to as "the regulations").

2.2 This procedure will apply in all areas of the Trust and to all individuals employed by the Trust who act as duty holders under the regulations, including supernumerary staff, students, locum and agency staff, and to individuals holding honorary employment contracts.

3 Definitions

3.1 Ionising Radiations in the context of this procedure include x-rays, electrons, neutrons, and emissions from radioactive sources.

3.2 Ionising Radiations (Medical Exposure) Regulations 2017 places a duty on employers to protect any person undergoing a medical exposure.

3.3 Radiation Safety Committee (RSC). Delegated committee with responsibility for policy and monitoring safety of use of ionising radiations.

3.4 Medical exposure means:

3.4.1. the exposure of patients as part of their own medical diagnosis or treatment;

3.4.2. the exposure of individuals as part of health screening programmes;

3.4.3. the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

3.4.4. the exposure of carers and comforters;

3.4.5. the exposure of asymptomatic individuals;

3.4.6. the exposure of individuals undergoing non-medical imaging using medical radiological equipment.

3.5 The Referrer. Requests for Medical Exposures can only be made by an entitled Referrer.

3.5.1. No person may be entitled as a referrer unless they meet the relevant statutory requirements.

3.5.2. Service Lines through, Departmental Operating Procedures (DOP) must identify those entitled to act as referrers.

3.6 The Practitioner. A Practitioner is entitled through DOP to take responsibility for and justify and authorise an individual medical exposure.

3.6.1. No person may be entitled as a Practitioner unless they meet the relevant statutory requirements.

3.6.2. Service Lines through DOP must identify those entitled to act as Practitioners.

3.7 The Operator. An Operator is any person who is entitled in accordance with the written DOP, to carry out practical aspects of the medical exposure.

3.7.1. An Operator is any person who is entitled in accordance with the written DOP, to carry out practical aspects of the medical exposure.

3.7.2. DOP must detail which staff, or groups of staff may act as Operators, and for which practical aspects.

3.7.3. Operators may authorise specific requests against specified justification criteria as detailed in DOP.

3.8 Medical Physics Expert. A Medical Physics Expert (MPE) is an individual whose competency to act in this role has been recognised by the secretary of state. Any person acting as MPE must hold relevant certification as required by the competent authority.

3.9 Research Exposure. A research exposure is a medical exposure required by the research protocol following initial patient consent. This includes exposures as part of normal clinical care as well as those additionally required for the purpose of the research.

3.10 Non-Medical Imaging. Non-medical imaging includes exposures using medical radiological equipment for the purposes for occupational health screening, for legal purposes, for sports assessments, and any other such exposure which falls outside 3.4.

4 Duties

4.1 Service Lines who conduct Medical Exposures must implement Department Operating Procedure (DOP) in order to comply with the regulations. These DOP have the status of Employers written procedures under Regulation 6. Section 5 gives details of the required DOP.

4.2 Such DOP must be appropriately managed and subject to regular review as part of a quality assurance process.

4.3 The overall responsibilities for radiation safety of **Service Line Clinical Directors**, **Service Line Managers and Departmental Heads** are described in Trust Procedure 425 “Managerial Responsibilities for Radiation Safety”.

4.4 Employees

4.4.1. Employees acting as duty holders **must** ensure that they comply with all relevant policies, procedures and protocols and Departmental Operating Procedures regarding any Medical Exposure in which they are involved.

4.4.2 Employees may only carry out duties for which they are entitled, and have been appropriately trained.

4.5 Referrers must provide sufficient accurate written information when requesting an exposure to:

4.5.1. Correctly identify the patient.

4.5.2. Provide sufficient clinical details to allow the practitioner to justify the risk of the examination.

4.5.3. Details of any pregnancy or possible pregnancy for women of child-bearing age.

4.5.4. Provide details of any known previous relevant medical exposures.

4.5.5. Uniquely identify themselves and provide contact details.

4.5.6. All referrals for examinations involving ionising radiation must: -

a) be made in accordance with the written referral criteria.
b) be completed in accordance with Service Line DOP and information systems.

4.5.7. Any request with insufficient detail must be rejected by the Practitioner or Operator until all necessary information has been supplied by the referrer.

4.5.8. Referrers must where appropriate provide the patient with information on the benefit (and risk of the exposure).

4.5.9. Referrers must undertake relevant training as required by the Trust.

4.6 Practitioners

4.6.1. All individuals entitled by DOP to act as Practitioner **must** ensure they are adequately trained to do so, and undertake continued training. Such continued training must include training relevant to their role under the regulations.

4.6.2. All individuals acting as Practitioners **must** do so in accordance with the written procedures.

4.7 Operators.

4.7.1. All individuals entitled by DOP to act as an Operator must ensure they are adequately trained to do so, and undertake continued training. Such continued training must include training relevant to their role under the regulations.

4.7.2. All individuals acting as Operators **must** do so in accordance with the written procedures.

4.8 Medical Physics Experts (MPEs)

4.8.1. The Trust must ensure appropriate Medical Physics Experts are appointed.

Medical Physics Experts must: -

a) be closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;
b) be involved in practices including standardised therapeutic nuclear medicine practices, diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography;
c) be involved as appropriate for consultation on optimisation, in all other radiological practices not mentioned in sub-paragraphs (b) and (c);
d) give advice on:-

(i) dosimetry and quality assurance matters relating to radiation protection concerning exposures;
(ii) physical measurements for the evaluation of dose delivered;
(iii) medical radiological equipment.

A Medical Physics Expert must also contribute to the following matters:-

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

The Medical Physics Expert must, where appropriate, liaise with a Radiation Protection Adviser and a Radioactive Waste Adviser.

5 Key elements (determined from guidance, templates, exemplars etc.)

5.1 Schedule 2 of the regulations requires the following:

The employer's written procedures for exposures must include procedures:-

a) to identify correctly the individual to be exposed to ionising radiation;
b) to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice;
c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding;
d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;
e) for the assessment of patient dose and administered activity;
f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f);
g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure;
h) for the giving of information and written instructions as referred to in regulation 12(6);
i) providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate

information relating to the benefits and risks associated with the radiation dose from the exposure;

j) for the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose;
k) to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable;
l) to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure;
m) to be observed in the case of non-medical imaging exposures;
n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.

Written procedures must also be implemented for any other aspects which are mandated in the regulations.

5.2 Service Lines must ensure DOPs are written, reflect practice and made available to relevant staff that are appropriate to each range of medical exposures of their service line. Duty holders should receive training in the written procedures.

5.3 Service Lines must take appropriate action to ensure duty holders comply with the written procedures.

5.4 Such DOPs must additionally include:

5.4.1. Referral criteria for medical exposures, including radiation doses, and shall ensure that these are available to the referrer.

5.4.2. The range of examinations each referrer can request with reference to written referral criteria.

5.4.3. The range of examinations which each Practitioner can justify.

5.4.4. Justification criteria for any procedure for which Operators are entitled to authorise.

5.4.5. Requirements for supervision of trainees (to include any staff not at that time entitled as an Operator or Practitioner)

5.4.6. Examination protocols for every examination.

5.4.7. Any other procedures which are required in order to comply with the provisions of the regulations.

5.5 DOPs must be sufficiently detailed to identify the role of each duty holder, have clarity around the actions they perform and detail the arrangements for documenting each step of the procedure.

Service Lines must ensure that all Practitioners and Operators are adequately trained

5.5.1. Theoretical training which meets the requirements of Schedule 3 of the regulations.

5.5.2. Practical training on each piece of equipment they use in conjunction with medical exposure.

5.5.3. Training records are maintained and available for inspection. This must include detailed records of training on each piece of equipment.

5.5.4. The employers training records must be kept separately from an individual's own records maintained for evidence of CME/CPD.

5.5.5. Service lines should liaise with the MPE regarding the scope, content and suitability of the training provided.

5.6 The Radiation Safety Committee shall be the ultimate arbitrator concerning training programmes.

5.7 For Research Exposures:

5.7.1. All Medical and Biomedical Research which includes any medical exposure must be subject to appropriate ethical consideration and R&D approval.

5.7.2. The R&D Department is responsible for ensuring for every research study appropriate approvals are in place according to national requirements and internal Trust procedures

5.7.3. Researchers must not carry out any research without appropriate approvals.

5.7.4. The Researcher is responsible for ensuring that appropriate authorisation and documentation is maintained to comply with the regulations.

5.8 Equipment used for medical Exposure

5.8.1. An inventory of equipment used for medical exposures, which 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.

The inventory as required will be held on Trust Medical Device Asset Register. Service Lines must cooperate with Clinical Technologies to ensure that the inventory is maintained.

5.9 Service lines must ensure an programme of quality assurance testing is in place for all equipment used for and in conjunction with medical exposures. The quality assurance programme must:

5.9.1. Detail the performance criteria to be met in respect of relevant tests:

5.9.2. Ensure:

a) testing of any equipment before it is first used for a medical radiological purpose;

b) performance testing at regular intervals;

c) performance testing following a maintenance procedure which is capable of affecting the equipment's performance.

d) define action to be taken in the event of defective equipment, including what action to be taken when performance is outside of the specified performance criteria.

5.10 Radiation Incidents

All incidents involving medical exposures, or procedural errors, must be investigated in accordance with the Procedure for Incidents Involving Ionising Radiation.

5.10.1 Service Lines must implement systems for the analysis of events involving or potentially involving accidental or unintended exposures.

5.11 Use of External Contractors

Where the Trust engages with others to carry out medical exposures on its behalf, it must ensure the same standards are applied in respect of any medical exposures. Service Lines are responsible for ensuring the necessary arrangements to ensure this is the case are in place prior to the commencement of such activities. A tool is available to help with this.

6 Overall Responsibility for the Document

6.10 The Radiation Safety Committee is responsible for the development, implementation and review of this procedure.

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of two years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Radiation Safety Committee and ratified by the Executive Director (RSC member).

Non-significant amendments to this document may be made, under delegated authority from the Executive Director (RSC member), by the nominated author. These must be ratified by the Executive Director (RSC member) and should be reported, retrospectively, to the approving committee.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Master documents are held within the "QPulse" document management system by the Directorate of Healthcare Science and Technology.

9 Monitoring Compliance and Effectiveness

9.10 The Radiation Safety Committee will be responsible for the production of a programme of audit covering all aspects of radiation safety, "the 'Radiation Protection Assurance Programme (RAP)"

9.11 All Service Lines involved in the use of ionising radiation will be required to take part in and cooperate with this audit process.

9.12 The results of these audits will be used to monitor compliance with and the effectiveness of this procedure and will be used to provide assurance to the Trust.

10 References and Associated Documentation

The Ionising Radiation (Medical Exposure) Regulations 2017

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018

Ionising Radiation (Medical Exposure) Regulations 2017: guidance

TRW.H&S.POL.218 Ionising Radiation Safety Policy

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	RADIATION SAFETY POLICY Procedure For Medical Exposures
Date Finalised	February 2021
Previous Documents	
Action to retrieve old copies	Trust document controller, update on QPulse

Dissemination Plan			
Recipient(s)	**When**	**How**	**Responsibility**
All Trust staff		IG StaffNet Page	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	✓
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	✓
	Does the style & format comply?	✓
Rationale	Are reasons for development of the document stated?	✓
Development Process	Is the method described in brief?	✓
	Are people involved in the development identified?	✓
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	✓
	Is there evidence of consultation with stakeholders and users?	✓
Content	Is the objective of the document clear?	✓
	Is the target population clear and unambiguous?	✓
	Are the intended outcomes described?	✓
	Are the statements clear and unambiguous?	✓
Evidence Base	Is the type of evidence to support the document identified explicitly?	✓
	Are key references cited and in full?	✓
	Are supporting documents referenced?	✓
Approval	Does the document identify which committee/group will review it?	✓
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	✓
	Does the document identify which Executive Director will ratify it?	✓
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	✓
	Does the plan include the necessary training/support to ensure compliance?	✓
Document Control	Does the document identify where it will be held?	✓
	Have archiving arrangements for superseded documents been addressed?	✓
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	✓
	Is there a plan to review or audit compliance with the document?	✓
Review Date	Is the review date identified?	
	Is the frequency of review identified? If so is it acceptable?	✓
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	✓