Developing One NHS in Dorset

NHS

NHS
Dorset County Hospital
NHS Foundation Trust

One Dorset IR(ME)R Policy

including the

Employer's Procedures

in accordance with the Ionising Radiation (Medical Exposure) Regulations 2017

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SUMMARY POINTS / KEY CHANGES

A One Dorset Policy to meet the needs of the four Dorset NHS Trusts.
Details the roles and responsibilities for the exposure of patients to ionising radiation as outlined in the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R).
Includes a reference list of the Employer's Procedures which are a set of procedures in daily use.
Adherence to this Policy and the associated Employer's Procedures should ensure compliance with IR(ME)R.

DOCUMENT DETAILS

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Job Title:	X-ray Superintendent / Head of Nuclear Medicine, PHFT
Signed:	
Organisation & Directorate:	PHFT Radiology
Target Audience:	All staff who work with ionising radiation at DCHFT, PHFT, RBCH, DHUFT
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DISTRIBUTION LIST

Intranet	Internet Website	Communications Bulletin	External stakeholders
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VERSION CONTROL

Date of Issue	*Version No.*	*Nature of Change*	*Section No / Page No*	*Name of Responsible Person*
Feb 2019	*1.0*	*One Dorset Policy*	*All*	*Michael Cox / Kat Dixon*
Dec 2019	*2.0*	*Ensure applies to each trust individually. Change in wording of pregnancy section.*	*Section 1, 2, 4, 8 and 9c*	*Kat Dixon*
July 2020	*3.0*	*Edits as per agreement on guidance docs, change from SOPs to Employer's Procedures, removal of consent*	*Whole document*	*Kat Dixon / Jim Thurston / Andrew Hunt*

APPROVAL RECORD

Approving Body / Committee:	
Chairperson:	
Signed:	
Organisation & Directorate:	
Date Approved:	
Sponsor:	
Review Date:	

CONSULTATION PROCESS

Version No.	**Level of Consultation**	**Author**	**Review Date**
1.0	One Dorset Medical Physics Group	Mike Cox / Kat Dixon	n/a
2.0	One Dorset Medical Physics Group	Kat Dixon	Dec 2021
3.0	One Dorset Medical Physics Group	Kat Dixon / Jim Thurston / Andrew Hunt	July 2022

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1. Executive Summary

This is a One Dorset Policy to meet the needs of the four NHS Trusts in Dorset. The policy should be applied to each Trust individually. All relevant employees of each Trust are required to comply with this Policy and the arrangements it puts in place.

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) legislation is for the protection of patients undergoing medical examination or treatment using ionising radiation from unnecessary and un-optimised radiation used as part of their diagnosis or treatment.

This policy describes the employer's responsibilities and those of other duty holders under this legislation. The policy also includes a list of the Employer's Procedures, which are a set of procedures detailing individual aspects of each administration as required by IR(ME)R.

2. Relevant To

All staff that work with ionising radiation in workplaces owned or managed by each individual Trust.

3. Introduction

All medical procedures involving exposure to ionising radiation for diagnostic and therapeutic purposes may carry some personal risk to the patient. It is important, therefore, that only those medical exposures that are justified are performed, taking into account the clinical objectives of the exposure for the individual concerned. This involves ensuring that the potential benefit of the exposure to the patient outweighs the radiation detriment that the exposure may cause. It is also important to ensure that for those exposures that are justified, the radiation risk is reduced to the minimum whilst still retaining the benefit of the exposure.

The Ionising Radiation (Medical Exposure) Regulations 2017 govern the use of ionising radiation in healthcare for the protection of the patient. They apply to any facility that carries out medical exposures, and are regulated and enforced by the Care Quality Commission.

4. Scope

The policy should be applied to each Trust individually.

The requirements of IR(ME)R apply regardless of the Trust, the size of the directorate or department, number of staff employed or number of exams performed.

This policy states each Trust's best practice in reference to IR(ME)R.

This policy states the duties of the Trust staff who are responsible for administering ionising radiation to persons undergoing medical exposure. There are 5 classes of 'duty holder' defined within IR(ME)R:

- The Employer
- The Referrer
- The Practitioner
- The Operator
- The Medical Physics Expert

These legal responsibilities apply even when the same person is acting as multiple duty holders.

5. Purpose

The purpose of this policy is to provide a framework for the radiation protection of the patient through the provision of Employer's Procedures. Each Trust will ensure the Employer's Procedures referenced within are correctly named for local compliance.

6. Definitions

- **ARSAC** – Administration of Radioactive Substances Advisory Committee
- **IR(ME)R** – Ionising Radiation (Medical Exposure) Regulations 2017
- **DRL** – 'diagnostic reference level' means dose levels for typical examinations for groups of standard-sized individuals for broadly defined types of equipment.
- **MPE** – 'Medical Physics Expert' as defined in section 8.
- **RIS** – 'Radiology Information System' on which all diagnostic procedures are detailed.
- **PACS** – 'Picture archiving communication system' on which the images from all diagnostic procedures are made available for viewing.
- **QC** – 'quality control' a set of operations intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be measured, and controlled.
- **Employer's Procedure** – a procedure for daily use required by IRMER to ensure the safe exposure of patients to ionising radiation. Such a procedure may be known locally as a SOP (Standard Operating Procedure).
- **Protocol** – a written work instruction for carrying out examinations or therapies involving the exposure of patients to ionising radiation.

7. Consultation

The following stakeholders will be consulted in the preparation of this policy:

- One Dorset Medical Physics Group
- Radiology Vanguard Board

- MPEs and Lead IR(ME)R Practitioners across the acute Dorset Trusts
- Radiation Protection Committees across the acute Dorset Trusts.

8. Roles and Responsibilities

General Responsibilities for each individual Trust:

Chief Executive

The Chief Executive has overall responsible for the statutory duty of quality and clinical governance and takes overall responsibility for this policy.

General / Directorate Managers

The General / Directorate Managers are responsible for ensuring that all relevant services are compliant with this Policy.

Service Leads / Line Managers

Service Leads and Line Managers are responsible for ensuring that:

- Their staff are made aware of this Policy, and
- All relevant staff are compliant with this policy.

All staff

All staff must adhere to this policy.

IR(ME)R Duty Holders for each individual Trust:

The Employer

The primary responsibility for providing a framework for the radiation protection of the patient lies with the employer through the provision of the Employer's Procedures.

It may not be practical for the employer to personally carry out all the duties but, whilst the task may be delegated to others, the legal responsibility will always remain with the employer.

Employer duties include:

- To ensure that suitable employer and practitioner licences (issued by ARSAC) are in place to support each site at which radioactive substances are to be administered to patients.
- To ensure that appropriate written Employer's Procedures are in place and are subject to a programme for document maintenance.
- To ensure that the Procedures are complied with by entitled Referrers, Practitioners and Operators.
- To ensure that the training needs of entitled Practitioners and Operators are met and that there is continuing education for these duty holders. To ensure there is an up to date training record for all entitled practitioners and operators.
- To establish recommendations on referral criteria for medical exposures and make these available to all entitled referrers.
- To ensure that appropriate written protocols are in place for every type of standard radiological practice, including non-medical imaging where applicable.

- To establish diagnostic reference levels (DRLs) for standard examinations and ensure that there is a mechanism for assessment of compliance with these DRLs.
- If research is carried out at the practice, to establish 'dose constraints' for biomedical and medical research programmes where there is no direct medical benefit to the individual, and for carers and comforters.
- To raise awareness of the effects of ionising radiation amongst individuals capable of childbearing and breastfeeding.
- To provide for the carrying out of clinical audit as appropriate.
- To establish a process for the investigation of incidents resulting in clinically significant unintended or accidental exposures and for reporting such incidents to the appropriate authority.
- To collect dose estimates from medical exposures, including information on age and gender, and provide this data to the Secretary of State when requested.
- To ensure that a sufficient number of appropriately experienced Medical Physics Experts are appointed and involved in matters relating to radiation protection concerning medical exposures.
- To keep an inventory of equipment, ensure a quality assurance programme is implemented and maintained for that equipment, and ensure measures are in place to improve inadequate or defective performance of that equipment.

The Referrer

The Referrer must be a registered medical practitioner, dental practitioner or other health professional who is entitled to refer individuals for medical exposure to a practitioner under the Employer's Procedures.

Any non-medical referrer must have undergone suitable training and refer only within their scope of authorisation – i.e. the patient groups and range of diagnostic radiological examinations for which they are entitled. This scope of authorisation must be set out in writing.

The referrer requesting the exam does so under a protocol that conforms to the Employer's Procedures and the appropriate referral criteria. The request must be clear and legible and the following information must be supplied by the referrer:

- at least three points of identification for the patient (i.e. name, address, date of birth, hospital number, NHS number);
- sufficient relevant details of the clinical problem for the practitioner to justify the medical exposure or an operator to authorise the exposure against justification guidelines produced by the practitioner;
- if applicable, information on the patient's menstrual status (possible pregnancy);
- if applicable to a referral to Nuclear Medicine, information on the patient's breastfeeding status;
- a signature uniquely identifying the referrer (which may be electronic if detailed in the Employer's Procedures).

The Practitioner

The Practitioner is defined as a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the Employer's Procedures to take responsibility for an individual medical exposure. Suitable practitioners can be

Consultant Radiologists or Oncologists or other appropriately trained senior medical staff.

The primary responsibility of the Practitioner is to ensure the requested medical exposure is justified in accordance with the Employer's Procedures.

The Practitioner must be appropriately trained and possess the necessary understanding and knowledge to interpret and apply:

- the clinical information supplied by the referrer;
- the specific objectives of the requested procedure and its relevance to the individual involved;
- the potential benefit and detriment associated with the requested procedure, both to the individual patient and taking into consideration any possible dose to a carer and comforter;
- the efficacy, benefits and risks of suitable available alternative techniques involving less exposure to ionising radiation.

The legal responsibility for justification always remains with the Practitioner. However, authorising that the exposure has been justified is a separate function and can be delegated in certain circumstances under protocol to suitably trained and experienced Operators. Such protocols are detailed in the Employer's Procedures, and set out the scope of such delegated authorisation.

The Operator

The Operator is any person who carries out any practical aspects of the medical exposure. The primary responsibility of the Operator is to optimise those practical aspects of the exposure for which they are responsible, in accordance with the Employer's Procedures.

The term practical aspect covers a range of functions, each of which will have a direct influence on the medical exposure and can be separately identified. Therefore it is not only performing the medical exposure, but also undertaking any supporting aspect in the optimisation process, and there may be more than one Operator involved in a single medical exposure.

The Operator must be identified as specified in the Employer's Procedures.

The Operator must ensure that the patient is correctly identified, that the exposure has been authorised and that, for female patients, status regarding their possible pregnancy is confirmed.

The Medical Physics Expert

The Medical Physics Expert (MPE) is defined as an individual having the knowledge, training and experience to act or give advice on matters related to radiation physics applied to exposure whose competence is recognised by the Secretary of State.

There is a legal requirement on the employer that an MPE shall be appointed and involved in every type of medical exposure to an extent related to the relative risk of that type of exposure.

The MPE must give advice on or contribute to:

- Optimisation of radiation protection to patients including the application of DRLs,
- Dosimetry and physical measurements for the evaluation of dose delivered,
- Preparation of technical specifications for equipment and installation design,

- Acceptance testing and quality assurance of equipment,
- Surveillance of medical radiological installations,
- Analysis of incidents involving accidental or unintentional exposures,
- Training of practitioners and other staff in relevant aspects of radiation protection,
- Advice to the employer on compliance with IR(ME)R.

9. Employer's Procedures

IR(ME)R Schedule 2 details the individual Employer's Procedures that must be written and adhered to. These are:

(a) Procedure to identify correctly the individual to be exposed to ionising radiation;

(b) Procedure to identify individuals entitled to act as a referrer, practitioner or operator within a specified scope of practice;

(c) Procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or, if applicable, breastfeeding;

(d) Procedure to ensure that quality assurance programmes for both written procedures and equipment, are followed;

(e) Procedure for assessing patient dose and administered activity;

(f) Procedure for the use and review of diagnostic reference levels;

(g) Procedure for medical research programs involving ionising radiation;

(h) Procedure for giving information and instructions to patients to which radioactive substances will be administered;

(i) Procedure for communicating adequate information to the patient relating to the benefits and risks associated with the radiation dose from the exposure;

(j) Procedure for the carrying out and recording of an evaluation for each medical exposure;

(k) Procedure to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable;

(l) Procedure for the investigation of radiation incidents of persons undergoing medical exposure to ionising radiation;

(m) Procedure for non-medical imaging exposures;

(n) Procedure for dose constraints and guidance for the exposure of carers and comforters.

Compliance with these procedures is detailed in each Trust's local Employer's Procedures documentation.

10. Training *(if applicable)*

All Radiology staff are required to read this policy and training is provided on individual Employer's Procedures should that be required.

11. Monitoring and Compliance

An audit of compliance will take place at least every two years by the Radiology Manager, the Radiation Protection Supervisor and the MPE.

12. Supporting Documents and References

12.1 IR(ME)R Ionising Radiation (Medical Exposure) Regulations 2017 (SI 2017 No 1322) London, HMSO. [online]:

www.legislation.gov.uk/uksi/2017/1322/made/data.htm

12.2 Changes to the IR(ME)R17 regulations

www.hse.gov.uk/radiation/ionising/index.htm

12.3 NRPB, CoR, RCR. Diagnostic medical exposures: advice on exposure to ionising radiation during pregnancy. Chilton, NRPB, 1998. [online]:

http://www.e-radiography.net/regsetc/nrpb_asp8/Diagnostic%20Medical%20Exposures%20Advice%20on%20Exposure%20to%20Ionising%20Radiation%20during%20Pregnancy.htm

12.4 Guidance on the establishment and use of diagnostic reference levels for medical X-Ray examinations. IPEM Report 88, York, IPEM, 2004. [online]:

http://www.xrqa.com/downloads/DRL/Guidance%20on%20the%20establishment%20and%20use%20of%20%E2%80%9CDiagnostic%20Reference%20Levels%E2%80%9D.pdf

12.5 RCR Working Party. Making the Best Use of Department of Clinical Radiology: Guidelines for Doctors (Fifth Edition). London: The Royal College of Radiologists, 2003.

http://books.google.co.uk/books?id=J9pQOQAACAAJ&dq=the+Best+Use+of+Department+of+Clinical+Radiology:+Guidelines+for+Doctors&hl=en

12.6 Bull, S. (2005). Skeletal Radiography: A concise introduction to projection radiography, (2nd Eds), Toolkit publications: London. [online]:

http://books.google.co.uk/books/about/Skeletal_Radiography.html?id=NePk5A1Y1NAC&redir_esc=y

12.6 European Commission Directorate-General for the Environment, (2001). Radiation Protection 118: Referral guidelines for Imaging, Adapted by experts representing European radiology and nuclear medicine. Office for official publications of the European Communities: Luxembourg. [online]:

http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_en.pdf

12.7 European Union. Council directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, [online]:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf

12.8 Government Legislation, (1974). Health and Safety at Work etc. Act 1974, [online]:

http://www.legislation.gov.uk/ukpga/1974/37/section/15

12.9 Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation, Advice from the Health Protection Agency, The Royal College of Radiologists & the College of Radiographers, 2009 [online]:

https://www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=296

13. Dissemination and Implementation

This policy will be disseminated by the members of the Radiation Safety Group or Radiation Protection Committee to the managers and RPSs in each area of the Trusts which uses ionising radiation.

The policy will be published on the Trust's document management system.

14. Approval and Ratification

Approval and ratification will be performed by the Trust.

The document will be agreed by the Radiation Safety Group or Radiation Protection Committee where it will be recommended to the Risk Management and Safety Group.

This document will then be approved by the Risk Management and Safety Group where it will be ratified on behalf of that Trust, or recommended to the Hospital Executive Group for ratification.

15. Equality Impact Assessment

Please see Appendix 1

APPENDIX 1: EQUALITY IMPACT ASSESSMENT

1. Title of document/service for assessment	**One Dorset IR(ME)R Policy including the Employer's Procedures**
2. Date of assessment	**11/02/2019**
3. Date for review	**February 2022**
4. Directorate/Service	**Radiology**
5. Approval Committee	**Board of Directors**

	Yes/No	Rationale
6. Does the document/service affect one group less or more favourably than another on the basis of: N.B. The 'Rationale' box must be completed whether the answer is Yes or No.		
• **Age – where this is referred to, it refers to a person belonging to a particular age (for example 32 year olds) or range of ages (for example 18 to 30 year olds).**	N	
• **Disability – a person has a disability if she or he has a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.**	N	
• **Gender reassignment – the process of transitioning from one gender to another.**	N	
• **Marriage and civil partnership – marriage can include a union between a man and a woman and a marriage between a same-sex couple.**	N	
• **Pregnancy and maternity – pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth, and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.**	N	
• **Race – refers to the protected characteristic of Race. It refers to a group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.**	N	

• **Religion and belief – religion has the meaning usually given to it but belief includes religious and philosophical beliefs including lack of belief (such as Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition.**	N	
• **Sex – a man or a woman.**	N	
• **Sexual orientation – whether a person's sexual attraction is towards their own sex, the opposite sex or to both sexes.**	N	
8. If you have identified potential discrimination, are the exceptions valid, legal and/or justified?	N	

9. If the answers to any of the above questions is 'yes' then:	**Tick**	**Rationale**
Demonstrate that such a disadvantage or advantage can be justified or is valid		
Adjust the policy to remove disadvantage identified or better promote equality	-	
If neither of the above possible, seek advice from the Trust equality lead.	-	

APPENDIX 2: Checklist of Associated Employer's Procedures

This list should reflect the titles of the local Employer's Procedures:

	Patient Identification and Consent Procedure
	Authorised Referrers Procedure
	Authorised Practitioners Procedure
	Justification and vetting of x-ray examinations Procedure
	Authorised Operators Procedure
	Pregnant (or Breastfeeding) Patient Procedure
	Document Management System (Q Pulse/SharePoint) Procedure
	Procedural Audits Procedure
	Radiological Equipment QC Procedure
	Equipment Inventory Procedure
	Assessment of Patient Dose Procedure
	DRL Procedure
	Medical Research Programs Procedure (if applicable)
	Giving Information to Patients Procedure (if applicable)
	One Dorset Risk and Benefit Communication Procedure
	Recording and Evaluating Exposures Procedure
	Avoidance of Accidental Exposures Procedure
	Radiation Incidents Procedure
	Non-medical Exposure Procedure (if applicable)
	One Dorset Carers and Comforters Procedure