IONISING RADIATION MEDICAL EXPOSURE POLICY
IOW PROCEDURES

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<td>Policy Owner</td>
<td>Chief Operating Officer – Acute &amp; Ambulance</td>
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<td>Policy Author</td>
<td>Radiation Protection Advisor</td>
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<td>Next Author Review Date</td>
<td>1st September 2023</td>
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<tr>
<td>Approving Body</td>
<td>Clinical Standards Group 26th February 2021</td>
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<tr>
<td>Version No.</td>
<td>2.0</td>
</tr>
<tr>
<td>Policy Valid from date</td>
<td>1st February 2021</td>
</tr>
<tr>
<td>Policy Valid to date:</td>
<td>28th February 2024</td>
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‘During the COVID19 crisis, please read the policies in conjunction with any updates provided by National Guidance, which we are actively seeking to incorporate into policies through the Clinical Ethics Advisory Group and where necessary other relevant Oversight Groups’
**DOCUMENT HISTORY**

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

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<th>Date of Issue</th>
<th>Version No.</th>
<th>Date Approved</th>
<th>Director Responsible for Change</th>
<th>Nature of Change</th>
<th>Ratification / Approval</th>
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<td>26/02/21</td>
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NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust
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1 Executive Summary

The Ionising Radiation (Medical Exposure) Regulations 2017, Regulation 6(1) require that every employer establishes written procedures for medical exposures. Schedule 2 of the regulations lists the procedures that are specifically required by the legislation but the accompanying guidance states that these are the minimum requirement.

The IRMER 2017 regulations place a duty on the employer to ensure compliance with these procedures.

Although the responsibilities of the employer cannot be delegated, within the Trust the duties of the employer are delegated to the Lead Clinician in Diagnostic Imaging, Radiology Services Manager and the Radiation Protection Team (provided by contract from Southampton University Hospitals NHS Foundation Trust).

There is a requirement that compliance with the procedures is audited and that the procedures are reviewed to identify any necessary amendments.

Each procedure will have a footer that includes the issue date.

The Diagnostic Imaging Department will issue updated versions of individual procedures to the Clinical Standards Group (CSG) and Medical Director as and when the procedures are reviewed and amended.

2 Introduction

The Trust’s Employer’s Procedures for Medical Exposures are the mechanism by which the Trust complies with the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017. The regulations requires that every employer who carries out, or engages others to carry out, medical exposures has written procedures for medical exposures. The procedures listed here are those required by Schedule 1 of the regulations.

The employer has a legal duty to ensure that the procedures are complied with by practitioners and operators. Similarly the practitioner and operator each have a legal duty to comply with the procedures.

Although the responsibilities of the employer cannot be delegated, within Isle of Wight NHS Trust the duties of the employer are delegated as described in the Policy for the Safe Use of Ionising Radiations.

There is a requirement that compliance with the procedures is audited and that the procedures are reviewed to identify any necessary amendments.

3 Definitions

"Ionising radiation" means radiation from radiographic equipment, the decay of radioactive material, radiation from linear accelerators, etc, as used in radiology, breast imaging, DEXA, nuclear medicine and radiotherapy. It does not include MRI, lasers or ultraviolet light; these use non-ionising radiations and are covered by the Trust’s policy for the safe use of magnetic resonance imaging and the Trust’s policy for the safe use of optical radiation respectively.

IRMER is The Ionising Radiation (Medical Exposure) Regulations 2017.

IRR is The Ionising Radiations Regulations 2017.
EPR
“Operator”
is The Environmental Permitting (England & Wales) Regulations 2016 means any person who is entitled in accordance with the Trust’s written procedures to undertake the practical aspects of a medical exposure and is adequately trained. An untrained person acting under the direct supervision of a trained person may undertake equivalent duties.

“Medical staff”
means qualified medical doctors.

“Practitioner”
means a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the Trust’s written IRMER procedures to take responsibility for a medical exposure.

“Referrer”
means a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the Trust's written IRMER procedures to refer individuals for medical exposure to a practitioner.

“Radiation Protection Supervisor” (RPS)
is an appointed person who has sufficient knowledge, training and management status to supervise observance of statutory regulations, Local Rules and Systems of Work.

“Radiation Protection Adviser” (RPA)
is a recognised expert with a certificate of competence from RPA2000, An RPA may advise on any aspect of compliance with IRR. The Trust must consult an RPA on specific matters listed in Schedule 4 of IRR.

“Radiation Waste Adviser” (RWA)
is a recognised expert with a certificate of competence from RPA2000, An RWA may advise on any aspect of compliance with EPR.

“Medical Physics Expert” (MPE)
is a recognised expert on the national MPE register, An MPE may advise on any aspect of compliance with IRMER or the implementation of medical exposures within the scope of their expertise (either Diagnostic Radiology, Nuclear Medicine or Radiotherapy). Some MPEs may have more restricted scopes of expertise.

4 Scope
The scope of this procedure includes staff members from:
- Radiology, including Interventional Radiology
- Dental Radiology
- CT scanning
- Breast Screening

5 Purpose
The purpose of these procedures is:
- To comply with the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017.
- To ensure that the exposure of patients, undergoing medical examination or treatment, is carried out safely.
To minimise the number of adverse events involving radiation exposure to patients

6 Roles and Responsibilities

6.1 Employer

In the context of the Ionising Radiation (Medical Exposure) Regulations 2017, the employer is considered to be Isle of Wight NHS Trust. If the Organisation contracts a third party to provide services then the Organisation will be the employer as regards the operators for the purpose of the Regulations, but the third party is the employer of the operators for employment law purposes. Equipment ownership has no impact on the employer responsibilities under these Regulations.

6.2 Referrers

The referrer is a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the Trust’s written procedures to refer individuals for medical exposure to a practitioner.

6.3 Practitioners

The practitioner is a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the Trust’s written procedures to take responsibility for an individual medical exposure. The primary responsibility of the practitioner is to justify medical exposures. In some cases the practitioner may also undertake practical aspects of an exposure and so become an operator with regard to these specific functions.

6.4 Operators

The operator is any person who is entitled, in accordance with the Trust’s written procedures, to undertake the practical aspects of a medical exposure and is adequately trained. Operators may include radiographers, doctors, medical physicists, medical physics technicians, nurses and assistant practitioners.

6.5 Medical Physics Expert (MPE)

The MPE is a person who is recognised as able to give advice on the safe use of ionising radiation on patients. They should be state registered and recognised by DHSC as a competent person.

7 Policy Detail/Course of Action

7.1 List of Procedures

Procedure Title

A Verification of Identity and Correct Examination
B Identifying Individuals Entitled to be Duty Holders
C Medical Exposures on Individuals of Childbearing Capacity
D Quality Assurance of Imaging Procedures, Protocols and Equipment
E Assessment of Patient Dose
Procedure A to correctly identify individuals to be exposed to ionising radiation

1) Responsibility

It is the responsibility of the referrer to ensure that the correct and appropriate details of the patient are recorded on the request form.

The ultimate responsibility for correctly identifying the patient to be exposed lies with the Operator who makes the exposure.

Introduction

This procedure is intended to ensure the correct identification of patients who undergo medical exposures. This procedure applies to all referrals.

Procedure

1.1 Prior to the procedure /examination, the Radiologist / Radiographer (in the role of Operator) must ask patients to state THREE of the following:
   a. Date of Birth
   b. Full name
   c. Address
   d. Hospital or NHS number

1.2 Incapable patient: if the patient is incapable of confirming their own identity, 2 separate forms of identification must be obtained. Examples of this are patient notes, wristband and accompanying personnel. The referral form is not to be used as a method of identification.

1.3 Non-English Speaking Patients: in the absence of an accompanying person, use crib cards or local interpreter if possible or contact switchboard for the interpreter service.

1.4 Unknown Identity: If the identity of the patient is unknown in the cases of trauma, the unique identification number on the wristband /case card provided by the Emergency Department must be used until the real patient details can be obtained. This will either be an IW number or a unique U number.
1.5 Theatre patients: if the patient is sedated/anaesthetised check the wristband or ask the surgeon/nurse in charge to confirm the patient was correctly identified following operating theatre procedures prior to being sedated/anaesthetised.

1.6 Where more than one operator is involved in an exposure, a lead operator responsible for asking the ID questions should be decided.

1.7 In all cases, the Radiographer should also satisfy themselves that the clinical indications given by the patient match those on the request (right side/body part etc). This can be carried out by the following:
   a. Ask “Do you know why you are having this test?”
   b. Do the Clinical details match the request (site/side/symptoms)?
   c. Has any preparation required has been followed?
   d. Confirm with the patient that they have not received imaging suitable for this request recently. This may have been at another hospital.
   e. Is the scheduling of examination correct (if appropriate)?

1.8 If there is any doubt that you have the right patient or investigation then every effort must be made to contact the referrer for confirmation. If this is not possible and it is apparent that an examination is required, re-justification by a practitioner should be considered. All changes must be fully documented.

2) Records
The method used for identifying the patient must be recorded on the Radiology Computer System.

Procedure B to identify individuals entitled to act as referrer or practitioner or operator

1) Responsibility
The responsibility for ensuring that a referral has come from an entitled Referrer lies with the Practitioner who justifies the medical exposure.

The responsibility for identifying Referrers, Practitioners and Operators, checking eligibility and submitting their details for adding to the Organisation lists, lies with the appropriate Manager.

The responsibility for maintaining a current list of Referrers, Practitioners and Operators lies with the Radiology Services Manager.

2) Introduction
IRMER prohibits any Practitioner or Operator from carrying out a medical exposure or any practical aspect without having been adequately trained and authorised by the employer.

An exception is made for trainees where they participate in practical aspects under the supervision of someone who is adequately trained. Decisions on who is entitled to act as a Referrer, Practitioner or Operator are taken at a local level by agreement between the employer and healthcare professions involved in medical exposures. The Ionising Radiation (Medical Exposure) Regulations 2017 require that all Referrers and Practitioners are registered healthcare professionals.

This procedure is intended to ensure that Referrers, Practitioners and Operators are identified and that referrals are not accepted from any other personnel.
3) Procedure

3.1 Referrer

Those entitled to refer patients for medical exposures are listed in Approved Referrers to Radiology List. Where appropriate, the list indicates the type of medical exposure for which they are entitled to make referrals.

Those persons employed as medical practitioners are entitled to refer patients for any radiological investigation. Other appropriately qualified healthcare professionals may be permitted to refer patients for radiological investigation under an agreed ESP as approved by RPG. The names of individual non-medical referrers must be listed on the ESP. The agreement must be documented in accordance with the Trust’s Expanded Scope of Practice Policy.

The application will be assessed by the relevant Medical Physics Expert and the RPG. Once agreement in principle is granted by RPG, responsibility for implementation and governance of the ESP lies with the Clinical or Practice Lead as identified in the ESP. Additional referrers may be added to an ESP if they meet the training and competency requirements in the ESP.

Responsibilities of Referrers are described in Appendix A.

3.2 Practitioner

Any qualified Radiologists (to FRCR part two) are deemed to be IRMER Practitioners within their area of expertise. Radiologists in training will have the scope of their practitioner entitlement defined through their training plan.

Other healthcare professionals, by virtue of primary qualifications and training (e.g. Radiographers), may act as Practitioners for specific and agreed arrangements. The employer will maintain a list of all such Practitioner and any constraints or limitations on their practice.

All practitioners must be adequately trained and undertake CPD activities. Trainees may participate in practical aspects under the supervision of someone who is adequately trained. Practitioners in training will have restricted scope of expertise as agreed with their training supervisor.

Under certain circumstances, Operators may carry out some of the functions of a Practitioner on their behalf. Where this occurs it must be through a documented and agreed process.

Responsibilities of Practitioners are described in Appendix A.

3.3 Operator

Certain healthcare professionals, by virtue of primary qualifications and training, act as Operators within their area of expertise, e.g. Radiographers, Medical Physicists, and Clinical Technologists. Other medical or non-medical healthcare professionals may be given suitable training to enable them to act as Operators with limitations. The employer will maintain a list of all Operators and any constraints or limitations.

All Operators may only undertake the tasks for which their competency has been recorded in their individual training records.

Where more than one operator is directly involved in an exposure the operators must identify between themselves who is the lead operator. The lead operator takes on the operator responsibilities.

Responsibilities of Operators are described in Appendix A.
3.4 Image Evaluators

The responsibility for formal image evaluation lies with the Practitioner; however an agreement may be made with other staff groups to delegate this responsibility when working to an ESP agreed by RPG in keeping with the Trust policy for Extended Scope of Practice.

Those who are entitled to act as Image Evaluators are listed in the Approved IRMER Image Evaluators List.

Responsibilities of Image Evaluators are described in Appendix A.

3.5 Medical Physics Experts

Those who are entitled to act as Medical Physics Expert are listed in the Approved IRMER Medical Physics Expert List and have a letter of appointment which describes the scope of their duties. A named lead MPE will be identified for each area of imaging who bears overall responsibility for MPE activities in that area.

Medical Physics Experts must be registered clinical scientists, appropriately qualified with sufficient and relevant experience in their field of expertise, consistent with the guidance and MPE syllabus given by Department of Health and Social Care. MPEs must hold a valid certificate of competency issued by a body recognised by Department of Health and Social Care to issue such a certificate (e.g. RPA2000), or be named on the RPA2000 register of MPEs until such time as a certificate can be issued.
Procedure C for making enquiries of individuals of childbearing age to establish whether the individual is or may be pregnant

1) Responsibility

The responsibility for establishing the patient’s pregnancy status lies with the Operator who makes the exposure unless the patient is already anaesthetised in theatre. In this case the responsibility lies with the surgeon under whose care the patient has been placed.

2) Introduction

Before exposing individuals to ionising radiation it is important to ensure, as far as is reasonably practicable, that the individual has confirmed that they are not pregnant, and understands the implications behind giving that information. In the case of the administration of radioactive substances it is also important to establish whether the patient is breastfeeding. This response must be documented in the appropriate patient record, e.g. CRIS system in Radiology.

This policy applies whenever a person of reproductive capacity. This is normally women between the ages of 12 and 55, but care should be taken at the boundaries of this range to ensure eligible women are not excluded. Pregnancy status will only be enquired of for X-ray examinations which will irradiate between the knees and diaphragm.

3) Procedure

3.1 Enquiry of pregnancy / breastfeeding status

In order to ascertain that the individual clearly understands the implications of the question it is important that the questioner introduces the question. For example: ‘Radiation can be harmful to any unborn foetus/baby. For this reason it is vital that you tell me if there is even a remote possibility you could be pregnant’ is better than ’Are you pregnant?’

Individuals will require varying levels of questioning probing, according to their age, pain, fear, etc., but this must be done with due regard to their privacy and dignity. However, eventually the Operator must establish whether the patient is or might be pregnant before exposure.

3.2 Privacy and Trust

Where possible, the individual must be given privacy before being asked sensitive questions. Never ask in the waiting room. It may be possible to ask in the changing cubicle if there is no chance of being overheard. The X-ray room/controlled area may be the best place to ask, although this means the patient may have got undressed unnecessarily.

3.3 Female patients under 16 years of age

There is a legal concept known as the ‘Gillick Competence’ which holds that, for a person under the age of 16, valid consent can be given by her (without intervention from a parent or even their knowledge) if, in the opinion of a health professional, she fully understands what is being asked or explained and demonstrate competence to make her own decisions.

Asking in the presence of a parent may not obtain an honest answer. It may be appropriate to say something like: ‘I need to ask your daughter a sensitive question, please would you wait outside the room for a moment?’

In the case of young people, who may not understand, it may be appropriate to first ask: ‘Have you started your periods yet?’ If the answer is negative, there is no need to pursue questioning.
3.4 **Male professionals asking the questions**
Where possible, female staff should ask girls about their pregnancy status. Out of hours, it may be necessary for a nurse to obtain the consent. This must be documented.

3.5 **Unconscious patients**
In the case of unconscious patients it may be reasonable to ask the individual's partner. In this case, the practitioner should be informed of the source of the information, and the decision to go ahead made on the grounds of clinical need. This must be documented.

With patients in theatre, the relevant information must be recorded on the relevant consent form. If this information is missing, assurance must be sought from the anaesthetist or surgeon and an incident report completed.

3.6 **Non English speaking patients**
In the case of patients who are unable to understand English, it may be possible to use an interpreter, but as this is likely to be a relative of the patient, the referring clinician should be informed of the source of the information, and the decision to go ahead made on the grounds of clinical need / patients best interests. This must be documented.

If there is any doubt about the validity of the information, the situation must be decided following discussion between a Radiologist (acting as Practitioner) and the referring clinician.

3.7 **If Pregnancy confirmed or probable**
The justification for the proposed examination or treatment should be reviewed and consideration should be given to deferring the examination or treatment until after delivery. However, a procedure of clinical benefit to the mother may also be of indirect benefit to the unborn child. If the procedure is undertaken, the foetal dose should be kept to the minimum consistent with the diagnostic purpose.

3.8 **Low dose procedure and pregnancy can not be excluded (known as 28 day rule)**
The examination may proceed provided that the period is not overdue. If the period is overdue, the instructions above should be followed.

3.9 **High dose diagnostic procedure (known as 10 day rule)**
High dose procedures should be booked for the first 10 days of the menstrual cycle, when conception is unlikely to have occurred. Patients who attend for high dose examinations and are identified to be in the second half of their cycle, and for whom pregnancy cannot be excluded should be re-booked. The risk to the unknown foetus increases in the months following the first missed period and high dose procedures should only be re-booked if they can safely be postponed until after delivery should the patient prove to be pregnant.

The following examinations are ‘High Dose’:

- CT of abdomen, pelvis, hips or thorax
- Lumbar/Sacral Spine X-ray
- IVU
- Fluoroscopy examinations of the torso (e.g. Barium Enema)

A Radiologist, acting as Practitioner, will make the decision on any complex cases following discussion with the referrer. The referrer may not justify the examination.
Further information and example foetal doses are available in: Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation. Health Protection Agency 2009. ISBN 978-085951635-8

Procedure D to ensure that quality assurance programmes are followed

1) Responsibility
The relevant Superintendents are responsible for producing a programme of audits for Diagnostic Imaging.

2) Introduction
IRMER requires the employer to establish quality assurance programmes for standard operating procedures. Since 6th May 2018, this also includes quality assurance of equipment.

This procedure describes the audit of compliance with the standard operating procedures that is necessary to demonstrate that the procedures are being followed. The procedure is based on audits of the records that are described in each procedure and on the incident reporting system.

3) Procedure

3.1 Audit
Each procedure is subject to audit at least once a year. These audits should form part of the annual clinical audit plan.

A report of each audit is produced which describes deficiencies in compliance or in the procedure that are identified by the audit and may suggest corrective action. Copies of the report are sent to the Superintendent and to the Medical Physics Expert.

Deficiencies highlighted by the audit should be investigated and appropriate corrective action taken. The audit and corrections should be presented at the Trust Radiation Protection Group and the relevant Clinical Governance group should be notified.

A summary of all audits is presented to the Trust Radiation Protection Group

3.2 Clinical Audit
Clinical audits will be used to optimise the IRMER procedures. Clinical audits will be carried out as appropriate within Radiology. A lead auditor will be identified for each audit and is responsible for providing a summary of findings.

3.3 Equipment Quality Assurance
All equipment used for medical imaging using Ionising Radiation will be performance tested prior to first clinical use and at regular intervals thereafter. The guidance given by professional bodies and standards organisations (e.g. IPEM, AAPM, NEMA) will inform the test regime and frequency. Regular performance testing will be carried out by Radiographers and Medical Physics at agreed frequencies, under the direction and supervision of an MPE.

Performance testing will also take place following any modification of equipment which might have an effect on patient dose or image quality. This performance testing may be carried out by local Operators or Medical Physics, but must be under the direction of an MPE.

Any equipment that fails performance tests beyond remedial level may remain in use if corrective action is planned. Any equipment that fails performance tests beyond suspension level will not be used clinically until corrective action has been successfully carried out and the system is deemed safe for use by an MPE.

The performance standards set by the Trust are defined in the Medical Physics Quality Management System.
3.4 Incident reporting

Failure to comply with a procedure is reported using the incident reporting system which ensures that the Superintendent is informed of such failure. The Superintendent considers the implications of the non-compliance and advises the Head of Department or senior Organisation officer on the appropriate action to be taken. This may entail reporting the incident to the Care Quality Commission after advice is sought from Medical Physics/Medical Physics Expert. See Procedure M for more information on incident reporting.

Procedure E for the assessment of patient dose

1) Responsibility
It is the responsibility of the Operator making the exposure to ensure that the required information is recorded.

2) Introduction
This procedure is intended to ensure that sufficient information regarding medical exposures is recorded to enable a retrospective estimation of the radiation dose to the patient.

3) Procedure

3.1 Plain image radiography:
Sufficient information for dose estimation is automatically recorded for direct digital (DR) systems. Where CR is used, the information is entered on the Radiology Information System (RIS). The preferred parameter is the dose-area product (DAP) if available, otherwise the cumulative post exposure mAs value and the highest kV should be recorded. The FDD is taken to be the standard distance according to the relevant protocol.

3.2 Fluoroscopic procedures:
The information is entered on the RIS. The preferred parameter is the dose-area product (DAP) if available; otherwise the highest kV, mA and screening time is recorded.

3.3 CT procedures:
Sufficient information for dose estimation (CTDI\text{vol} and DLP) for all scans is recorded on the CT system.

3.4 Calculating patient doses
When it may be useful to inform an investigation or to provide advice to patients or clinicians a calculation of effective or equivalent dose may be carried out. Such dose calculations will only be carried out under the supervision of a Medical Physics Expert for that modality using a recognised and validated dose calculation technique and using accepted radiation risk factors. The radiation and tissue weighting factors used should be those recommended by the International Commission on Radiological Protection report (in ICRP Report 103 or superseding reports) in the first instance and where further detail is required age and sex factors are pertinent HPA-CRCE-028 Radiation risks from medical X-ray examinations as a function of the age and sex of the patient HPA, Chilton 2011 or relevant ICRP publications for radionuclide doses

Any dose calculated will be indicative of the actual patient dose based on population averaged dose models but there may be significant error in the calculation, depending on the information available. Where possible the MPE should state the error in the calculation.
3.5 Making doses available

Patients should be provided with information about the radiation dose of their exposure where this is practicable to do so. This should be provided alongside the benefit received from their exposure. This will be ideally in their appointment letter but can be given at any time prior to exposure in written or verbal form. See Procedure I for more details.

Referrers may also request information about standard exposures* carried out by the Trust. Where an effective dose can be meaningfully calculated this will be presented alongside DRL values and made available on Staffnet for internal referrers. The list is available on request from Radiology for outside referrers or the doses in iRefer can be referenced.

*standard exposures are those carried out at least 50 times per year for adults or 20 times per year for paediatrics.

3.6 Collecting doses

Medical Physics will coordinate the collation of dose estimates from medical exposures taking into account age and sex distributions as appropriate. This information will be provided on request to Public Health England, Department of Health and Social Care or other authorised bodies.

Procedure F for the use of diagnostic reference levels

1) Responsibility

Diagnostic Superintendents are responsible for supplying the relevant data to the Department of Medical Physics, University Hospital Southampton.

2) Introduction

This procedure is for the use of diagnostic reference levels (DRLs) established by the employer for common diagnostic examinations. Patient doses are not expected to be exceeded DRLs for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. DRLs apply only to standard size patients.

Diagnostic reference levels (DRLs) are intended to be used as one of the many tools to ensure that the radiation dose to patients is optimised. The units of the DRL should relate to a dose measurement available on the equipment (e.g. cGy.cm², mGy, mGy.cm).

Locally set DRLs should not exceed the national reference doses published by Public Health England (PHE). If, after corrective action has been taken, it is not possible to keep a DRL below a reference dose, justification of this situation should be recorded.

3) Procedure

3.1 Procurement of equipment

A dose-area product meter is included in the specification of all new plain radiographic equipment, with the exception of mammographic units. For CT scanners, a display of dose-length product is included. Any other equipment must have a display of patient dose in a relevant format.

Any new equipment purchased must have the ability to transfer dose data electronically.

3.2 Setting of DRLs

The setting of a local DRL requires the supply of relevant information to Medical Physics at Southampton. This may be in the form of exposure factors, DAP readings, screening times or DLP
values. Medical Physics will provide template forms or advice on information to be extracted from RIS/PACS.

The Department of Medical Physics collates the information provided and where there are sufficient data, sets a local DRL at the third quartile or the national or European reference dose value, whichever is the lower.

### 3.3 Monitoring of patient dose against DRL

The data will be collected periodically over a calendar year and used to set the local DRL for the following year. DRLs are available in the exam rooms for radiographers to check if they are consistently exceeding a DRL. The mean dose data is compared with the DRL when it is provided and an investigation is made by the relevant department if the mean dose exceeds the DRL.

### 3.4 Investigating consistently exceeded DRLs

Where audit or operator awareness has shown that a Local DRL has been regularly exceeded Medical Physics will work with the Superintendent to investigate the cause and if appropriate suggest a remedy.

If action cannot be carried out to reduce the DRL, such as where change of practice has changed the procedure dose or equipment age has reduced performance, it may be appropriate to set a new DRL at a higher level. If this exceeds the corresponding national or European DRL, a justification should be given.

**Procedure G to be followed for biomedical and medical research programmes**

1) **Responsibility**

The Principal Investigator is responsible for ensuring that the ‘radiation’ sections of the National Research Ethics Service (NRES) form are completed as appropriate and in consultation with the Medical Physics Expert (MPE) and Clinical Radiation Expert (CRE). The MPE will set the dose constraints for research exposures and supply the dose and risk assessment.

The Principal Investigator is responsible for informing Practitioners and Operators of the dose constraints, for the recording and monitoring of the dose received by each volunteer/patient and reporting any adverse variation to the Director of R&D and the MPE.

For studies involving the administration of radioactive material, the Principal Investigator is responsible for ensuring that the appropriate doctor obtains an ARSAC certificate for the study and that this is renewed as appropriate.

The Referrer is responsible for indicating on each referral that the exposure will form part of a research procedure and should state the name of the trial.

2) **Introduction**

In the case of research exposures, a dose constraint must be applied to all imaging procedures within the trial. The Practitioner and Operator must comply with requirements of the trial and the dose constraints set within the trial and locally.

3) **Procedure**

Dose constraints must be set for the following:

a) volunteers or patients for whom the exposure to ionising radiation has no net benefit

b) patients for whom the exposure to ionising radiation might reasonably yield improved clinical management and therefore derive some benefit.

c) patients for whom the exposure to ionising radiations might reasonably derive a net therapeutic benefit.
The agreed dose constraints are monitored on a project by project basis by Trust R&D Coordinators who will only sign off the R&D Project when satisfied that the dose constraint has been considered and compliance will be achieved. The Principal Investigator is responsible for recording and monitoring the dose received by each volunteer/patient against the dose constraint and reporting any adverse variation to the Director of R&D and the Medical Physics Expert.

**Procedure H: Giving of information and written instructions**

1) **Introduction**

There are no administrations of radioactive materials to patients in Radiology, so there is no requirement under this procedure.

**Procedure I: Patient Information on Benefits and Risks of exposures**

1) **Introduction**

The aim of this procedure is to ensure that all patients are given adequate information relating to the benefit of diagnosis and risk associated with the radiation dose from the radiation exposure. Information should be provided prior to entering the examination room to avoid any implicit bias or persuasion in the information given. Information need only be provided when to do so is practicable.

2) **Responsibility**

Clerical staff are responsible for sending the appropriate information sheets with appointment letters.

Operators are responsible for checking that information has been given before exposures take place.

3) **Procedure**

For booked examinations, information will be provided prior to exposure in written form as part of the invitation letter or a separate information sheet. For other examinations, information should be provided to patients or their representatives immediately prior to investigations, unless it is not practicable to do so.

The information provided must include the specific benefit to the patient (i.e. outcome of clinical question) and the risk to a typical individual as a result of intended radiation exposures. Where appropriate, radiation doses should be used (based on DRLs or individual planned doses) and compared to everyday risks or equivalent natural background radiation.

Where radiation doses are below 50 mSv it is acceptable to use a risk descriptor from the table below:

**Radiation Risk Descriptors (based on “X-rays – how safe are they?” - NRPB 2001)**

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Maximum Dose</th>
<th>Cancer Risk Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>0.02 mSv</td>
<td>&lt; 1 in a million</td>
</tr>
<tr>
<td>Minimal</td>
<td>0.2 mSv</td>
<td>1 in a million to 1 in 100,000</td>
</tr>
<tr>
<td>Very Low</td>
<td>2 mSv</td>
<td>1 in 100,000 to 1 in 10,000</td>
</tr>
<tr>
<td>Low</td>
<td>20 mSv</td>
<td>1 in 10,000 to 1 in 1000</td>
</tr>
</tbody>
</table>
Some typical Radiation Doses for comparison:
Natural background radiation in UK is around 2.3mSv per year (0.2mSv per month / 6µSv per day)
Flights: UK to Spain 20 µSv
        UK to USA  80 µSv
        UK to Australia 0.2 mSv
If practicable, operators should verify that this information has been given to the individual prior to exposure.
Where it is not practicable to deliver the information before exposure to either the patient or their representative, (e.g. language or diminished capacity issues may lead to overestimation of the risk, the patient is unconscious or insensible or the necessary delay in imaging would be detrimental to the patient's health) this information does not need to be provided.
All women should be made aware of the effects of ionising radiation on the unborn foetus and breastfeeding infants through the use of posters and signs in waiting areas and standard information included with invitation letters.

4) Records
A record should be made when this information is provided in a non-standard format (e.g. verbally), or where it was not practicable to deliver the information prior to exposure.

Procedure J for carrying out and recording of an evaluation for each medical exposure

1) Responsibility
The responsibilities for evaluating and recording the evaluation of a medical exposure lie with the Practitioner. Under certain circumstances this is responsibility is delegate to another staff group (as listed in Appendix D).

2) Introduction
This procedure is for carrying out and recording of an evaluation for each medical exposure including factors relevant to patient dose.
All radiographs and radiographic procedures must be formally reported in a time period appropriate to the clinical requirements of the investigation. There must be a record of every clinical evaluation of a medical exposure and of the factors relevant to patient dose.

3) Procedure
There are four ways in which diagnostic exposures may be evaluated:
1. a single, medically qualified member of staff (doctor) or appropriately trained reporting radiographer may evaluate the image and report his/her findings
2. a non-medically qualified member of staff may undertake a preliminary evaluation of the image which can lead to a clinical intervention before the image is evaluated and reported by a doctor or reporting radiographer
3. a non-medically qualified member of staff may undertake an autonomous evaluation of the image and report his/her findings and the image is never seen by a doctor.

Non-medically qualified members of staff who wish to undertake reporting (i.e. as in 2 & 3 above) must submit an application for expanded scope of practice to Radiology. They may not commence this practice until they have been notified that their application has been successful and they have been added to the electronic Expanded Practice list. Meeting the recommended training criteria is a condition of approval to practice.

Every radiological episode that is not evaluated by a Radiologist or Reporting Radiographer must have its evaluation documented in the patient’s case notes. The record must include a full clinical evaluation of the episode. The table in Appendix F lists the examinations for which the evaluation is not undertaken by a Radiologist (delegated reporting).

A record of the dose-area product (DAP) reading or exposure factors (cumulative mAs and highest kVp) are recorded on the radiology computer system by the Operator.

4) Records

For episodes reported by a Radiologist or reporting radiographer, the report is made using the CRIS system and the report is retained on the system.

For episodes reported by other clinicians, the evaluation is recorded in a patient record. An evaluation referral form when used will ensure that a report indicating clinical evaluation is recorded on CRIS.

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

1) Introduction

This procedure is intended to minimise the risk of accidental or unintended doses to patients so far as reasonably practicable. This process starts with the selection and installation of the equipment and continues through to the actual exposure of the patient.

2) Responsibility

2.1 Procurement of equipment

The individual department is responsible for ensuring that an appropriate specification is produced prior to the purchase of equipment.

2.2 Consideration of non-ionising alternatives

The Practitioner is responsible for ensuring that other appropriate techniques are considered in preference to those using ionising radiation.

2.3 Equipment

The Lead Superintendent Radiographer is responsible for the QA programme of equipment and for ensuring adequate training of the staff operating the equipment.

2.4 Exposures

The Operator making the exposure is responsible for ensuring that the dose to the patient is optimised. Only appropriately trained operators are allowed to make exposures. Those in training may do so under supervision.
2.5 Training
The department manager is responsible for training, however this will normally be delegated to the Lead Superintendent who will ensure adequate training of radiography staff operating the equipment and the Clinical Lead will ensure adequate training of radiologist staff operating the equipment.

2.6 Incident Learning
The department manager is responsible for ensuring that learning from incidents is appropriately disseminated and integrated into working practices.

3) Procedure
All practical aspects of medical exposures are conducted with due regard to minimising unintended doses to patients.

3.1 Procurement of equipment
The specification of diagnostic equipment to be purchased includes appropriate safety devices and dose-reduction features, commensurate with current best practice. The relevant Medical Physics Expert must be involved in the specification of all new equipment.

Diagnostic radiology equipment is only to be installed in suitably protected rooms.

Installations are subjected to a prior risk assessment as required by the Ionising Radiations Regulations 2017.

Installations are subjected to a critical examination as required by the Ionising Radiations Regulations 2017 and acceptance tested as required by IRMER.

Non-installed equipment should be subject to the same level of scrutiny and risk assessment before use.

3.2 Consideration of non-ionising alternatives
Consideration is given to the use of imaging techniques that employ non-ionising radiation in preference to those that use ionising radiation.

3.3 Equipment
Equipment must be maintained according to manufacturers' instructions.

Equipment must be subject to a documented QA program.

Diagnostic equipment that shows signs of a fault must be withdrawn from service until it has been examined and passed as fit for purpose by a qualified engineer or by Medical Physics.

Equipment which has been modified in any way which may affect the dose to a patient will be performance checked before returning to clinical use.

3.4 Exposure
The patient is positioned by an appropriately trained operator. Diagnostic exposure factors are chosen by an appropriately trained operator.

When new clinical techniques are introduced, it is particularly important that the Medical Physics Expert should be involved in the optimisation of exposure.
3.5 Training

The manager in each area will ensure that all staff working as Operators or Practitioners have received adequate training to carry out their role (as defined in IRMER Schedule 3). An up-to-date record of dates and nature of adequate training will be kept in each area.

Any other Employer contracted to provide operators or practitioners must provide evidence of adequate training immediately on request.

Any person in training may carry out operator or practitioner roles if they are adequately supervised by a trained and competent person, entitled to carry out that role.

3.6 Pause and Check

Immediately prior to any radiation exposure, the operator should Pause and Check to confirm at least the following:

- Right Patient (check ID)
- Pregnancy Status Checked (check pregnancy)
- Right Examination/Laterality (check referral)
- Right Timing (check referral)
- Right Exposure Settings or Dose/Radionuclide (check equipment)
- Right Detector (check equipment)

The process for pause and check does not require to be documented.

3.7 Review of Practice

To ensure that quality of imaging is continuously improved, processes and procedures are reviewed on a regular basis.

3.8 Incident Follow up

Where the outcome of an incident results in actions to reduce the likelihood of reoccurrence of incidents, these are integrated into practice through review of documentation and dissemination of key learning points in team meetings and via email messages to staff.

3.9 Expert Advice

Medical Physics experts will be involved in diagnostic and therapeutic nuclear medicine, high dose interventional radiology and CT.

Medical Physics experts will be available for consultation for all other radiological practices.

The scope of the advice of MPEs on a regular basis must include:

- Dosimetry
- Quality Assurance
- Radiation Protection
- Equipment support
- Measurement of radiation contributing to patient dose

MPEs must also contribute to the following matters, liaising with an RPA or RWA where appropriate:

- Optimisation, including use of DRLs
- Quality assurance of equipment (Regular and Acceptance testing)
- Technical Specifications for new equipment and facilities
- Surveillance of medical radiological installations
- Investigation of incidents
• Selection of test equipment
• Training of staff in radiation protection
• Compliance with IRMER 2017

Procedure L for reporting of clinically significant incidents involving ionising radiation

1) Responsibility
The Superintendent is responsible for ensuring that relevant Adverse Event report forms are sent to Medical Physics. The Superintendent is responsible for ensuring that Risk Management is notified of incidents requiring reporting to a regulatory authority.
The member of staff identifying an incident is responsible for the initial reporting on Datix.

2) Introduction
This procedure is intended to ensure that incidents involving ionising radiation are recorded on the Organisation’s risk management database and, where appropriate, reported to the relevant regulatory authority.

3) Procedure
When an incident is identified, it should be entered on Datix as soon as possible.
All incidents involving ionising radiation should be sent to the Radiation Protection Adviser and Medical Physics Expert. They will identify if the incident is externally reportable. Timely reporting is essential and must comply with the Trust Incident Reporting and Management policy.

On receipt of an incident report the RPA will inform the relevant Medical Physics Expert (MPE) and they will together carry out an initial investigation and decide if the event is reportable to a Regulatory Authority as a Significant Accidental or Unintended Exposure (SAUE) or Clinically Significant Accidental or Unintended Exposure (CSAUE), including calculating the patient dose, if relevant. This decision will normally be informed by the following table (where an exposure has actually occurred):

All externally reportable incidents must be notified to CQC within 2 weeks of the incident occurring.

1. Accidental Exposures – where the patient was not intended to have any exposure

<table>
<thead>
<tr>
<th>Notification Code</th>
<th>Exposure Category</th>
<th>Criteria for Notification</th>
</tr>
</thead>
</table>
| 1                 | All modalities    | 3mSv effective dose or above (adult)  
|                   |                   | 1mSv effective dose or above (child < 18) |

2. Unintended Exposures – where the exposure was more than intended

<table>
<thead>
<tr>
<th>Notification Code</th>
<th>Exposure Category</th>
<th>Criteria for Notification</th>
</tr>
</thead>
</table>
| 2.1               | Intended dose less than 0.3mSv | 3mSv or above (adult)  
|                   |                   | 1mSv or above (child) |
| 2.2               | Intended dose between 0.3mSv and 2.5mSv | 10 or more times than intended |
| 2.3               | Intended dose between 2.5mSv and 10mSv | 25mSv or above |
### 2.4 Intended dose more than 10mSv

#### 2.5 or more times than intended

<table>
<thead>
<tr>
<th>Notification Code</th>
<th>Exposure Category</th>
<th>Criteria for Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Intervventional / Cardiology</td>
<td>Where there has been NO procedural failure AND 10 or more times the Local Diagnostic Reference Level AND/OR observable deterministic effects excluding transient erythema</td>
</tr>
<tr>
<td>5</td>
<td>Foetal</td>
<td>Where there has been a failure in the procedure for making pregnancy enquiries AND the resultant foetal dose is 1mGy or more</td>
</tr>
<tr>
<td>M</td>
<td>More than one individual exposed within the same incident/theme.</td>
<td>All cases regardless of dose</td>
</tr>
</tbody>
</table>

If the incident is reportable, the Medical Physics will inform the Superintendent. The Superintendent and Medical Physics will liaise with the relevant managers and the Risk Management Department regarding the notification. Medical Physics and Superintendent should agree on who will report the incident, this will normally be the RPA or MPE from Medical Physics. This person will be the point of contact for the external reporting of this incident.

The Superintendent will ensure that an investigation regarding the circumstances and causes of the incident is undertaken and that a suitable report, with supporting documentation, is written. When the report is complete the Superintendent forward the report to the RPA/MPE and send copies to relevant parties, including Risk Management and External Bodies.

**Being Open**

The Trust’s Being Open and Duty of Candour Policy requires that the patients are informed of any incident involving them, with the exception of “no harm” incidents. The level of harm to be considered are:

- **‘No harm’** – The incident had potential to cause harm, but harm was prevented and no harm was caused to the patient OR the incident was not prevented, but no harm came to the patient.
  
  All plain film diagnostic examinations carried out in error are in this category (and any other examination with a total dose of >2mSv).

- **‘Low harm’** – Any patient safety incident that occurred but no harm was caused to the patient.
  
  The majority of CT examinations carried out in error are in this category (2-20mSv).

- **‘Moderate harm’** – Any patient safety incident that required extra observation or minor treatment and caused minimal harm to one or more patients.
  
  This kind of incident implies deterministic radiation injuries such as might occur in cardiology or interventional radiology (skin burns). This kind of injury is only an accident if it could not reasonably have been prevented in the course of treatment.

  Moderate harm applies if this unintended/accidental dose exceeds 20mSv.
A patient safety incident is defined as “any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care”.

‘Severe harm’ – Any patient safety incident that appears to have resulted in permanent harm (defined as harm that is enduring and cannot be rectified by treatment) – related directly to the incident and not to the natural course of the patient’s illness or underlying condition. This is extremely unlikely in diagnostic imaging unless the result incorrect action following misreporting of imaging.

IMPORTANT: Moderate and Severe Harm incidents fall under Duty of Candour requirements and are CSAUE events.

Information for Staff informing Patients of Incidents

The majority of diagnostic examinations carried out in error will be no harm events as there will be no definitive harm to the patient. There will be an increased risk of cancer as a result of the additional exposure but even a relatively high dose examination (e.g. CT Head+CAP with cancer risk of 1 in 1000 or 0.1%) is unlikely to significantly increase the patient’s overall risk of cancer (1 in

Therefore any cancer later in the life of the patient cannot be definitively traced to a single radiation exposure at this dose level.

Patients may struggle to understand risk and the magnitude of risks. It is therefore necessary to avoid overstating the risk and causing the patient unwarranted anxiety. For low levels of risk it is sufficient to apologise to the patient that an examination needs to be repeated. It is important, that the patient is told in a way that will not cause him/her unnecessary alarm.

The dose descriptors in procedure I may be used as a guide.

Where psychological harm (for greater than 28 days) is likely to occur this will increase the harm rating of the event and the patient should be informed in a sensitive manner.

For moderate and above incidents (CSAUE), the patient, Practitioner and Referrer must be notified of the investigation and outcome. The Practitioner responsible for that exposure is responsible for deciding how and when the patient should be notified. In exceptional circumstances it may not be appropriate to notify the patient; in such cases this decision, with its reason(s), should be documented in the patient’s notes. For patients who have left the hospital and do not require a recall, the Practitioner may write to the patient to notify him/her of the exposure but reassuring the patient to avoid unnecessary anxiety.

Where an incident causes severe harm, or it is useful in communicating with the patient, full access to the internal investigation may be given to the patient.

Procedure M to be observed in the case of non-medical imaging

1) Responsibility
The Practitioner is responsible for deciding whether the requested procedure falls into the category of a non-medical exposure.

The responsibility for adherence to the appropriate protocol lies with the Operator.

2) Introduction
Non-medical imaging means a procedure performed on medical imaging equipment but not for the purpose of diagnosis, for example insurance, medical report or legal purposes without a medical indication and with no direct health benefit to the individual exposed. There may be an medical benefit to the individual or society.
3) Procedure

The patient must be made aware that they will receive a small radiation dose that is not for their medical benefit. Possible non-medical examinations outside those listed below are possible but must only be carried out after a clinical protocol is agreed.

3.1 Emigration Chests

These are not done for the direct medical benefit of patient, but can be justified as a 'benefit to society' (regulation 6(2) b) and are an entry requirement for various countries for TB screening etc. These examinations can only be done when accompanied by a request form signed by a medical practitioner. The Radiographer must ensure that all the necessary paperwork and identification procedure (e.g. Radiographer signing photograph) is correct before the examination so that it is not invalidated for administrative reasons.

3.2 For ingested / inserted drug packages or contraband

This should only be performed if for the direct medical benefit of the patient, with adherence to all the normal safeguards relating to medical exposures, including the consent of the patient. For example, if there is a danger of bowel perforation or rupture of ingested drug package. If requested purely for litigation or prison discipline reasons, then other techniques such as ultrasound should be used if possible.

3.3 Radiography of Patients Sectioned Under The Mental Health Act

The Mental Health Act permits treatment for psychiatric conditions, but not medical ones. Therefore 'sectioned' patients cannot be forced to undergo radiological investigation against their will.

A Court order is necessary before any examination can be undertaken against the patient's will. In this event the radiographer must see the necessary order and only proceed with the approval of a Consultant Radiologist.

Procedure N for justification and authorisation of medical exposures

1) Responsibility

The Practitioner is responsible for the justification of the medical exposure or for producing written guidelines for “authorisation as justified” by the Operator where appropriate.

For the avoidance of doubt, the Clinical Lead for Radiology will be the Practitioner for all examinations authorised under protocol by an Operator, unless otherwise stated.

The Clinical Standards Group is responsible for recognising referral criteria and administrating delegated authorisation on behalf of all Practitioners.

Only Specialist Registrars in Radiology with sufficient training and Radiographers are permitted to authorise on behalf of the Practitioner.

The Lead Operator must ensure that the name of the person who authorised the exposure (the Practitioner) or the person who “authorised as justified” on behalf of the Practitioner (the Operator) is recorded on CRIS.

2) Introduction

No medical exposure is permitted unless it has been justified as showing a sufficient net benefit. The justification is normally made by the Practitioner but the regulations recognise that this may not always be practicable. The Operator may authorise certain individual exposures following guidelines written by the Practitioner.
3) Procedure

3.1 Criteria for the basis of justification

All referrals must be based on the Trust’s referral guidelines. The Trust recognises the most recent edition of the Royal College of Radiologists’ imaging referral guidelines, “iRefer” as the de facto standard of referral guidelines.

Alternative referral criteria may be accepted if they supersede the latest RCR guidance or are for examinations not described in iRefer or describe specific local arrangements. These alternative criteria should be supported by a recognised as best practice by another professional body.

Referral criteria for research studies are dealt with in G: Procedure to be followed for biomedical and medical research programmes.

The information provided by the referrer (supporting medical information or previous imaging) and information available within CRIS or PACS (previous imaging history) should be taken into account when considering justification.

The justification must ensure sufficient net benefit to the patient, considering:

a) the objective of the investigation and characteristics of the individual
b) direct health benefit to the individual or society
c) the individual detriment that the exposure may cause
d) the efficacy of alternative techniques
e) pregnancy status (also considering net benefit to unborn foetus)

The Practitioner is required to give special consideration to the urgency of the exposure for individuals where pregnancy or breastfeeding cannot be excluded and is relevant to the examination.

For asymptomatic individuals exposed through a screening programme, for early detection of a disease or for a specific justification for that individual, any guidelines issued by medical scientific societies, relevant bodies should be considered.

For exposures on paediatrics, justification should be provided by a Specialist Paediatric Radiologist wherever possible and always for high dose examinations (except where a delay would be detrimental to the health of the individual).

Where exposures will be authorised as justified by an Operator, the referral criteria to be considered will be noted in the guidelines. For plain film examinations carried out by qualified Radiographers, the iRefer guidelines will be used unless otherwise stated in Appendix D. For other examinations see Appendix D for guidelines.

3.2 Justification by Practitioner

When a Practitioner identified in the list of Practitioners undertakes the justification, the Practitioner makes a record that this has been done. This may be by signing the request card, a record on the Radiology Information System or in the patient’s notes.

If the Practitioner is unable to justify an exposure the Practitioner should contact the Referrer for more information or return the request card or referral letter stating why the exposure cannot be justified.

When a Practitioner has justified an exposure that requires specific instruction to the Operator this should be included in the protocol notes included on CRIS. Particular care should be taken to
ensure these notes are clear and unambiguous, especially when planning exposures on children and pregnant individuals.

### 3.3 Authorisation by Operator

Practitioners may produce written guidelines to enable Operators to authorise an individual medical exposure as justified. The guidelines must include examples of when an exposure is NOT justified. Such guidelines must be approved by the Clinical Standards Group or Clinical Lead for Radiology.

The Clinical Standards Group permits all Radiographers to authorise plain film examinations requests which comply with the most recent RCR guidelines (iRefer) and main departmental imaging guidelines. For other examinations written guidelines issued by the Practitioner must be followed. See Appendix D for details of how this is implemented.

The Clinical Standards Group permits all Radiographers to authorise Carer and Comforter exposures which comply with criteria in Procedure c). For other examinations written guidelines issued by the Practitioner must be followed. See Appendix D for details of how this is implemented.

An Operator who authorises an exposure which does not accord with the guidelines is acting unlawfully; the Operator's action does not change the status of the Operator to that of Practitioner.

A record of the authorisation must be made. This may be by signing the request card, a record on the radiology computer system or in the patient's notes.

If the Operator is unable to authorise an exposure because it does not comply with the guidelines, the Operator should take one of the following courses of action:

- a) refer to a Practitioner
- b) contact the Referrer for more information
- c) return the request card (or referral letter) stating the reason for return

### Procedure O: Carers and Comforters

#### 1) Introduction

This procedure relates to exposure of those supporting an individual during the exposure that individual. Dose constraints and guidance for the exposure of these individuals must be produced. Each exposure must be justified in the context of the individuals’ positive effect on the imaging process and the radiation detriment that results.

#### 2) Responsibility

The Practitioner is responsible for deciding whether a comforter and carer exposure is justified and for setting the dose constraint.

The Operator is responsible for ensuring that consent is received and that the dose constraint should not exceeded.

The relevant MPE will provide guidance as to likely effective doses.

#### 3) Procedure

##### 3.1 Requirement

There is no lower dose limit below which the exclusion from the Carer and Comforter requirements applies. In all cases a number of safeguards should be in place to ensure doses are optimised:

- The need for imaging, and the likely success of imaging should be reviewed prior to any assistance being provided to the patient.
- Mechanical restraints or tools should be used in preference to persons
Family members or friends should always support in preference to members of staff. Where a staff member regularly supports patients, a number of staff members should be exposed in rotation rather than a single person (dose sharing).

The dose to a person supporting another during all diagnostic radiology plain film examinations is much less than 0.1mSv. This should be considered a dose constraint for the purposes of IRMER. No person may support a patient undergoing an interventional X-ray procedure.

In all cases a record of supporting or holding a patient should be kept such that a retrospective dose calculation can be made for the person supporting or holding and they can be identified. This applies to staff and volunteers (as occupational exposures) as well as family and friends of the patient.

3.2 Justification and Consent

Where it is deemed necessary to expose a Carer and Comforter, the exposure is only justified if it would show a sufficient net benefit. The Practitioner should consider:

- The likely direct benefit to the patient
- The possible benefits to carer or comforter
- The detriment the exposure may cause

Before the exposure is to be carried out:

- The comforter or carer’s details should be recorded on CRIS and exposure authorised by the practitioner for the medical exposure.
- An individual assessment of the likely dose should be made by an MPE, providing an effective dose and equivalent risks in terms of everyday occurrences (e.g. background radiation, flights to Spain). This will inform the dose constraint set for the Comforter and Carer.
- The practitioner or operator must explain to the Carer and Comforter the risks associated with the exposure.
- The Carer and Comforter must sign to confirm they are knowingly and willingly exposed.

Should a calculated dose constraint exceed 5mSv for the episode of care, the provision of care or the caring arrangements should be re-evaluated.

8. Consultation

In the production of this document, the following have been consulted:

Radiation Protection Group
Radiography Staff
Radiation Protection Adviser
Medical Physics Experts

9. Training

These procedures will be placed on the Trust’s intranet.

Radiation Protection Supervisors and Radiology Specialist Managers will be informed of any revision.

Changes in these procedures will be notified to staff at staff meetings and meetings of Radiation Protection Supervisors

Staff using ionising radiation have access to Radiation Protection Supervisors, Radiation Protection Advisers, etc.

Every policy, and any other procedural document that has training requirements must have one of the statements below within the implementation/training-awareness section.
“Procedures for Ionising Radiations (Medical Exposures) does not have a mandatory training requirement but the following non-mandatory training is recommended:

- Radiation Protection Training for Non-Medical Referrers.

Any new proposals regarding mandatory training must be done in consultation with the Mandatory Training Group.

10. Monitoring Compliance and Effectiveness

Compliance monitoring is required from within this policy under Procedure F. Audits of all procedures should be undertaken regularly and reported back to Trust Radiation Protection Committee (RPC). The RPC will be responsible for recognising and correcting incorrect activity.

11. Links to other Organisational Documents

Policy for safe use ionising Radiation
Expanded Professional Practice Policy

12. References

Legislation applying to the safe use of Ionising Radiations for medical use:
The Medicines Act 1968
The Medicines (Administration of Radioactive Substances) Regulations 1978
Ionising Radiations Regulations 2017 (IRR)
Ionising Radiation (Medical Exposures) Regulations 2017 (IRMER)
Radioactive Substances Act 1993 (RSA 1993)
Environmental Permitting Regulations 2010 (EPR10)

13. Appendices
Appendix A

Roles and Responsibilities of Duty Holders

This appendix describes the responsibilities of duty holders under IRMER at IOW. To act as a duty holder for any of these roles at IOW, you must accept these responsibilities. All duty holders are expected to be familiar with, and to comply with the Radiology IRMER employers procedures (available on staffnet).

IRMER Referrer

- Accurately identify the individual for referral.
- Clearly state the clinical question to be addressed.
- Provide accurate, relevant and complete clinical details for the individual to allow justification of the exposure (including details of previous imaging or relevant events).
- Where possible give an indication of pregnancy status.
- To make every effort to contact the practitioner and operator when a referral error is discovered.
- Where appropriate, inform patients of a radiation incident.

IRMER Practitioner

- Provide justification for exposures based on the information provided
- Judge referrals against the most up to date referral criteria (as recognised by NHSBSP, RCR and other professional bodies), with preference for non-ionising and low dose techniques.
- Carry out the justification process with additional care and attention for pregnant individuals and children.
- Reject referrals that are inadequate or incomplete.
- Provide written instructions for operators who authorise diagnostic exposures on the practitioner’s behalf with the aim of keeping doses ALARP.
- For every exposure authorised, to ensure that a written evaluation of that exposure will take place (through an agreed delegated reporting ESP if required).
- Participate in clinical audit to ensure best practice.
- Participate in optimisation studies with the aim of reducing patient dose.
- To cooperate with Operators, other specialists and staff regarding practical aspects of exposures.
- Where appropriate, follow up potential tissue injury (e.g. skin burns)
- Where appropriate, inform patients of a radiation incident.
- To report infringements of the IRMER regulations when they are discovered.
- To hold a ‘practitioner’ licence to administer radioactive materials (if relevant)

IRMER Operator (LEVEL A – human exposures)

- Correctly identify the individual and examination required prior to the exposure.
- Determine pregnancy status prior to exposure.
- Operate equipment in a safe and controlled manner, in keeping with the ALARP principle and within the limits of individual competence and training.
- Record the exposure factors or administered activity for each exposure or series of exposures.
- Where permitted, to authorise exposures on behalf of the practitioner.
- Carry out the examination as directed by the practitioner.
- Participate in optimisation studies with the aim of reducing patient dose.
- To cooperate with Practitioners, specialists and other staff regarding practical aspects of exposures
- To inform Medical Physics and IISS when equipment fails.
- Where appropriate, inform patients of a radiation incident.
- To report infringements of the IRMER regulations when they are discovered.

**IRMER Operator (LEVEL B – non-human exposures only)**

- Operate equipment in a safe and controlled manner, in keeping with the ALARP principle and within the limits of individual competence and training.
- To carry out routine quality control checks on equipment
- To inform Medical Physics and IISS when equipment fails.
- To inform LEVEL A operators of any change in equipment performance.

**IRMER Medical Physics Expert**

- Advise the employer on optimisation, specifically relating to equipment procurement, exposure protocols, patient dose reduction techniques and image processing.
- Carry out a 'physics level' quality assurance programme for all equipment used for medical exposures.
- Calculate patient radiation doses when required for incidents and research ethics applications.
- Assist with organisation of dose audits and the setting of diagnostic reference levels.
- Advise on the suitability of local equipment for research exposures.
List of Authorised Referrers

Registered Medical or Dental Practitioners from the following organisations may refer for radiological investigations:

Isle of Wight NHS Trust
Primary Care
University Hospital Southampton NHS Foundation Trust
Royal National Hospital for Rheumatic Diseases
Portsmouth Hospitals
Salisbury Hospitals
Odstock Plastic Surgery Dept.

The following medically qualified personnel may refer for radiotherapy to mainland centres:

Oncologists

Other staff groups

Designated Radiographers

Mammographer-with COR Mammographic Certificate of Competence
Trainees under the auspices of their Consultant

Coroner / Police / Social services / Judges / JPs

Named Nurse Practitioners, extended role health practitioners (As listed in expanded practice file)

Type(s) of medical exposure

Diagnostic Imaging
Breast Screening
All
Non-medical imaging

Limited low dose examinations as per protocol
### APPENDIX C

**List of Authorised Practitioners**

<table>
<thead>
<tr>
<th>Staff groups</th>
<th>Type(s) of medical exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant Radiologists</td>
<td>Diagnostic &amp; Interventional Imaging procedures</td>
</tr>
<tr>
<td>Mammographer with COR Mammographic Certificate of Competence</td>
<td>Breast Imaging and Assessment</td>
</tr>
</tbody>
</table>

*A current list of all staff eligible to act as Practitioners is held by Radiology*
APPENDIX D

Guidance on ‘Authorised as Justified’ Process

Where it is not practical for the Practitioner to justify and authorise exposures, they may provide written guidelines to the Operator on when authorisation is permitted. These examinations are ‘pre-justified’ on the basis of a well defined clinical situation. Any situation which does not fit with the situations below must be passed back to a qualified and trained practitioner.

The following rules apply for adults only (except where indicated).

**Planar Diagnostic X-Ray Imaging**

Qualified Radiographers who are IRMER Operators may authorise any examination listed in iRefer where the appropriate indications and contra-indications match the request. Where a local variation to iRefer exists this is documented in the departmental examination protocols.

Agreed by: [Name] Clinical Lead for Radiology (date)

**Cross-Sectional Diagnostic X-Ray Imaging (CT)**

This is outside the normal scope of practice for Radiographers so is dealt with by an extended scope of practice agreement (ESP). ESPs are approved by the Clinical Standards Group where the lead Practitioner is represented.

Specialist Registrars may authorise as justified where it is within their scope of practice as described in the SpR training records and a Consultant Radiologist is not immediately available.

In both cases, any uncertainty in how to proceed should result in deferring the request to a Consultant Radiologist (on-call when out of hours).

Under no circumstances may paediatric cases be authorised as justified by an Operator.

Agreed by: [Name] Clinical Lead for Radiology (date)

**Fluoroscopic Diagnostic X-Ray Imaging**

Where an ESP exists which details clinical indications, any operator listed in the ESP may authorise as justified.

Agreed by: [Name] Clinical Lead for Radiology (date)

**Interventional X-Ray Imaging (inc. Cardiology)**

Operators are not permitted to authorise as justified. All requests must be reviewed by a Consultant Radiologist.

**Carers and Comforters (C&C)**

Any Operator may authorise as justified the exposure of a Carer and Comforter on behalf of the Clinical Lead for Radiology named above for diagnostic imaging procedures where the dose to the carer and comforter does not exceed 0.3mSv per imaging episode. This will apply in all plain film and diagnostic fluoroscopy and may also apply in other modalities. The justification and consent process documented in Procedure N should be observed. Where the dose to the C&C is uncertain, please ask the advice of an MPE.
List of Authorised Operators

i.e. those who set exposure parameters and/or activate the exposure switch for medical exposures or who administer radioactive material or may affect the dose administered.

<table>
<thead>
<tr>
<th>Staff groups</th>
<th>Type(s) of medical exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant Radiologists</td>
<td>Diagnostic &amp; Interventional Imaging procedures</td>
</tr>
<tr>
<td>Designated Radiographers</td>
<td>Diagnostic &amp; Interventional Imaging procedures and CT</td>
</tr>
<tr>
<td>Assistant Practitioner</td>
<td>Limited Diagnostic radiography and fluoroscopy within set protocols</td>
</tr>
<tr>
<td>Dental officer / dental practitioner</td>
<td>Dental Radiography within recorded scope of competence</td>
</tr>
<tr>
<td>Medical Physics Scientific &amp; Technical Staff</td>
<td>None – equipment quality assurance exposures only</td>
</tr>
</tbody>
</table>

A current list of all staff eligible to act as Operators is held by Radiology in the IRMER duty holder file.
### Diagnostic Reference Levels

See external document for current DRLs.

Where an local DRL is not set, the national reference dose in the latest PHE/HPA/NRPB dose review publication is used instead.

#### Evaluators

<table>
<thead>
<tr>
<th>Staff groups</th>
<th>Type(s) of medical exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiologists</td>
<td>All Diagnostic &amp; Interventional Imaging procedures</td>
</tr>
<tr>
<td>Reporting Radiographers</td>
<td>Plain film imaging</td>
</tr>
<tr>
<td>Cross-sectional Radiographers</td>
<td>IOFB plain films</td>
</tr>
<tr>
<td>Medical or dental qualified maxillo-facial and orthodontic personnel (including external General Dental Practitioners)</td>
<td>Plain film dental, orthodontic and maxillofacial examinations</td>
</tr>
<tr>
<td>Orthopaedic Surgeons</td>
<td>Post-operative plain film examinations, Fracture Clinic follow-up films, adult Orthopaedic Outpatient Clinic plain films, Pre-operative imaging</td>
</tr>
<tr>
<td>Neuro and general surgeons</td>
<td>Pre-operative imaging</td>
</tr>
<tr>
<td>Relevant referrer</td>
<td>DEXA bone density scans</td>
</tr>
<tr>
<td>Mammography advanced practitioners (film readers)</td>
<td>Mammography imaging and relevant interventions</td>
</tr>
<tr>
<td>Other registered healthcare practitioners operating under expanded practice</td>
<td>As agreed by Radiology – see expanded practice list for details.</td>
</tr>
</tbody>
</table>
APPENDIX G

Financial and Resourcing Impact Assessment on Policy Implementation

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

<table>
<thead>
<tr>
<th>Document title</th>
<th>Procedures for Ionising Radiation Medical Exposure 2018</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Totals</th>
<th>WTE</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manpower Costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training Staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment &amp; Provision of resources</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Summary of Impact:

Risk Management Issues:

Benefits / Savings to the organisation:

Equality Impact Assessment

- Has this been appropriately carried out? YES/NO
- Are there any reported equality issues? YES/NO

If “YES” please specify:

Use additional sheets if necessary.

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

<table>
<thead>
<tr>
<th>Manpower</th>
<th>WTE</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational running costs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Totals:

<table>
<thead>
<tr>
<th>Staff Training Impact</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Totals:
### Equipment and Provision of Resources

<table>
<thead>
<tr>
<th></th>
<th>Recurring £ *</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accommodation / facilities needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building alterations (extensions/new)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT Hardware / software / licences</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stationery / publicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utilities e.g. telephones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rolling replacement of equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketing – booklets/posters/handouts, etc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Totals:**

- Capital implications £5,000 with life expectancy of more than one year.

---

**Funding / costs checked & agreed by finance:**

**Signature & date of financial accountant:**

**Funding / costs have been agreed and are in place:**

**Signature of appropriate Executive or Associate Director:**

---

![Uncontrolled when printed](image-url)
**APPENDIX H**

Equality Impact Assessment (EIA) Screening Tool

<table>
<thead>
<tr>
<th>Document Title:</th>
<th>Procedures for Ionising Radiation Medical Exposure 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of document</td>
<td>To comply with the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017. To ensure that the exposure of patients, undergoing medical examination or treatment, is carried out safely. To minimise the number of adverse events involving radiation exposure to patients</td>
</tr>
<tr>
<td>Target Audience</td>
<td>See Roles and Responsibilities on Page 6</td>
</tr>
<tr>
<td>Person or Committee undertaken the Equality Impact Assessment</td>
<td>Diagnostic Imaging IT Systems Lead/Radiographer Practitioner</td>
</tr>
</tbody>
</table>

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

   If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

   If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
<th>Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>Positive Impact</td>
<td>Negative Impact</td>
<td>Reasons</td>
</tr>
<tr>
<td>Asian or Asian British People</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Black or Black British People</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Chinese people</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>People of Mixed Race</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>White people (including Irish people)</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
### Level of Impact

If you have indicated that there is a negative impact, is that impact:

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal (it is not discriminatory under anti-discriminatory law)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:

3.2 Could you improve the strategy, function or policy positive impact? Explain how below:

3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?

### Notes:
Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sexual Orientation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transgender</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lesbian, Gay men and bisexual</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Older People (60+)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Younger People (17 to 25 yrs)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Faith Group</strong></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Pregnancy &amp; Maternity</strong></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Equal Opportunities and/or improved relations</strong></td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>