Document Control

Title **Ionising Radiation (Medical Exposures) Regulations 2017 (IR(ME)R 2017) Northern Devon Healthcare Trust Employer's Procedures**			
Author			**Author's job title** Radiology Governance Lead
Directorate Operations			**Department** Diagnostic Imaging
Version	**Date Issued**	**Status**	**Comment / Changes / Approval**
0.1	Oct 2017	Draft	Initial version for consultation.
0.2	Oct 2017	Draft	Checking for detail and amendments to text
1.0	Nov 2017	Final	Approved and signed off by Radiology Management Group
1.1	March 2018	Draft	Updated following issue of new IR(ME)R regulations 2017, Amendments made following consultation.
2.0	May 2018	Final	Approved and Signed off by Radiology Management Group
3.0	Aug 2018	Final	Updated to include external operatives entitled to work as Operators under schedule 2:b of these procedures.
4.0	May 2020	Final	Updated to include Operators, under schedule 2:b of these procedures, entitled to use the mini c-arm.
5.0	Sept 2020	Final	Reviewed in line with 3 year Review date under IR(ME)R – no changes to make.
5.1	Dec 2020	Review	Reviewed due to update in guidance
Main Contact Principle Radiographer Radiology Department North Devon District Hospital Raleigh Park Barnstaple, EX31 4JB			**Tel: Direct Dial** – **Tel: Internal** – **Email**:
Lead Director Lead Clinician in Clinical Radiology			
Superseded Documents			
Issue Date Sept 2020	**Review Date** Sept 2023		**Review Cycle** Three years

Consulted with the following stakeholders: (list all)

- Clinical Audit Lead Radiology
- Radiologists
- Radiographers
- Medical Physics
- Practitioner Referrers

Approval and Review Process

- Lead Clinician in Clinical Radiology
- Radiology Management Group
- NDHT Radiation Safety Group

Local Archive Reference

G:\Radiology Public Drive

Local Path

Radiology Clinical Governance /IR(ME)R

Filename

Ionising Radiation (Medical Exposures) Regulations 2017 (IR(ME)R 2017)
Northern Devon Healthcare Trust Employer's Procedures

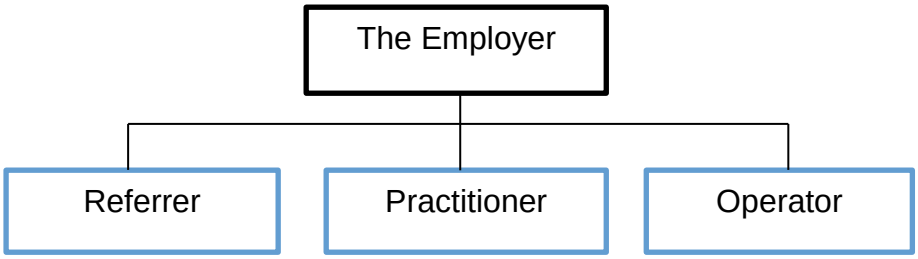
Policy categories for Trust's internal website (Bob)	Tags for Trust's internal website (Bob)
Diagnostic Imaging Trust's internal website	Duty Holder, Referral, Referrer, Practitioner, Operator

CONTENTS

Document Control 1
1. Entitlement of Duty Holders (Schedule 2: b) *IR(ME)R 2017* 4
2. Personnel identification (Schedule 2: b) IR(ME)R 2017 5
3. Referral criteria (Schedule 2: b) *IR(ME)R 2017* 6
4. Patient identification process (Schedule 2: a) IR(ME)R 2017 7
5. Radiological Examination of Individuals of Reproductive Capacity (Schedule 2: c) *IR(ME)R 2017* 8
6. Justification and authorisation of medical exposures (Schedule 2: b) *IR(ME)R 2017* 8
7. Medico-legal and non-accidental injury requests (Schedule 2: b & m) *IR(ME)R 2017* 10
8. Non-Medical Imaging Exposures (Schedule 2: m) *IR(ME)R 2017* 10
9. Research exposures (Schedule 2: g) *IR(ME)R 2017* 11
10. Exposure Optimisation (Schedule 2: e, g & h) *IR(ME)R 2017* 12
11. Recording clinical evaluation and dose (Schedule 2: j) *IR(ME)R 2017* 13
12. Assessment of patient dose (Schedule 2: e) *IR(ME)R 2017* 14
13. Diagnostic reference levels (DRLs) (Schedule 2: f) IR(ME)R 2017 14
14. Carers and Comforters (Schedule 2: n) *IR(ME)R 2017* 15
15. Providing information on risk and benefit of radiation exposures (Schedule 2:i) *IR(ME)R 2017* 17
16. Minimising unintentional irradiation of patients (Schedule 2: k) IR(ME)R 2017 17
17. Reporting and investigation of over-exposures (Schedule 2: k) *IR(ME)R 2017* 18
18. Informing the Referrer, Practitioner and individual exposed of clinically significant unintended exposure (Schedule 2:l) *IR(ME)R 2017* 19
19. Clinical audit (Schedule 2: d) *IR(ME)R 2017* 20
20. Quality Assurance of Procedures (Schedule 2: d) *IR(ME)R 2017* 20
21. Quality Assurance of Equipment (Schedule 2:d) *IR(ME)R 2017* 21
22. Expert Advice (Schedule 3) *IR(ME)R 2017* 21
23. Inventory of Equipment *IR(ME)R 2017* 22
24. Training *IR(ME)R 2017* 24
25. Archiving arrangements *IR(ME)R 2017* 23
26. References *IR(ME)R 2017* 23

1. Entitlement of Duty Holders (Schedule 2: b) *IR(ME)R 2017*

The responsibility for compliance with IR(ME)R 2017 lies with the Employer and each of the Entitled Duty Holders. There are four categories of Duty Holder:



For effective implementation of the statutory responsibilities that rest with the Trust as Employer please refer to: Medical Radiation Policy.

Under IR(ME)R the Employer is the natural or legal person who carries out or engages others to carry out medical exposures at any given radiological establishment. They are responsible for ensuring that all written procedures for medical exposures are in place, including employer's procedures, standard operating procedures and protocols for all procedures and equipment.

The Employer is able to delegate entitlement to others; being entitled by the Employer, means that permission has been given to act, in compliance with the Regulations, according to the specific responsibilities of a Duty Holder role.

Entitlement is delegated by the Employer to Referrers to be able to request imaging, and to the Practitioner and Operator (see section 'personnel identification' below for definitions) who are able to undertake medical exposures following appropriate training and working within a strict scope of entitlement.

The scopes of entitlement will be reviewed every three years unless deemed necessary before and should be discussed with individuals during annual appraisal.

Scope of entitlement documents can be found here.

IR(ME)R training for Duty Holders is available on the Staff Training Access Resources (STAR) programme. All Referrers, Practitioners and Operators will be required to complete these IR(ME)R training modules. Completion of these modules will be recorded and monitored to ensure compliance. Modules will be repeated every three years unless following an investigation where a refresher is deemed necessary.

The STAR training for Referrers is role specific in that medical and non-medical referrers complete IR(ME)R modules that are specific to their referral role responsibilities. Practitioners and Operators, namely: Radiologists, Radiographers and Assistant Practitioners will all complete these modules every three years in line with the IR(ME)R responsibilities for their role.

The Employer must ensure that Operator and Practitioner are competently trained to undertake procedures involving medical exposures. Competency must be assessed by an experienced individual deemed competent to be able to assess others and who has themselves been assessed for competency by such a person.

Competency records and all training records for radiology staff are stored on the radiology department public (G:) drive; these will be reviewed and reassessed every three years unless the need arises sooner or new equipment is introduced (public (G:)/radiology clinical governance/IR(MER)R/).

The Employer also has a duty to investigate incidents where exposures much greater than intended have been delivered to any persons undergoing radiological procedures (please see section 'Reporting and investigation of over-exposures' below).

2. Personnel identification (Schedule 2: b) IR(ME)R 2017

IR(ME)R 2017 identifies several different personnel or duty holders involved in requesting, justifying, authorising and exposing the patient to radiation. It is imperative that these personnel are correctly and unambiguously identified to prevent the unnecessary irradiation of patients.

Referrer Any registered medical or dental practitioner.
Any registered healthcare professional given authority to act as a referrer under a protocol approved by the Department of Radiology.
Any request received that is not by one of the above is to be passed to a Radiologist who may then decide to act as referrer.
A list of Referrers is held on the radiology G:/ drive; the Radiology Governance Lead is responsible for maintaining this list.

Practitioner Any Consultant Radiologist employed by the NDHT can justify and authorise medical exposures.
The Lead Clinical Radiologist is responsible for delegating Practitioner status on behalf of the Trust.
Radiology Registrars are able to justify and authorise medical exposures.
Cardiology Consultants can justify for the purpose of Cardiac CT.
Any Diagnostic Radiographer employed by the Trust is entitled to authorise an exposure under written justification guidelines approved by the Department of Radiology (please see section 'Justification and authorisation of medical exposures').
Others can act as Practitioner as approved by the Radiology Lead Clinician.
This definition is to apply equally to Theatres as well as Radiology.
A list of Practitioners, together with their most recent IR(ME)R training is held on the radiology G:/ drive; the Radiology Governance Lead is responsible for maintaining this list.

Operator Any Radiologist or Diagnostic Radiographer employed by the Trust and in possession of a certificate of competence can act as an Operator issued by the Principle Radiographer. *
A list of Operators is held on the radiology G:/ drive; the Radiology Governance Lead is responsible for maintaining this list.

Any (Radiographic) Assistant Practitioner employed by the Trust and in possession of a certificate of competence and accredited by the Society of Radiographers may undertake practical aspects of an examination under the supervision of a Radiographer

Any Medical Physicist/Technician employed by the trust and in possession of a certificate of competence to act as an operator issued by the Head of Diagnostic Radiology Physics.
A list of Entitled Medical Physicists and Technicians is held on the radiology G:/ drive; the Radiology Governance Lead is responsible for maintaining this list.

Any Student Radiographers on official placement in the department or Radiographer Apprentices may undertake practical aspects of an examination under the supervision of a radiographer.

Any Manufacturer's Service Engineers and Applications Specialists working under the supervision of a Superintendent Radiographer/Radiologist.

Any Other trained Radiographers/Radiologists working in the Trust, listed (alongside other operators) and working under their own specific Scope of Practice.

Any 2nd year Student Radiographers working as an Assistant Practitioner in the department, on receipt of their Cert HE, may undertake practical aspects of an examination under the supervision of a radiographer.

Any Orthopaedic Surgeon or Other Healthcare Professional who has been adequately trained, is documented as competent and is working in accordance with the Local Rules and IR(ME)R procedures for the Mini C-arm.
A list of Operators for the mini c-arm is held on the radiology G:/ drive; the Radiology Governance Lead is responsible for maintaining this list.

Any (CT) Assistant Practitioner employed by the Trust and working under the strict supervision of a Radiographer may make exposures for specific basic CT scans, following documented training, and in accordance with their scope of practice, both as a trainee and once qualified.

Any Associate Apprentice Mammographer employed by the Trust working under the supervision of a Radiographer, both as a trainee and once qualified may undertake the practical aspects of an examination in accordance to their scope of practice.

* The Principle Radiographer keeps lists of all Radiographers and the procedures that they are entitled to authorise/perform.

All of these lists can be found here:

3. Referral criteria (Schedule 2: b) *IR(ME)R 2017*

Medical and Non-medical Practitioners who act as Referrers are classed as Duty Holders who are entitled in accordance with the employer's procedures to refer individuals for medical exposure to a Practitioner, and must be aware of their responsibilities under

IR(ME)R 2017 before they may refer patients for diagnostic imaging examinations involving the use of ionising radiation.

There is no legal requirement within the Regulations that medical / non-medical referrers are trained in radiation safety / IRMER awareness prior to being entitled to act as referrers; however it is normal practice for Radiology Departments to require such training to be undertaken.

Medical Referrers holding current GMC registration are deemed to have received this training prior to their registration. IR(ME)R Training for Medical and Non-Medical Referrers is available via the Trust's e-learning platform 'STAR'

Referrals for medical exposures shall be made in accordance with documented **Referral Criteria**.

The criteria to be used by the Trust will be based on those provided in the ***"iRefer - Making the best use of clinical radiology"*** document, published by the **Royal College of Radiologists***.

**iRefer is available via the radiology pages of the intranet here*

Referrals can be made to the Radiology Department electronically via Trackcare or via written request.

For guidance on making a referral for diagnostic imaging please refer to: Making a Referral for Diagnostic Imaging Standard Operating Procedure

4. Patient identification process (Schedule 2: a) IR(ME)R 2017

It is a legal requirement and professional obligation to ensure that the correct patient has the correct examination performed on them. It is therefore important that all staff groups adhere to the local and trust policy for patient identification at all times. This must include obtaining three forms of identification by asking open questions to the patient to confirm their name, date of birth and first line of their address.

Where patients are unable to give this information through lack of capacity, age, illness, anaesthesia, unconsciousness or language barriers then it is especially important that these forms of identification are sought from other sources in accordance with local policy before examinations are commenced and sources documented following procedure.

The ID check is documented on the Computerised Radiology Information System (CRIS) by placing a '1' in the appropriate ID check box on the post processing screen. Any other ID information should be documented in the comments section of the examination details section on CRIS.

All staff groups are responsible for ensuring that the correct patient has the correct examination performed on them, however ultimately it is the Operator who must be satisfied

that they have correctly identified the patient according to protocol before undertaking the exposure.

Please refer to: Identification of Patients in Radiology Standard Operating Procedure.

5. Radiological Examination of Individuals of Reproductive Capacity (Schedule 2: c) *IR(ME)R 2017*

Irradiation of the foetus should be avoided whenever possible. This includes situations when pregnancy is not suspected by the Individual themselves; this will include those individuals whose gender was female at birth and are transgender or non-binary. Alternative imaging techniques that do not involve ionising radiation should have been considered before a decision is taken to use ionising radiation in individuals of reproductive age, particularly those exposing the abdomen and pelvic area.

Definition of “reproductive age”

At this Trust the reproductive age for individuals is taken to be between the ages of 12 and 55 years inclusive. Any patient between these ages must be asked whether they may be pregnant and a pre-defined response actioned according to each potential reply.

Definition of the “abdominal or pelvic area”

This is taken to be the area lying between the diaphragm and distal 1/3 of femur.

In an individual of reproductive age, this area should not be irradiated by the primary beam, where possible:

- If the abdominal or pelvic area is not to be irradiated by the primary beam, the procedure may proceed.
- If the pelvic area is to be irradiated the examination/treatment must not proceed until the implications of a possible pregnancy have been considered.

It is the responsibility of the Referrer, Practitioner and Operator to ensure that procedures for the examination of individuals of reproductive capacity are followed.

Please refer to: Radiological Examination of Individuals of Reproductive Capacity Standard Operating Procedure

6. Justification and authorisation of medical exposures (Schedule 2: b) *IR(ME)R 2017*

No person will carry out a medical exposure unless:

a) It has been justified by a practitioner.
b) It has been authorised by the practitioner or under certain circumstances, the operator (see below).

c) In the case of a research exposure, it has been approved by the Local Research Ethics Committee (LREC).
d) For a medico-legal exposure, it falls within the local procedure.
e) In the case of a female aged 12-55, the local procedure for women of reproductive capacity has been followed.

In order to justify the exposure the Practitioner must take account of the following:

a) The specific objectives of the exposure and the characteristics of the individual involved.
b) The potential diagnostic benefits to the patient.
c) Any detriment that the exposure may cause.
d) The efficacy, risks and benefits of alternative procedures having the same objective but involving no or less exposure to ionising radiation.
e) Must ensure that the request is from a recognised Medical, Dental or Non- Medical Referrer.

When considering these points the practitioner must pay special attention to:

a) Exposures on medico-legal grounds (please see section 'Medico-legal and non-accidental injury requests').
b) Exposures that have no direct health benefit to the patient.
c) The urgency of the exposure where pregnancy cannot be excluded taking into account of the exposure of both the expectant mother and unborn child (please see section 'Radiological Examination of Women of Reproductive Capacity').
d) Whether there is to be an exposure to a comforter or carer, taking into account the likely direct health benefit to a patient, possible benefits and the detriment the exposure might cause to a comforter or carer (see section 14 Comforters and Carers)
e) Whether information on the risk and benefit of radiation exposures has been readily available to the patient prior to exposure.

The Practitioner must take into account the clinical information provided by the Referrer, this should be carefully considered in order to avoid unnecessary exposure.

Where it is not possible for a Practitioner to authorise an exposure, the Operator can do so but only in accordance with justification guidelines provided by the Practitioner. If the clinical information on the request form does not fall within the guidelines, a Practitioner must be consulted and his/her authorisation given before the exposure can take place. Where it is impractical to consult a Practitioner, the request form must be returned to the referrer. It is then the referrer's responsibility to either cancel the request or supply further clinical information.

Please refer to: Justification and Authorisation Standard Operating Procedure

7. Medico-legal and non-accidental injury requests (Schedule 2: b & m) *IR(ME)R 2017*

A Medico-Legal procedure under IR(ME)R 2017 is defined as “a procedure performed for insurance or legal purposes without a medical indication”.

All requests for medico-legal X-rays must be referred to a Consultant Radiologist for justification/authorization who should take into account possible non-medical benefits to the patient. Medico-legal procedures will only be undertaken with the consent of the patient or in the case of adults or children without capacity their legal guardian or person with parental responsibility.

All requests for X-rays in cases of suspected non-accidental injury in children should be referred to a Consultant Radiologist. Imaging should be performed in accordance with departmental standard operating procedures.

All requests for X-rays for other forensic investigations and post mortem skeletal surveys will be referred to a Consultant Radiologist. All imaging should be performed in accordance to local standard operating procedures. Although IR(ME)R doesn’t apply to post mortem investigations as the patient is deceased there are implications under IRR99 for occupational exposure and so need to be considered.

For those medico-legal requests that relate to the exposure of ionising radiation for the purpose of research special consideration needs to be given to justification and optimisation of exposures (please see sections ‘Research exposures’ and ‘Exposure optimisation’).

Please refer to:

Medico-Legal and Non-Accidental Injury Requests Standard Operating Procedure.

Radiographers Undertaking Imaging of Patients for Forensic Purposes Standard Operating Procedure.

Radiographers Undertaking Post Mortem Skeletal Surveys - Standard Operating Procedure.

8. Non-Medical Imaging Exposures (Schedule 2: m) *IR(ME)R 2017*

Non-medical imaging exposures under IR(ME)R 2017 are defined as “any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring health benefit to the individual being exposed”.

All requests for Non-medical imaging exposures must be referred to a Consultant Radiologist for justification/authorization who should take into account possible non-medical benefits to the patient.

Non-medical Imaging exposures will only be undertaken with the consent of the patient or in the case of adults or children without capacity their legal guardian or person with parental responsibility.

All Non-medical imaging should be performed in accordance with departmental standard operating procedures.

For those Non-medical requests that relate to the exposure of ionising radiation for the purpose of research special consideration needs to be given to justification and optimisation of exposures (please see sections '9. Research exposures' and '10. Exposure optimisation')

9. Research exposures (Schedule 2: g) *IR(ME)R 2017*

- **Practitioner** and **Operator** have the normal definitions for Radiology.
- All research procedures involving ionisation radiation require specific Research Ethics Committee approval in advance of the study commencement. These exposures to ionising radiation are described within the IRAS ethics form, including details of expected exposures and justification for those exposures.
- As part of the Local Research Ethics Committee (LREC) approval process for research projects, the Practitioner (Radiologist) provides generic justification for exposures identified in that research proposal. Only where the LREC has referred the proposal to the Practitioner for approval is the Practitioner in a position to carry out justification.
- In cases where the person undergoing the examination benefits from the exposure, the practitioner is required to plan individual target levels of dose. These are set at the time of justification and take into account the age of the individual and any other factors which affect the risk of that examination.
- In the rare cases where there is no benefit to the individual, the setting of a dose constraint is required. This is determined from the level of benefit to society, as detailed below:

Required benefit to Society	Dose Constraint (mSv)	Risk	Level of risk
Minor	0.1	1×10^{-5}	Trivial
Intermediate	0.5	5×10^{-5}	Minor
Moderate	5	5×10^{-4}	Intermediate
Substantial	10	1×10^{-3}	Moderate

Definitions of Benefit

Minor:	expected only to increase knowledge.
Intermediate:	related to increases in knowledge leading to health benefit.
Moderate:	aimed directly at the diagnosis, cure or prevention of disease.
Substantial:	directly related to the saving of a life or the prevention or mitigation of serious disease.

These constraints are for **adults under 50 years**. The values are increased by a factor of 5 for those over 50 and reduced by a factor of 3 for children.

Patients concerned must participate voluntarily and pass through a formal consent process including discussion of ionising radiation risks; Patients concerned must be informed of the risks of the exposure.

Please refer to: Making Ionising Radiation Exposures for the Purpose of Research – Standard Operating Procedure.

10. Exposure Optimisation (Schedule 2: e, g & h) *IR(ME)R 2017*

The Practitioner and the Operator shall both ensure that the doses arising from an exposure are kept as low as reasonably practical consistent with the intended purpose. The Operator will take into account the equipment and methods employed and pay special attention to:

a. quality assurance
b. assessment of patient dose
c. adherence to diagnostic reference levels (DRL's)
d. adherence to department procedures.

For exposures requested for research purposes the Trust will ensure that:

a. the patients concerned participate voluntarily and pass through a formal consent process including discussion of ionising radiation risks
b. the patients concerned are informed in advance of the risks of the exposure
c. dose constraints set by an Ethics committee are adhered to in patients for whom no direct benefit is expected from the exposure
d. for patients undergoing experimental diagnostic or therapeutic exposures which are expected to give direct benefit to the patient, target doses set by the practitioner are adhered to.

The Practitioner and Operator will pay special attention to:

a) the need to keep doses arising from medico-legal exposures as low as reasonably practicable
b) medical exposures of children; where the risks of causing future cancer or genetic injury is greatest.
c) medical exposures as part of a health screening programme
d) medical exposures involving high doses to the patient
e) females in whom the possibility of pregnancy cannot be excluded taking into account the exposure to the expectant mother and the unborn baby.

It is the responsibility of the referrer to ensure that a clinical evaluation of the outcome of each exposure is recorded in the patient's case-notes.

In the case of Nuclear Medicine:

a) There are no Nuclear Medicine facilities or examinations performed at this Hospital.

In the case of fluoroscopy:

a) The operator shall ensure that, except in exceptional circumstances, the AEC must be used.
b) No person shall carry out fluoroscopy without image intensification.

Please refer to: Exposure Optimisation – Standard Operating Procedure.

11. Recording clinical evaluation and dose (Schedule 2: j) *IR(ME)R 2017*

It is a requirement of IR(ME)R 2000 that the dose given for each examination and a clinical evaluation of each examination are recorded.

Radiographers are required to record the dose indication (DLP/DAP reading/ kV & mAs) for each examination on the Computerised Radiology Information System (CRIS). For radiographic examinations the dose indication for each projection must be recorded on CRIS.

It is the responsibility of the referrer (or nominated representative) to carry out and record a clinical evaluation of each examination in the patient's case-notes. This shall take place irrespective of whether a formal report is issued by a Radiologist and will be audited at regular intervals as part of the employer's procedures quality assurance programme.

Where Radiologist reports are available, they are entered onto CRIS where they are also visible on the PACS system. If the examination is marked "report by referring clinician" (RRC) the result is recorded in the patient's clinical notes by the referring clinician. This has been agreed with the relevant departments (Orthopaedics, Fracture Clinic, Dental Clinicians and Gynaecology*). (*in relation to Hystersalpingogram examinations only).

Referrers who are entitled to carry out a clinical evaluation following their referral are identified as a list of Referrers that is held on the radiology G:/ drive; the Radiology Governance Lead is responsible for maintaining this list.

Please refer to: Recording Clinical Evaluation and Dose – Standard operating Procedure.

12. Assessment of patient dose (Schedule 2: e) *IR(ME)R 2017*

For each patient examination, the dose of ionising radiation will be kept as low as reasonably practicable (ALARP) in order to obtain the necessary clinical information whilst minimising the risk.

Information on the exposure/dose received by the patient is recorded for each procedure by the Operator; these should include:

- Dose Area Product (DAP) value
- kVp & mAs where DAP meters are not fitted
- Dose Length Product (DLP) for CT examinations

DAP meters are calibrated annually by the Medical Physics Department.

Diagnostic Reference Levels (DRLs) are displayed in all general rooms; interventional room and the CT scanner for reference (please see section 'Diagnostic Reference Levels').

It is the responsibility of the Operator to ensure that all relevant exposure information for each patient is recorded on the Computerised Radiology Information System (CRIS), to allow patient doses to be calculated as necessary by a Medical Physics Expert.

Upon request from the Principle Radiographer or nominated deputy, a Medical Physics Expert will provide an estimate of patient dose (for "normal" patient build) using methods derived from and traceable techniques published by national authorities (e.g. PHE) or otherwise published in peer-reviewed scientific journals that use current risk and weighted factors.

Assessment of patient dose is monitored by annual audit of exposure information by Medical Physics, Royal Devon and Exeter NHS Foundation Trust.

For procedures for the assessment of patient dose please refer to: Assessment of Patient Dose - Standard Operating Procedure.

13. Diagnostic reference levels (DRLs) (Schedule 2: f) IR(ME)R 2017

The Diagnostic Imaging Department has a duty to optimise radiation exposure to the patient such that it is commensurate with the necessary clinical purpose. To assist in auditing patient doses Local Diagnostic Reference Level's (LDRLs), required by the IR(ME)R Regulations, must be identified.

NDHT are responsible for auditing patient doses and establishing LDRLs; this work is performed in collaboration with the Medical Physics Department, Royal Devon and Exeter NHS Foundation Trust (RD&E). A full patient dose audit will be performed, across all modalities, over a three year cycle, unless new equipment or techniques are adopted; where new equipment or techniques are adopted, a dose audit shall be performed as soon as is practicable and LDRLs checked, and modified as appropriate. LDRLs will be based on mean patient dose values from patient dose audits. LDRLs will be implemented through NDHT's Radiation Safety Committee.

Medical Physics shall routinely review patient dose data against both LDRLs and National Diagnostic Reference Levels (NDRLs) and present findings at the Radiation Safety Committee. LDRLs may be amended by the Radiation Safety Committee. It should be noted that justification should always be made and documented for increasing an LDRL. It is anticipated that increasing an LDRL will be very unlikely.

Examinations requiring LDRLs will be identified based upon either the existence of an NDRL, provided the frequency of the examination provides "sufficient data", or whereby any standard examination contributes >1% of a given modality for a standard projection. At present "sufficient data" is defined as ten patients per examination per room.

If the LDRL exceeds the equivalent NDRL, formal justification, accepted by the Radiation Safety Committee, is required to apply this higher value as an LDRL. Where possible LDRLs will be in the form of Dose Area Product (DAP) or Dose Length Product (DLP).

LDRLs and NDRLs for each examination will be displayed in each relevant X-ray room and are also recorded on local protocols for each examination. This is to enable IR(ME)R Operators to assess whether a patient has received a dose that is deemed to be reasonable. Before entering a patient dose on to CRIS the IR(ME)R Operator should assess whether the patient dose is reasonable. It should be noted that it is difficult to prescribe a level at which an individual patient dose is deemed to be excessive, due to variations in patient weight, size, difficulty of case etc.

When an IR(ME)R Operator thinks that an individual's dose may be excessive they should consult the senior radiographer responsible for that particular area of work. The senior radiographer should make a decision as to whether the dose is excessive. If the senior radiographer deems that the dose may be excessive or DRLs are being consistently exceeded they should contact a Diagnostic Radiology Medical Physics Expert (MPE) in Medical Physics at RD&E. The senior radiographer and MPE shall work together, and decide upon any necessary remedial action.

Please refer to: Diagnostic Reference Levels – Standard Operating Procedure.

14. Carers and Comforters (Schedule 2: n) *IR(ME)R 2017*

Carers and Comforters under IR(ME)R 2017 are defined as "individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone exposure".

It is sometimes necessary for a Carer or Comforter to be present during an x-ray examination, either to hold or to reassure the patient. This may be a relative, friend or a member of staff. All Carers and Comforters present during the examination will receive a small dose of radiation.

Carers and Comforters who are Parents, Guardians or Family members

The Operator will explain the risks and benefits of being exposed to the exposure of ionising radiation prior to the examination, lead rubber protection will be given and a consent form signed by the Carer or Comforter.

This consent form will also explain the risks and records the Patients details, examination, Radiographer, exposure factors/dose and protection provided; this will be scanned onto the Patients CRIS event and saved on the radiology G:drive for audit and dose monitoring purposes.

Carers and Comforters who are Staff

Under IR(ME)R 17 Staff are not classed as Carers and Comforters, however for purposes of audit and continued monitoring of staff groups' exposure to radiation it has been decided that staff working at NDHT will be treated the same as other Carers and Comforters. This means that as above the risks and benefits of the exposure will be explained, lead rubber protection will be given and a consent form signed; this will then be scanned onto the radiology G:drive in the appropriate folder to ensure continued monitoring of staff dose levels.

G:\Radiology Clinical Governance\IRMER\Carers and Comforters\2018 Completed Carers and Comforters forms\Radiology Staff

G:\Radiology Clinical Governance\IRMER\Carers and Comforters\2018 Completed Carers and Comforters forms\Hospital Staff

For staff working on SCBU the patient name, examination, exposure factors and where the nurse was stood holding the baby should be recorded in the folder on the mobile machine; this will then be used to update departmental records, alternatively a Carers and Comforters consent form can be used for locum staff and staff that infrequently hold on SCBU and scanned onto the Radiology G: drive.

G:\Radiology Clinical Governance\IRMER\Carers and Comforters\2018 Completed Carers and Comforters forms\SCBU Staff

Dose Constraints

All imaging where Carers and Comforters are utilised should be monitored to ensure that repeated doses are not incurred by the same people repeatedly acting as Carers and Comforters. A total annual calendar year dose constraint of 1mSv should be applied for any individual Carer and Comforter; this includes those under the age of 18.

Carers and Comforters under the age of 18.

Whilst it is always preferable to have a Carer or Comforter who is over the age of 18 if the Parent is under 18 then careful consideration should be given to them incurring the exposure "knowingly and willingly".

If the Carer or Comforter is the Parent and is under the age of 18: if they have had adequate information given to them by the Operator, and they understand the implications of this information before the exposure takes place, then they may sign the Carers and Comforters consent form and be present during the exposure. Documentation must be made on CRIS and the consent form that the Carer or Comforter is under 18 and care taken to record both the exposure factors and resultant dose on the form.

Where practicable it is always preferable to have a Carer or Comforter who is over the age of 18 which maybe another Parent, Relative or Friend.

Careful consideration also needs to be given to the type of examination that a comforter or carer under the age of 18 is supporting the patient for, for example, whether it is a low dose procedure such as a chest x-ray; so incurring a small dose, or a procedure such as a skeletal survey which might incur multiple exposures and so considerably higher dose.

Staff members who are under the age of 18 should never be used as Carers or Comforters during ionising radiation exposures.

15. Providing information on risk and benefit of radiation exposures (Schedule 2:i) *IR(ME)R 2017*

According to IR(ME)R 2017 “wherever practicable, and prior to an exposure taking place, the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from exposure”.

The risks and benefits of having the radiation exposure should always be discussed with the Patient, in the first instance, by the Referrer prior to referral for imaging.

Once in the radiology department information on the risks and benefits of having radiation exposure will be provided in the form of posters in the waiting room and displayed in the x-ray rooms, and booklets in the waiting room. There will also be information on the GP pages of the NDHT website and on the radiology pages of BOB

For Carers and Comforters this information is also provided on the carers and comforters consent form.

Operators and Practitioners are also able to give this information and discuss this with the Patient prior to exposure.

16. Minimising unintentional irradiation of patients (Schedule 2: k) IR(ME)R 2017

It is a requirement of IR(ME)R 2017 that the probability and magnitude of accidental or unintentional doses to patients from radiological practices are reduced so far as is reasonably practicable.

This will be accomplished by:

a) Application of good practice and technique as specified in the IR(ME)R Procedures and SOPs. All Practitioners and Operators should adhere to these procedures.
b) Ensuring staffing levels and equipment are appropriate to the workload of the Department.
c) All radiological equipment being regularly maintained and serviced.
d) All radiological equipment being subjected to regular QA and operational safety device tests by Medical Physics staff and the QA Radiographer.

e) All operators having appropriate training for the procedures being undertaken and regularly updated. This will be accomplished mainly through Continuous Professional Development and Competency Assessments that will be reviewed every 3 years.
f) A documented induction programme for new staff, preceptors and locum staff.
g) New procedures and equipment being introduced must be accompanied by thorough training for the relevant staff.
h) Ensuring adequate feedback to staff following any incident by means of departmental meetings, monthly radiology newsletter, and email cascade.

Operators will:

a) Select the most appropriate equipment available and operate in accordance with the manufacturers' recommendations.
b) Only undertake procedures for which s(he) has received the appropriate training
c) Follow the correct patient identification process prior to any radiation exposure.
d) Report any faults and take equipment out of use as necessary until reviewed by an appropriate engineer, and ensure that it is checked for safety before returning to clinical use.
e) Investigating situations where image quality is deemed to be unacceptable. The Principle Radiographer should inform Medical Physics in such situations.
f) Report any unintended or unusual exposures via a radiation incident form and the trust incident reporting system (DATIX).

Regular reject analysis will be undertaken by the RPS and QA radiographer and feedback given to staff via annual departmental audit meetings, monthly radiology newsletter and CPD sessions.

Please refer to: Minimising the Unintentional Irradiation of Patients – Standard Operating Procedure.

17. Reporting and investigation of over-exposures (Schedule 2: k) *IR(ME)R 2017*

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 were introduced to protect patients against the hazards associated with the use of ionising radiation in medical settings. It is a requirement of IR(ME)R 2017 that all notifiable incidents should be reported.

Notifiable incidents under IR(ME)R are those where a dose "much greater than intended" has been delivered to an individual and should be reported to the appropriate authority.

It is the responsibility of the Operator to record any known or suspected over-exposure of a patient using the radiation incident form (to be given to the Principle Radiographer) and the Trusts Incident Reporting system ("Datix"). Potential over-exposure should be indicated in the <Description of Incident>, and relevant exposure details included (DRP or DRL, or exposure factors; kVp etc.).

The definition of "over-exposure" is that used in the guidance published by the Department of Health in January 2017: "Guidance on investigation and notification of medical exposures much greater than intended"

The incident will be investigated and reported as detailed in:

The Trust Medical Radiation Policy

Reporting and Investigation of Over Exposures – Standard Operating Procedure.

Feedback will be given to staff following any incident via departmental meetings, radiology audit meeting, monthly radiology newsletter and CPD session

18. Informing the Referrer, Practitioner and individual exposed of clinically significant unintended exposure (Schedule 2:l) *IR(ME)R 2017*

It is the employers duty under IR(ME)R 2017 to ensure "that the referrer, the practitioner, and the patient or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure".

A 'clinically significant' unintended exposure would constitute an exposure large enough to cause a skin burn or a 20mSv exposure (risk of cancer of 1 in 1,000); this should be a 'never' event. However, in the event of a clinically significant unintended exposure it must be reported immediately.

It is the responsibility of the Operator to record any known or suspected over-exposure of a patient using the radiation incident form (to be given to the Principle Radiographer) and the Trusts Incident Reporting system ("Datix"). Potential over-exposure should be indicated in the <Description of Incident>, and relevant exposure details included (DRP or DRL, or exposure factors; kVp etc.).

The incident will be investigated and reported as detailed in:

The Trust Medical Radiation Policy

And,

Reporting and Investigation of Over Exposures – Standard Operating Procedure.

The Principle Radiographer will be responsible for ensuring that following an investigation the Referrer, Practitioner and Patient or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure.

19. Clinical audit (Schedule 2: d) *IR(ME)R 2017*

Clinical Audit of IR(ME)R 2017 procedures must be carried out at appropriate and regular intervals.

The Clinical Audit Programme ensures that:

- Regular audit of the IR(ME)R Employer's procedures is being performed
- The IR(ME)R procedures are being adhered to
- The IR(ME)R Procedures are up to date
- Audit is being carried out by the appropriate group
- Feedback from the audits is being disseminated
- Findings are examined and necessary actions taken.

Audit of the IR(ME)R employers procedures will take place in their entirety every three years. This will be accomplished by auditing at least four of the procedures per year.

All Audits will be registered with the Trust Clinical Audit and Effectiveness Programme which allows them to be monitored and documented through each phase (planned, active, action phase and completed). It will also allow transparency throughout the Trust as to what is being audited and results published.

To ensure continued good practice as well as the registered audits of procedures regular dose and DRL audits, reject analysis and clinical imaging examinations audits will be performed monthly within the department by the RPS, Radiology Audit Lead, or delegated individual, to ensure doses are being kept as low as is reasonably practicable. These 'mini' audits will be documented on the radiology G Drive (Public G:/ Clinical governance/IR(ME)R/Audit) and will be produced for review at the biannual Radiation Safety Group meeting.

The results of these audits will ensure that the procedures are current, appropriate for use and being adhered to. It will also highlight any shortcomings in the procedures that can then be amended.

The Annual Radiology Department Audit Meeting will involve all staff groups within the department; results and feedback from audits will be disseminated here. Any urgent or unexpected findings of audit that need immediate dissemination will be done via the email cascade, radiology newsletter and staff meetings.

Please refer to: Clinical Audit – Standard Operating Procedure.

20. Quality Assurance of Procedures (Schedule 2: d) *IR(ME)R 2017*

It is important that all procedures work and are seen to work. It is therefore imperative that the procedures outlined in this document are audited at regular intervals to ensure that there are no problems and all aspects are being adhered to.

The IR(ME)R 2017 Employer's procedures and Standard Operating Procedures shall be reviewed every three years. If practice changes before then the documents will be amended accordingly.

The Radiation Protection Supervisor and Radiology Audit Lead will ensure audits are carried out. A minimum of 10 patients will be selected at each audit and checked to ensure that the employer's procedure being audited is being adhered to in each case. Where the employer's procedure does not specifically relate to individual cases, such as DRLs, dose audit, investigation of doses much greater than intended, and optimisation programmes, audits will take place to specifically focus on those procedures to ensure continued quality assurance.

If a discrepancy or non-compliance is found, this will be investigated and rectified, and a follow-up audit carried out 6 months later. All non-compliant audits will be discussed at the biannual Radiation Safety Group Meeting and all compliant audits noted.

The Annual Radiology Department Audit Meeting will involve all staff groups within the department; results and feedback from audits will be disseminated here. Any urgent or unexpected findings of audit that need immediate dissemination will be done via the email cascade, radiology newsletter and staff meetings.

Please refer to: Quality Assurance of Procedures – Standard Operating Procedure.

21. Quality Assurance of Equipment (Schedule 2:d) *IR(ME)R 2017*

To ensure equipment is fit for use and maintained effectively to provide optimum imaging it is essential that regular Quality Assurance (QA) tests are undertaken and monitored.

QA testing of equipment will be performed on a monthly basis; the results of these tests will be documented on the radiology G: drive here.

Any faulty or non-performing equipment that fails QA tests will be removed from use and reported immediately to the RPS who may inform Medical Physics; this equipment will not be returned to use until an engineer is available and the equipment can be fixed, or Medical Physics agree that it is safe and within normal limits to use.

Medical Physics will monitor all local QA testing of equipment. They will also perform testing on all new equipment and all reconditioned or mended equipment before it is released for general use.

22. Expert Advice (Schedule 3) *IR(ME)R 2017*

The Employer shall employ the services of a Medical Physics Expert. There is a Service Level Agreement in place with the Royal Devon and Exeter NHS Foundation Trust to engage the services of the Medical Physics Expert.

Medical Physicists/Technicians are employed by the Trust to undertake QA of X-ray equipment. Each must be signed off to act as an Operator by the Head of Diagnostic

Radiology Physics. The Head of Diagnostic Radiology Physics is responsible for delegating Medical Physics Operator status on behalf of the Trust.

The Medical Physics Expert will be involved as appropriate for consultation on optimisation, including dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices.

A list of Entitled Medical Physicists and Technicians is held on the radiology G:/ drive here; The Radiology Governance Lead is responsible for maintaining this list.

23. Inventory of Equipment *IR(ME)R 2017*

An up to date inventory of all radiological equipment must be kept and maintained, so as to be produced if requested by the appropriate authority.

Please refer to: Radiology Equipment age and Replacement List.

This list should include:

a) Name of manufacturer and equipment
b) Model number
c) Serial number and other unique identifier
d) Year of manufacture
e) Year of installation
f) Location of equipment
g) Age of equipment
h) Life expectancy
i) Whether service is supported
j) When equipment is due for replacement.

24. Training *IR(ME)R 2017*

No Practitioner or Operator shall carry out a medical exposure or any practical aspect without being adequately trained to do so within their scope of practice.

All Referrers, Practitioners and Operators will be required to complete the IR(ME)R 2017 training modules on the Staff Training Access Resources (STAR) programme. Completion of these modules will be recorded and monitored to ensure compliance. Modules will be repeated every three years unless following an investigation where a refresher is deemed necessary.

Documented induction programmes are followed for the induction of new staff, preceptorship and locum staff.

Student radiographers are supervised at all times during their training placement within the department by qualified and appropriately trained staff, mentors and assessors as well as supported by the university link radiographers.

Other trainees or third party employees are strictly supervised in the department during their training or observation of practice. A documented timetable of training/observation is followed; this includes the assessment of whether they are allowed into controlled areas under supervision in accordance with IR(ME)R.

A monthly lunchtime departmental CPD programme is available for staff to attend.

A record will be kept, and be available for inspection, of all Professional Qualifications and Certified CPD, Professional Registration details (HCPC) and Documented Competency.

Please refer to:

Professional Qualifications and Certified CPD

Radiographers HCPC Registrations

Radiographer Competencies

Radiologist Competencies

25. Archiving arrangements *IR(ME)R 2017*

The original of these Employers Procedures will remain with the author as listed on the front sheet, (please see page one).

This document will be stored electronically on the radiology G:drive here.

A paper copy will be retained in the IR(ME)R folder for use in accordance with IR(ME)R for inspection purposes.

Archived electronic copies will be stored in the obsolete documentation/archive folder here.

All paper copies past the review date will be destroyed with only the electronic obsolete copy available (as above).

26. References *IR(ME)R 2017*

- Ionising Radiation (Medical Exposures) Regulations 2017. Statutory Instruments 2017 No 1322 http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksi_20171322_en.pdf

- British Institute of Radiology, Society and College of Radiographers and The Royal College of Radiologists (2015) *A guide to understanding the implications of the ionising Radiation (Medical Exposure) Regulations in diagnostic and Interventional radiology.* London: The Royal College of Radiologists.

- Ionising (Medical Exposures) Regulations 2000. Statutory Instruments 2000 No 1059 http://www.opsi.gov.uk/si/si2000/20001059.htm
- IRMER – Ionising Radiation (Medical Exposures) Amendment Regulations 2006 http://www.opsi.gov.uk/si/si2006/uksi_20062523_en.pdf
- Northern Devon healthcare Trust Medical Radiation Policy http://ndht.ndevon.swest.nhs.uk/wp-content/uploads/2015/07/Medical-Radiation-Policy-v1.0-30Jul15.pdf
- NCRP 168. Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures, 2010. https://www.ncrppublications.org/Reports/168
- The Ionising Radiation Regulations 1999 http://www.legislation.gov.uk/uksi/1999/3232/contents/made