

Health Sciences University

Employers Procedures

Ionising Radiation (Medical Exposure)
Regulations 2017

(IR(ME)R 17)

Summary

This manual describes the framework under which medical exposures of patients, and research exposures of participants, will be undertaken at Health Sciences University. It has been prepared in accordance with the Ionising Radiation (Medical Exposures) Regulations 2017, Ionising Radiation Regulations 2017, supporting legislation and guidance documents. It details the arrangements that will be followed by those involved in requesting and performing ionising radiation examinations,

Document Details

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Target Audience:	All employees involved in the application or use of ionising radiation at Health Sciences University including (but not exclusive to): • Radiographers • Assistant Practitioners • Radiology Department Assistants • Radiation Protection Advisor (RPA) • Radiation Protection Supervisors (RPS) • Employees undertaking teaching involving the use of ionising radiation • Clinical and administration staff who undertake bookings for ionising radiation procedures • Medical Physicists • Staff involved in image reporting • Students undergoing training which involves the use of ionising radiation

Document History

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Staff should note that a breach of these procedures is, in effect, a breach of the law and may lead to disciplinary action.

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2 INTRODUCTION

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) govern the use of ionising radiation, including x-rays, in healthcare. The purpose of IR(ME)R is to minimise the risk to patients, and carers and comforters, undergoing, or involved in, medical exposures.

It is a requirement of IR(ME)R 17 that the Employer puts in place written Employer's Procedures for Referrers, Practitioners and Operators to ensure that radiation is used safely and appropriately.

The Employer's Procedures aim to standardise practice and ensure that all duty holders are working to the same standards, and to ensure that the employer conforms with IR(ME)R 17.

2.1 AIMS

Protect individuals from unintended, excessive or incorrect exposure to ionising radiation in relation to medical exposure.

Ensure that in each case, the expected clinical benefit is assessed against the potential risk from ionising radiation exposure.

Ensure that individuals receive no more ionising radiation than is necessary to achieve the desired benefit within the limits of current technology.

3 GLOSSARY AND DEFINITION OF TERMS

Accidental Exposure	An exposure of an individual as a result of an accident or the wrong person irradiated
Adequate Training	Training which satisfies the requirements of Schedule 3 and the Expression "adequately trained" is to be construed accordingly
HSU	Health Sciences University
ALARP	As Low as Reasonably Possible
Audit	A systematic examination or review of medical radiological procedures this seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated, and the application of new standards if necessary
Carers and Comforters	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 an exposure;
CIB	Clinical Imaging Board
CPD	Continuing Professional Development

CSAUE	Any incident, determined by the Practitioner or MPE, to have resulted in demonstrable moderate clinical harm or greater to the patient affected. Moderate harm being defined as a moderate increase in treatment, possible surgical intervention, or transfer to another area for treatment; and which caused significant but not permanent harm.
CQC	Care Quality Commission
DACBR	Diplomates of the American Chiropractic Board of Radiology
DAP	Dose Area Product
DoB	Date of Birth
DRL	Diagnostic Reference Level
Employers Procedures	Employer's procedures mean the procedures established by an employer in accordance with the Ionising Radiation (Medical Exposures) Regulations 2017. Regulation 6(1)
Equipment	Equipment which delivers ionising radiation to a person undergoing exposure, or directly controls or influences the extent of such exposure;
GCC	General Chiropractic Council
GDC	General Dental Council
GMC	General Medical Council
GOC	General Osteopathic Council
HCPC	Health and Care Professions Council
HSE	Health and Safety Executive
IEP	Image Exchange Portal
IPEM	Institute of Physics and Engineering in Medicine
IR(ME)R 17	Ionising Radiation (Medical Exposure) Regulations 2017
IRR 17	Ionising Radiation Regulations 2017
LDRL	Local Diagnostic Reference Level
MHRA	Medicines and Health Regulatory Authority
MPE	Medical Physics Expert as defined under IR(ME)R 17. an individual or a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State
Operator	Any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects of a medical exposure.
PACS	Picture Archiving and Communication System
Practitioner	A registered medical practitioner, dental practitioner or other professionally registered health professional who is entitled, in accordance with the employer's procedures, to take responsibility for authorising an individual medical exposure.

Quality Assurance	All planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards. Quality control is a part of quality assurance
Quality Control	The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled
RCR	Royal College of Radiologists
Referrer	A registered medical practitioner, dental practitioner or other professionally registered health professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposure to a practitioner.
Registered Professional	A person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(a)
Research or non-medical exposure	Any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed
RPA	Radiation Protection Advisor
RPG	Radiation Protection Group
RPS	Radiation Protection Supervisor
SCoR	Society and College of Radiographers
SMG	Senior Management Group
SoP	Standard Operating Procedure
Unintended Exposure	Any exposure to ionising radiation which is significantly different from the exposure intended for a given purpose. Includes wrong body part imaged

4 IDENTIFICATION OF INDIVIDUALS ENTITLED TO ACT AS DUTY HOLDERS

4.1 PURPOSE

To outline the method for identifying individuals to act as duty holders under IR(ME)R 17; Schedule 2, Regulation 6, Employers Procedures 1(b). Duty holders are defined as: Referrers, Practitioners, and Operators. The Medical Physics Expert (MPE) and Students are also covered in this section.

To ensure each duty holder has appropriate qualification, training, and registration (where appropriate), to act within their entitlement

To clarify who is responsible for holding training records for each duty holder

4.2 RESPONSIBILITIES

Health Sciences University (HSU) will maintain a list of all those who are identified as Referrers, Practitioners, and Operators.

Each duty holder is responsible for maintaining their own personal training record containing their evidence of training and continuing professional development. This must be provided to HSU upon request for audit purposes. (see section 16 Audits).

Practitioners and Operators must comply with the Employer's Procedures. At the HSU the Practitioner and Operator may be the same person (for instance a state registered radiographer, chiropractor or medical physicist, who has been suitably trained).

The HSU will maintain a list of all appropriate Referrers and Practitioners and ensure they are professionally registered with a relevant body under the National Health Service Reform and Health Care Professions Act 2002. All registered Referrers and Practitioners must provide evidence that they have received suitable training to act in the role and understand their responsibilities under IR(ME)R 17.

Students at HSU are being trained to act as Referrers, Practitioners and Operators and may undertake the tasks of these duty holders providing they are directly supervised at all times by a professionally registered, and suitably trained individual.

For research exposures refer to Research Exposures and Non-Medical Imaging.

4.3 PROCEDURE

4.3.1 Referrers

All referrers must register with HSU and provide evidence of their training to act as a referrer, including an understanding of their responsibilities under IR(ME)R 17. All referrers must provide

evidence of their registration with a professional body (i.e. with the GMC, HCPC, GDC, GCC, GOC or similar). Referrers may be designated as employees by the HSU, or outside referrers not directly employed by HSU.

The referrer must supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the exposure requested by the referrer to enable the Practitioner to decide whether there is a sufficient net benefit as required by regulation 11(1)(b) IR(ME)R 17).

This must include:

- Three forms of identifying the patient (name, address, date of birth)
- Sufficient clinical information relevant to the requested exposure
- Any relevant previous imaging
- If relevant, patient's pregnancy status

The Referrer must consider the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation (regulation 11 (2) (d) IR(ME)R 17).

It is the responsibility of the Referrer to ensure the clinical outcome of the imaging is recorded in the patient's notes.

4.3.2 Practitioners

Practitioners will be employees of HSU and will be professionally registered. Those identified as Practitioners will be names on the 'List of Practitioners' held by HSU.

They are responsible for authorising the radiation exposure. They will have received training on the justification and authorisation of ionising radiation exposures and will abide by the local technique protocols (HSU's referral criteria for imaging. V2. HSU 2021) and the College of Radiologists iRefer guidelines (RCR 2017).

Practitioners must consider the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation (regulation 11 (2) (d) IR(ME)R 17). Subsequently Practitioners may liaise with referrers if further information is required for the authorisation of exposures, and they may alter the imaging requested (for instance the radiographic views undertaken or suggesting that ultrasound or MRI or another non-ionising method which may be more appropriate) based on the justification supplied by the Referrer.

The Practitioner must sign the referral form to indicate the exposure has been authorised, this may be authorised electronically using a referral system.

4.3.3 Operators

The Operator is entitled by the employer to carry out practical aspects of the exposure. Those identified as Operators will be named on the 'List of Operators' held by HSU.

Operators must have adequate theoretical and practical training relevant as detailed in Schedule 3 (IR(ME)R 17) which is relevant to their scope of practice for general (plain film) radiography and fluoroscopy.

The primary responsibility of the Operator is to optimise the exposure. The Operator must ensure that the patient is correctly identified using verbal confirmation of three forms of identification (ID) to reduce the risk of accidental exposure. They must check that the exposure has been authorised (if they are not also acting as Practitioner), and the pregnancy status of the patient is recorded if necessary (refer to Pregnancy Enquiries). This must be recorded on the patient consent form.

Operators also take consent from patients which includes checking the expected area to be imaged with the patient (to reduce the probability of an unintended exposure), an explanation of risks and benefits, and where necessary the option of using anonymised images for teaching, research and audit. This must be documented with patient initials on the consent form.

Operators are responsible for ensuring that optimum exposure factors are selected paying particular attention to ALARP (As Low As Reasonably practicable), handling and using the equipment, recording patient dose and exposure factors, image processing, and assessing the technical quality of resultant images. They may also be responsible for calibration and maintenance of equipment and must report any issues with the equipment or images to the Employer.

If the Operator is not designated as the Practitioner, then they should consult a named Practitioner if there is any doubt as to the appropriateness of any referral.

4.3.4 Medical Physics Expert (MPE)

The Medical Physics Expert (MPE) is entitled on appointment. They should only be appointed if they are adequately trained and competent for this specific role. They will be appointed in writing by HSU. As per 14(d) (IR(ME)R 17) they will give advice on:

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

They will also contribute to quality assurance of equipment, installation design and specification of equipment, training of practitioners and other staff, analysis of unintended and accidental exposures, and other duties as specified in 14(3) IR(ME)R 17.

The MPE is responsible for providing advice and information regarding any changes in legislation that is used during the periodic review of the employer's procedures. Monitoring of this document will be the responsibility of the members of Radiation Protection Group at the HSU.

4.3.5 Students

The HSU is a teaching institute, and students may be training in the process of being a Referrer, Practitioner or Operator. However, no student can act as a Referrer and all student referrals must be countersigned by a suitable Referrer. No student can independently act as a Practitioner, and no student may undertake any practical aspects of the exposure without direct supervision of an Operator.

5 REFERRALS, JUSTIFICATION AND AUTHORISATION FOR EXPOSURE

5.1 PURPOSE

To outline the procedure for receiving and acting upon referrals to use ionising radiation to image patients (for research participants refer to Research Exposures and Non-Medical Imaging).

5.2 RESPONSIBILITIES

The Employer is responsible for ensuring paper referral forms are kept current, and the online referral portal reflects the HSU's local technique protocols (HSU's referral criteria for imaging. V2. HSU 2021)

The Employer is responsible for regular auditing of referrals ensuring they adhere to protocols for providing patient information (three forms of identification, a referrers signature (may be electronic), and adequate justification for exposure). The employer may delegate the audit to the Practitioner or Operator.

The Referrer is responsible for full and comprehensive completion of the referral forms as detailed in Section 4.3.1 Referrers.

The Practitioner is responsible for ensuring any referrals are authorised in a timely manner and the referral form is signed to indicate authorisation (Section 4.3.2 Practitioners). The Practitioner is also responsible for documenting unauthorised referrals. The Practitioner will ensure the referrals are passed to the appropriate team at HSU for an appointment to be made with the patient and will ensure that all referrals are made by a professionally registered individual.

The Operator is responsible for undertaking the practical aspects of the referral including checking the correct identification of the patient, documenting patient consent, and recording patient dose (Section 4.3.3 Operators). The Operator is also responsible for ensuring the referrer receives either the images and/or a clinical impression report within a timely manner.

The bookings team are responsible for ensuring the patient receives an appointment to attend for imaging and to ensure the patient is adequately informed as to the location of the imaging service at the HSU.

5.3 PROCEDURE

Authorisation should be carried out in advance of any exposure.

Upon receipt of the referral (either by paper or the online portal) the Practitioner will check the form for the following information:

- Three forms of patient ID (refer to Section 6 Correct Patient Identification)

- Referrers signature/electronic signing. In the case of an internal referral from a student the referral must be countersigned by a registered referrer
- Views requested
- Clinical justification which should comply with iRefer (RCR 2018) or local technique protocols HSU's referral criteria for imaging. V2. HSU 2021)
- Patient's pregnancy status if applicable
- Previous relevant imaging

If any of the above are missing or incomplete, then the Practitioner may contact the referrer for the extra information. The Practitioner may delegate this task to the operator. In the event the referrer cannot be contacted then imaging may NOT proceed.

If three forms of identification or a referrers signature are missing, then imaging must NOT proceed

The Practitioner will consider the following before authorising the exposure:

- The specific objectives of the exposure and the characteristics of the individual involved
- The total potential diagnostic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure
- The individual detriment that the exposure may cause
- The efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation

If the Practitioner is aware, at the time of authorisation, that a recorded clinical evaluation will not result from the exposure, then the exposure must not be authorised and cannot take place.

When the Practitioner has authorised the referral, they will sign the referral form.

The referral form will be handed to the bookings team who will arrange the appointment with the patient.

The bookings team will make the referral available to the operator prior to imaging to allow them to prepare for the exposure.

5.4 CANCELLING AND AMENDING IMAGING REFERRALS

It is the referrers responsibility to contact the imaging team to cancel any referrals which are no longer required. If the imaging team cancel a referral, they must provide the referrer with a reason either via electronic communication (e.g. egress) or letter.

In the event an imaging referral is incomplete or inaccurate, it is the referrer's responsibility to amend the request.

6 CORRECT PATIENT IDENTIFICATION

6.1 PURPOSE

IRMER17, Regulation 6, Employer's Procedures, Schedule 2 (1)(A)

The Employer's Procedures for ionising radiation exposures must include a procedure to correctly identify the individual to be exposed to ionising radiation.

This procedure is intended to ensure that all patients undergoing any diagnostic investigation or therapy involving ionising radiation are correctly identified at each visit prior to being exposed to ionising radiation to mitigate against accidental or unintended exposures.

6.2 RESPONSIBILITIES

It is the responsibility of the Operator who directly exposes the patient to ionising radiation to ensure that the patient has been correctly identified. If the Operator cannot satisfy themselves as to the identity of the patient, they should not proceed with the examination/treatment.

It is the responsibility of the Referrer to provide three forms of identification (name, address and DoB) and relevant clinical justification including the side to be imaged (left or right) if the area of interest is the appendicular skeleton.

6.3 PROCEDURE

When a referral, either paper or electronic is received the member of staff receiving it will check that all the essential demographic details have been completed correctly. In the event there is missing information this person may contact the referrer to complete the referral, or the referral may be rejected.

When the patient arrives in the department, and before imaging commences, the Operator will check the accuracy of the details by confirming full name, date of birth and address.

The Operator will initial the consent form to indicate these checks have been undertaken. In some instances, a student will undertake these checks, but this will always be under the direct supervision of an Operator. And the operator remains responsible

The patient must be asked to give these details rather than be asked to confirm them.

The Operator will also ask the patient to confirm the expected area to be imaged and check that this matches the referral form. The Operator (or student under direct supervision) will also initial the consent form to confirm this check has been undertaken. This is to mitigate against the risk of unintended exposures.

Identification of persons unable to confirm their own identity i.e. young children or mentally impaired, should be identified by immediate family member or an accompanying carer with personal knowledge of the patient. The name and relationship or professional position of this person should be recorded on the pre-imaging checklist under 'assistance required from accompanying person'.

If the patient requires a translator to answer the identification check questions, then an official translator should be used.

If any details are still correct, the Referrer should, where possible, be contacted. They must ensure that the patient is the correct patient, change the identification details on the referral form and associated software (Clinic Office, RIS and PACS) to correct the errors. The Operator must initial the changes made before the examination can proceed.

HSU's significant events policy must be followed for any accidental or unintended medical exposure with ionising radiation due to incorrect patient identification or wrong area imaged. Furthermore, the RPS and Clinical Imaging Lead should also be informed.

Display of Pause and Check posters are recommended to remind staff of their responsibilities.

7 PREGNANCY ENQUIRIES

7.1 PURPOSE

To establish the Employer's procedure for making enquiries of individuals of childbearing potential and to establish whether the individual is or may be pregnant as per IR(ME)R 17 Schedule 2 (1)(C).

To ensure there is no dose to the foetus during a radiation exposure.

The HSU identifies individuals of childbearing age to be between 12 and 55 years old.

7.2 RESPONSIBILITIES

Referrers must consider the possibility of pregnancy when assessing the requirement for examinations involving ionising radiation. This must be documented in the radiology referral.

Operators have the final responsibility to ensure that pregnancy status is checked prior to undertaking any imaging

7.3 PROCEDURE

Radiography of areas remote from the foetus may be safely carried out at any stage of pregnancy with good collimation and appropriately shielded equipment. Areas remote from the foetus are above the diaphragm, upper limbs and from the knees down. It is not necessary to enquire about the pregnancy status of these patients.

There may be difficulties confirming the pregnancy status with the patient if they are unconscious, non-English speaking, or have difficulty in communicating or understanding.

Safeguarding concerns must be raised if an individual under the age of 16 years old declares they are, or may be, pregnant. Refer to the HSU Safeguarding policy. Age-appropriate language should be used for establishing the possibility of pregnancy in under 16-year-olds.

The Operator will ask all patients of the relevant age, who are undergoing examinations where the primary beam is between the mid femur and diaphragm, to sign a consent form to state there is no possibility that they could be pregnant.

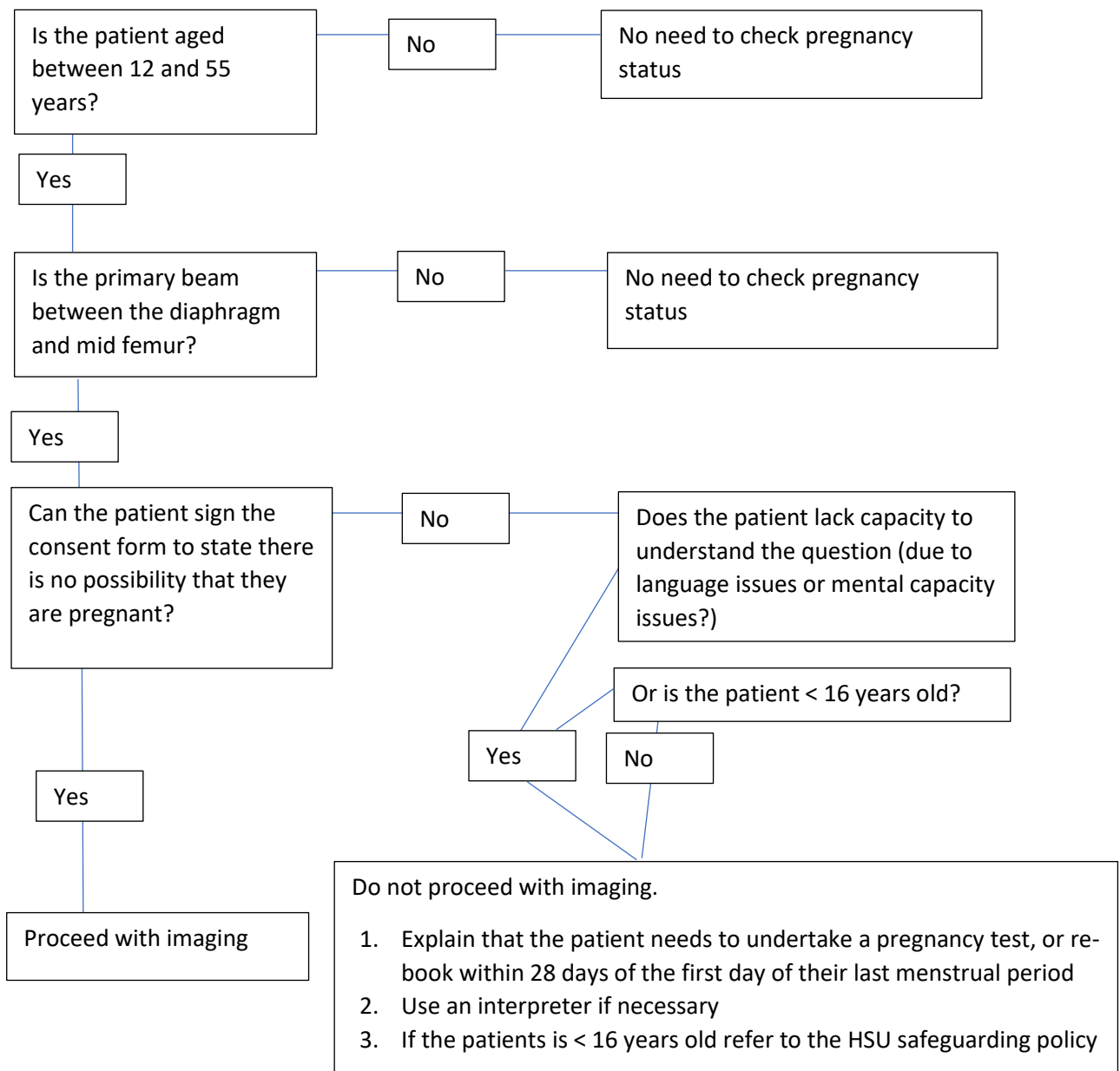
The consent form will be scanned and saved with the patient's images in PACS.

If the patient cannot deny pregnancy, or the possibility of pregnancy, imaging will not proceed. It is the patient's responsibility to either obtain a pregnancy test or wait to re-book the examination within 28 days of the first day of their menstrual period.

The HSU follow the 28-day rule for establishing pregnancy. If the patient cannot deny there are pregnant or is unsure, then imaging can proceed providing the patient is within 28 days of the 1st day of their last menstrual period.

The Operator will follow the algorithm below in establishing pregnancy.

7.3.1 Algorithm for establishing pregnancy or potential pregnancy



8 ASSESSMENT OF PATIENT DOSE AND ADMINISTERED ACTIVITY

8.1 PURPOSE

This document satisfies the requirements under Schedule 2(e) and describes the policy and the procedure for providing the requisite information for assessing the dose or administered activity to each patient.

There is no radioisotope service at the HSU therefore the employers' procedures do not cover administered activity.

Doses delivered to patients must be kept As Low As Reasonably Practicable (ALARP), consistent with the intended purpose of the exposure. To ensure the ALARP principle holds true and to comply with the requirements of the IR(ME)R Regulations, a system is in place to allow patient doses to be recorded and assessed as detailed below.

As well as the need to ensure compliance with the regulations, recording and assessing patient dose may be necessary for several different reasons. This could be to:

Assist with dose optimisation

- Compare against or establish diagnostic reference levels
- Enable the operator to determine if a dose has been given which is much greater than intended
- Satisfy an ethics committee for the use of radiation in research
- Compare different techniques or equipment

8.2 RESPONSIBILITIES

Operators must be aware of the dose indicator units of each system and ensure they are recorded appropriately. This task may be delegated to a student, but overall responsibility lies with the Operator.

Operators and the MPE must be aware of the appropriate units for equipment fitted with a DAP meter.

More detailed calculations of patient dose (e.g. to evaluate organ doses or doses to a foetus where a pregnant patient had been examined) must be referred to a Medical Physics Expert.

8.3 PROCEDURE

For plain x-ray exposures, patient doses will be assessed from the dose-area product (DAP) or exposure factors given at the end of the examination.

For fluoroscopic exposures, patient doses will be assessed from the DAP and screening time.

When DAP readings are not available, a record of kilovolts (kVp) and post - exposure mAs, should be made by the operator undertaking the exposure

The DAP and exposure readings should be scanned alongside patient images in RIS and also recorded on the 'Record of Exposures' excel sheet.

Any DAP readings above the Local Diagnostic Reference Level (LDRL) need to be noted with a reason why the exposure is higher than expected. The MPE or Operator will periodically review all DAPs above LDRL's with investigations initiated as appropriate (i.e. if the increase in exposure is due to equipment, changes in patient demographics, or changes to equipment or procedures).

The 'Record of Exposures' excel sheet should also detail when a repeat view is undertaken and the reasons for this repeat to enable 'Reject Analyses' to take place (See section 16 Audits). This sheet should also be made available to the MPE upon request to review LDRL's (see section 9 Diagnostic Reference Levels (DRL's)23).

9 DIAGNOSTIC REFERENCE LEVELS (DRL's)

9.1 PURPOSE

This document satisfies the requirements under Regulation 6 (6) and describes the policy and the procedure for measuring dose against national and local DRL's.

Diagnostic reference levels (DRLs) are dose levels for typical examinations on standard size adults and children for broadly defined types of equipment. They are used as a guide to help promote improvements in radiation protection practice. They can help to identify issues relating to equipment or practice by highlighting unusually high radiation doses. DRLs are a trigger to one of the steps of optimisation of patient dose and are not expected to be exceeded when good and normal practice is applied.

DRLs are average dose levels for typical diagnostic examinations and are not individual patient doses. They should be used in addition to professional judgement

9.2 RESPONSIBILITIES

The employer will ensure appropriate reviews are undertaken whenever diagnostic reference levels are consistently exceeded and ensure that corrective action is taken where appropriate. The employer may delegate this to the MPE or Operator.

The MPE will assist in regular reviews of LDRL's and advise on methods to maintain ALARP with respect to patient doses

The Operator will record all patient doses and record when any dose exceeds the LDRL.

9.3 PROCEDURE

The employer (HSU) will select the dose levels to be used as Local DRLs (LDRLs) in consultation with the MPE. These should be reviewed as part of a regular dose-audit programme or when new equipment is installed, or if clinical practice changes.

Deviation from the suggested exposure factors which results in an exposure being given which is outside the national DRL's or LDRL's must be logged by the Operator on the 'Record of Exposures' Excel sheet.

If there is no obvious explanation for a high dose being recorded this must be reported to the radiation lead and/or to a radiation protection supervisor.

Exposure factors are taken to mean any parameter that may be used to estimate the patient radiation exposure and in the case of a suspected over-exposure (unintended or accidental then the

MPE will be required to derive some of these parameters to calculate effective doses for any investigation.

LDRL's will be regularly audited and reviewed (see section 16 Audits).

9.4 ACTIONS TO BE TAKEN IF LDRL'S ARE CONSTANTLY EXCEEDED

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

10 EXPOSURE OF CARERS AND COMFORTERS

10.1 PURPOSE

This document satisfies the requirements under Schedule 1(b) as required under (IR(ME)R 17).

This procedure relates to exposure of those supporting an individual undergoing an examination using ionising radiation. 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.

"Carers and Comforters" means 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 an exposure¹.

"Dose constraint" means a restriction set on the prospective doses of individuals which may result from a given radiation source.

10.2 RESPONSIBILITIES

The Operator is responsible for determining whether the patient requires assistance from a comforter or carer. Such instances may be a parent or guardian or carer of the patient. Or to help with translation of instructions if the patient's understanding of spoken English is limited (In such instances however consider the use of a formal translator or instructing the patient outside of the controlled area).

The MPE will provide guidance as to the likely effective doses. Written consent from the Carer or Comforter is not required

10.3 PROCEDURE

10.3.1 Dose constraints

The exposure of a Carer and Comforter should be controlled, as far as reasonably practicable, by using time, distance and shielding, considering the wishes of the individual to offer comfort and support to the patient. As Carers and Comforters are not subject to dose limits, a dose constraint is set to restrict any unnecessary exposure. The Following dose constraints will be applied for plain radiography and fluoroscopy (Table 1)

Modality/Procedure	Dose constraint for an individual procedure ² (effective dose, mSv)	Information provided to Carer and Comforter
X-ray / Fluoroscopy	0.1	Discussion with Operator

Table 1 Dose Constraints for Carers and Comforters

10.3.2 Procedure for x-ray and fluoroscopy

Carers and Comforters should only be used if their presence is likely to ensure the successful diagnostic outcome of a procedure.

The Operator must consider if that exposure shows a net benefit considering the likely direct health benefits to the patient, the possible benefits to the Carer and Comforter, and the detriment that the exposure might cause. If stabilisation of a patient is required, then mechanical restraints or tools should be used in preference to Carers and Comforters.

Should the presence of a Carer and Comforter be appropriate:

- The Operator should ensure the Carer or Comforter stands in the Supervised area (behind the lead screen). If this is not possible then the Operator must provide the Carer and Comforter with a lead apron which should be worn at all times when in the controlled area.
- The Operator should inform the Carer and Comforter where they should stand and how they should behave to ensure their dose is kept as low as possible.
- The Operator should reassure the Carer and Comforter that should they follow this guidance that their radiation dose will be negligible.
- Signed consent is *not* required however the presence of a Carer and Comforter should be noted on the Pre-Imaging Checklist, including name and address and DoB of the Carer and Comforter and the exposure factors used, alongside the radiation protection provided (i.e. standing behind lead screen or wearing lead apron).
- If the Operator is confident that the Carer and Comforter will follow this guidance, then the exposure can go ahead.
- If the Operator is not convinced the Carer and Comforter will follow the guidance, then they should be asked to leave the controlled area before the exposure is undertaken. This could include standing in the control room if appropriate.

A pregnant person can act as a Carer and Comforter for X-ray or fluoroscopy procedures following the procedures above.

Dose constraints detailed in this procedure are derived from the One Dorset Policy for Poole Hospital NHS Trust. University Hospitals Dorset.

If quantification of dose is requested by the Carer and Comforter, then a suitable comparison would be a few hours of natural background radiation.

A Carer and Comforter would need to be involved in several hundred exposures per year before the dose limit for members of the public is reached.

11 CLINICAL AND TECHNICAL EVALUATION OF IMAGES

11.1 PURPOSE

This section satisfies the requirements under IRMER17, Schedule 2 (1)(j): and describes the policy and the procedure for carrying out and recording of an evaluation for each medical exposure. The policy states the procedure to ensure each medical exposure involving ionising radiation has a recorded evaluation including, where appropriate, factors relevant to patient dose.

Clinical evaluation of images also includes technical evaluation to ensure the images are suitable to provide information relating to the justification on the referral.

HSU receives both internal referrals from internal clinicians external referrals from registered healthcare professionals not employed by HSU.

For each exposure to ionising radiation received by a patient, a written Clinical Evaluation of Outcome of the exposure must be made and recorded. The procedure below sets out the responsibilities and procedure for this

11.2 RESPONSIBILITIES

11.2.1 External Referrers

Where the medical exposure is not evaluated at the HSU and the referrer is not an employee of HSU then it is the responsibility of the Referrer to provide a written evaluation in the patients' notes. This is most likely to be from an external referrer who has indicated they do not require a written report with the images.

Where external referrers have indicated they require a written report with the imaging it is the responsibility of the DACBRs (Chiropractors who are also Diplomates of the American Chiropractic Board of Radiology) or Reporting Radiographers to provide this report. The report is securely sent to the external referrer who will document this in the patient's notes (secure email, IEP or password protected media such as CD or USB)

11.2.2 Internal Referrers

Where the referral comes from a chiropractic intern it is the responsibility of the supervising, and professionally registered clinic tutor to countersign the referral form. They take ultimate responsibility for the referral.

The referring intern will write the report and record this in the patients notes, however this must be signed off by a DACBR or Reporting Radiographer before it can be recorded in the patient's notes

11.2.3 Practitioner

In the case of concerning pathology spotted on the imaging the Practitioner may instruct the Operator to undertake further radiographic views as necessary. Such an example may be an area of density in the lungs on a PA chest x-ray, in which case the Practitioner may proceed to a lateral chest x-ray without a separate referral.

In most instances at HSU the Practitioner and the Operator are the same person. In which case this person will act as Practitioner when deciding if further views are necessary, and Operator when undertaking the practical aspects of the exposure.

11.2.4 Operator

It is the responsibility of the Operator to ensure all images meet technical evaluation criteria and adequately demonstrate the required anatomy and pathology. This may be delegated to students but only under direct supervision of the Operator.

In any instance where the view does not meet technical image criteria then a repeat view may be necessary. The Operator must determine if a spot view is sufficient (as per ALARP) or a full repeat. The reason for the repeat must be documented in the 'Record of Exposure' excel file.

It is recommended that the Operator uses the PACEMAN acronym to check for technical evaluation (as below). Other technical evaluation acronyms or procedures may be used but they must cover the point below.

- P = Position: Is the patient suitably positioned? Check for rotation
- A = Artefacts: Any artefacts present on the imaging? Are they In or On the patient? If 'in' the patient make a note on the PACS system
- C = Collimation: Are four borders of radiographic collimation present?
- E =Exposure: Is the exposure index (E.I.) within the 'green range'? E.I. must be recorded on the 'Record of Exposure' excel file and any over exposures accounted for.

- M = Marker: Is it present and correct? If collimated out then check the scatter and include this in the original view by resetting the automatic collimation. Add an electronic marker if one is not present. Pay particular attention to the correct side
- A = Any need for further views? To further demonstrate pathology or include anatomy that may have been collimated out of the original field of view (consider spot views if so).
- N = Is the name, D.o.B and other identifying details correct?

If the Operator spots any pathology of concern they must inform the DACBR or Reporting Radiographer immediately. If the Operator is also the Practitioner they may undertake further views to demonstrate this pathology, maintaining ALARP.

11.3 PROCEDURE

11.3.1 External Referrals

If no clinical evaluation is required from HSU then the images will be transferred to the referrer as soon as possible by use of external media (CD or USB) or the Image Exchange Portal (IEP). It is then the responsibility of the external referrer to provide and document the clinical evaluation.

Where an external referrer has requested imaging and a clinical evaluation then the report must be issued by the DACBRs or Reporting Radiographers within 7 days. This will be securely emailed or posted to the referrer.

If a report is required for an external referrer, then the Operator will inform the DACBR or Reporting Radiographer that imaging has taken place. They will provide the patient's initials, DoB, clinic number and name of the referrer. This is usually undertaken via internal email.

The Operator will upload all relevant information to the patient's images on the PACS system. This includes the referral, patient consent, signed pregnancy form (if relevant) and the exposure factors and dose given for each view.

The report will be sent directly to the external referrer (via secure email or post) by the administration team.

11.3.2 Internal Referrals

The Operator will upload all relevant information to the patient's images on the PACS system. This includes the referral, patient consent, signed pregnancy form (if relevant) and the exposure factors and dose given for each view.

It is the responsibility of the referring intern to record the clinical evaluation and have this signed off from a DACBR or Reporting Radiographer within 7 days. The DACBR or reporting radiographer takes final responsibility for issuing this report.

11.3.3 All referrals

The clinical evaluation of all referrals will be uploaded to the PACS and/or RIS system.

12 INFORMATION RELATING TO BENEFITS AND RISK OF EXPOSURE

12.1 PURPOSE

This document satisfies the requirements under Schedule 2, Regulation 6, Employer's Procedures, 1 (i) and describes the policy and the procedure.

The Employer's Procedures for exposures must include a procedure providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure.

The Clinical Imaging Board (CIB) have now written and published a set of posters, to be displayed to support this communication work. The CIB provides guidance, oversight and support for the continuing development of high-quality clinical imaging services for patients in the UK. It was established by The Royal College of Radiologists (RCR), the Society and College of Radiographers (SCoR) and the Institute of Physics and Engineering in Medicine (IPEM).

There are many different approaches to describing the risks associated with exposure to ionising radiation and setting them in context to the potential benefit. In examinations involving X-rays the exact dose to an individual is not known until after the exposure has occurred. This is therefore a very complex subject with many different interpretations. It is essential to recognise that in the vast majority of cases the radiation risk from carrying out a radio-diagnostic examination (x-ray or fluoroscopy at HSU) is far lower than the risk of not doing the examination, potentially leading to a missed or incorrect diagnosis and subsequent inappropriate clinical management of the patient. Furthermore, the radiation risks are also far lower than those risks experienced by patients from many other medical interventions.

12.2 RESPONSIBILITIES

12.2.1 Department Managers:

To communicate this Employer's Procedure to all staff concerned.

12.3 PRACTITIONERS AND OPERATORS

To comply with the requirements of this Employer's Procedure and take consent from patients recorded on the consent form that they have had the opportunity to be further informed as to the risks and benefits of the exposure.

12.4 PROCEDURE

Adequate information relating to the benefit of diagnosis and risk associated with the radiation dose from the radiation exposure should be given by the Operator.

This task may be delegated to student under the direct supervision of the Operator.

Information should be provided prior to entering the examination room to avoid any implicit bias or persuasion in the information given.

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

Descriptor	Examination	Maximum Dose	Equivalent Period of Background Radiation	Cancer Risk Range
Negligible	Chest, Teeth, Arms and Legs, Hands and Feet.	0.02mSv	A few days	< 1 in a million
Minimal	Skull, Head, Neck	0.2mSv	A few weeks	1 in a million to 1 in 100,000
Very Low	Hip, Spine, Abdomen, Pelvis, CT scan of Head, Fluoroscopy of the spine	2mSv	A few months to a year	1 in 100,000 to 1 in 10,000
Low	CT scan of chest, CT scan of abdomen	20 mSv	A few years	1 in 10,000 to 1 in 1000

Table 2 Typical Radiation Doses for comparison: adapted from Radiation Risk Descriptors (based on "X-rays – how safe are they?" (NRPB 2001)

Natural background radiation in UK is around 2.7mSv per year.

Operators should verify that this information has been given to the individual prior to exposure by asking the patient to initial the consent form. The consent form must be scanned and saved alongside the patient images in PACS.

If further information is required, the Operator may refer to the leaflet; ("X-rays – how safe are they?" - NRPB 2001)

All persons of pregnancy bearing potential (see section 7 Pregnancy Enquiries) should be made aware of the effects of ionising radiation on the unborn foetus through the use of posters and signs in waiting areas.

13 TRAINING AND EDUCATION

13.1 PURPOSE

This section relates to Schedule 3 (1) IR(ME)R which specifies ‘adequate training’ and states that Practitioners and operators must have successfully completed training, including theoretical knowledge and practical experience covering radiation production, radiation protection and statutory obligations relating to ionising radiation.

“Adequate training” means training which satisfies the requirements of Schedule 3 and the expression “adequately trained” is to be construed accordingly (IR(ME)R 17).

Training for Practitioners and Operators under IR(ME)R 17 must cover the sections detailed in Table 3 p34 (below).

Fundamental Physics of Radiation Protection	
Properties of radiation	Excitation and ionisation Attenuation of ionising radiation Scattering and absorption
Radiation Hazards and Dosimetry	Biological effects of radiation, stochastic and deterministic Risks and benefits of radiation Absorbed dose, equivalent dose, effective dose, other dose indicators and their units
Management and Radiation Protection of the Individual being Exposed	
Special Attention Areas	Pregnancy and potential pregnancy Asymptomatic individuals Breastfeeding* Infants and Children Medical and Biomedical Research Health Screening Non-medical Imaging Cares and Comforters High dose techniques*
Justification	Justification of the individual exposure Use of existing appropriate radiological information Alternative techniques
Radiation Protection	Diagnostic reference levels
	Dose constraints
	Dose optimisation
	Dose reduction and techniques
	Dose recording and dose audit

	General radiation protection
	Quality assurance and quality control including routine inspection and testing of equipment Risk communication
	Use of radiation protection devices
Statutory Requirements and Non-Statutory Regulations	Regulations Non-statutory guidance Local procedures and Protocols Individual responsibilities relating to exposures Responsibilities for radiation safety Clinical audit
Modalities	
General (plain film and fluoroscopy)	Fundamentals of radiological anatomy Factors affecting radiation dose Fundamentals of clinical evaluation Identification of the individual being exposed Principles of radiological techniques Production of x-rays Equipment selection and use
Fundamentals of image acquisition	Optimisation of image quality and radiation dose Image formats, acquisition, processing, display and storage
Specialise techniques (i.e quantitative fluoroscopy)	Quantitative imaging – advance applications

Table 3 Areas required for adequate training under IR(ME)R Schedule 3 (adapted from IR(ME)R 17)

13.2 RESPONSIBILITIES

13.2.1 Employer

It is the responsibility of the employer (HSU) to ensure adequate training of staff operating the equipment.

13.2.2 Referrers

Maintain their own record of adequate training for referrers and provide this evidence to HSU upon request. The HSU usually requests that this training is updated every three years.

13.2.3 Practitioners and Operators

By way of their degree or other professional qualification, their professional registration, and CPD, made available to the employer upon request.

13.3 PROCEDURE

Upon admitting a referrer to the register of referrers the HSU will check that they are professionally registered and have completed suitable training to understand their obligations under the IR(ME)R 17 regulations.

Upon appointment of a Practitioner or Operator the HSU will check their professional qualifications in line with Human Resource Policy.

Upon request, the Practitioner or Operator will supply the HSU with their up to date training record and CPD to provide evidence of adequate training covering the areas in Table 3 p34.

Any other Employer contracted to provide services relating to ionising radiation must provide evidence of adequate training immediately on request.

14 INCIDENT REPORTING

14.1 PURPOSE

If the incident involves emission of radiation then his procedure should be used alongside Section 15 Reducing the Probability and Magnitude of Accidental or Unintended Exposures.

An incident covers both accidents, near misses, and undesired circumstances.

14.1.1 Definitions

Accident	Any accident or event that results in injury or ill health
Near Miss	An event not causing harm, but has the potential to cause injury or ill health
Dangerous Occurrence	One of a number of specific, reportable adverse events, as defined in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)

Table 4 Definition of Incidents taken from the Health and Safety Executive (reference)

14.2 RESPONSIBILITIES

All staff and students are responsible for reporting any incident involving any aspect of the ionising imaging service (including any problems with PACS or Clinical Evaluation of Images).

Outside workers are also encouraged to report any incidents to the HSU as well as their own employer.

14.3 PROCEDURE

Any incident involving the imaging service must be reported using the HSU 'significant events' forms.

The forms must be completed as soon as possible after the incident and emailed to the Clinical Imaging Lead or completed via online portal.

If any incident involved the emission of ionising radiation the RPS must also be immediately informed and the Section 15 Reducing the Probability and Magnitude of Accidental or Unintended Exposures consulted to determine if the RPA, HSE and/or CQC also need to be informed.

Be aware that in the case of an incident involving the emission of ionising radiation, in some instances there is a limit to the time within which it must be reported.

14.3.1 Incident Learning and Reporting

Incidents should be reported through the significant events policy and discussed at the relevant policy meetings (i.e. Health and Safety Group, Radiation Protection Group, Senior Management Group).

Where the investigation of an incident reports exposure is not much greater than intended, the Radiology Quality Group will take steps to minimise the risk of reoccurrence of such incidents and, upon request, share data with the CQC.

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

Where the employer knows or has reason to believe that an unnecessary radiation dose may have occurred to a person, while undergoing a medical exposure, he/she shall make an immediate preliminary investigation of the incident. When an accidental or unintended dose occurs the RPS, RPA and MPE must be informed Section 15 Reducing the Probability and Magnitude of Accidental or Unintended Exposures and an investigation launched.

The investigation will establish where the failure in the process occurred.

Steps must be taken to minimise the risk of reoccurrence, including any changes in protocols or procedures required.

Should the dose “much greater than intended” be a result of operator error then the incident should be reported to the CQC.

Should the dose “much greater than intended” be a result of a malfunction or defect in equipment the RPA will report to the HSE.

15 REDUCING THE PROBABILITY AND MAGNITUDE OF ACCIDENTAL OR UNINTENDED EXPOSURES

15.1 PURPOSE

This procedure covers the arrangement and management of incidents relating to the use of ionising radiation as required under IR(ME)R 17 Schedule 1k, and the Ionising Radiations Regulations 2017 (IRR17).

The Ionising Radiations Regulations 2017 (IRR17) and IR(ME)R 2017 require the establishment of procedures for investigation and reporting and possible notification of radiation incidents.

This Procedure deals with situations where a known or suspected radiation incident has occurred. This process starts with the selection and installation of the equipment and continues through to the actual exposure of the individual.

The incidents covered are those caused by:

- equipment failure
- failure of procedure
- failure to follow procedures
- inappropriate professional judgement
- human error

The Care Quality Commission (CQC) has published a list of notification codes, categories and criteria for IR(ME)R incidents. For reportable incidents, the CQC will expect this SAUE taxonomy and coding to be used in the notification. An MPE must be consulted in these instances.

The Royal College of Radiologists has published the report on behalf of the Clinical Imaging Board (CIB) of a working party on learning from incidents and near misses involving medical radiation, including a taxonomy and coding system for categorising all such incidents. For non-reportable incidents, this coding can be used instead or as well as the CQC coding.

Examples of procedural errors include:

- Imaging or performing therapy on the wrong patient
- Not checking previous history risking duplication of procedure
- Omitting pregnancy status checks
- Imaging or performing therapy on the wrong part of the body (site/side)
- Incorrect exposure set / incorrect radioisotope administered
- Accidental exposure of another member of staff

Use of these Employers Procedures and justification process reduce risk of accidental patient over exposure. Local Rules should mitigate the risk of overexposing staff and members of the public. Diagnostic radiography staff are required to adhere to the Society of Radiographers pre and post examination check list, known as 'PAUSED'.

Examples of errors or incorrect information occurring in the referral include:

- Incorrect patient demographics
- Incorrect type of imaging modality
- Laterality errors (i.e. wrong side requested)
- Wrong body part

Mistakes made in the referral process are not infrequent. All have the potential to give a patient a radiation dose much greater than intended. It is important to keep a record of **all** errors to help determine any patterns in reporting errors.

Guidance from the CQC states that "When accidental and unintended exposures are judged to be 'significant' (or SAUE – Significant Accidental Unintended Exposure), they need to be notified to the enforcement authority under Regulation 8(4)." They categorise SAUE as:

15.1.1 Accidental exposures

An individual has received an exposure in error, when no exposure of any kind was intended.

15.1.2 Unintended exposures

Although the exposure of an individual was intended, the exposure they received was significantly greater or different to that intended. For example, in the dose received, the modality or technique carried out, anatomy imaged, or timing of exposure. These can happen for many reasons including equipment failure, procedural, systematic or human error."

15.1.3 Clinically significant accidental or unintended exposures (CSAUE)

Any incident, determined by the Operator, Practitioner or MPE, to have resulted in demonstrable moderate clinical harm or greater to the patient affected. Moderate harm being defined as a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm.

15.2 RESPONSIBILITIES

It is the responsibility of all staff involved in the process of the exposure of patients to ionising radiation to ensure that these exposures are no greater than intended. However, in the event of an incident, this Employer's Procedure should be followed

15.2.1 Employer

Ensuring that the appropriate specification is produced prior to the purchase of equipment and ensuring the advice of the relevant RPA/MPE is sought.

Ensuring that learning from incidents is appropriately disseminated and integrated into working practices.

15.2.2 Practitioner

Ensuring that other appropriate techniques are considered in preference to those using ionising radiation.

15.2.3 RPA/MPE

To communicate with the HSE/MHRA/CQC as appropriate following an incident.

15.2.4 MPE/Operator

Design of the Quality Assurance (QA) programme, including acceptance testing, calibration and routine Quality Control (QC). The Lead MPE is responsible for those aspects of equipment QA that must be undertaken by Medical Physics staff. The relevant MPE and RPS is responsible for those aspects of equipment QA that should be undertaken by Radiographers.

15.2.5 Operator

Responsible for ensuring that the dose to the patient is optimised. Only appropriately trained operators must be allowed to make exposures. Those in training may do so under supervision.

15.3 PROCEDURE

15.3.1 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 MPE must be involved in the specification of all new equipment.

X-ray emitting equipment is only to be installed in suitably protected rooms.

Installations are subjected to a prior risk assessment as required by IRR 17.

Installations are subjected to a critical examination as required by IRR 17 and acceptance tested to the standards required by IPEM Equipment Quality Assurance Reports, Medical and Dental Guidance Notes, NHSBSP Equipment Reports or other publications of a similar standing.

No equipment will be procured that does not meet the minimum standards required by IRMER Regulation 15 & 16 with regard to dose reporting.

15.3.2 Equipment errors resulting in an ionising radiation incident

Examples of equipment errors include:

- Non-termination of exposure following release of exposure switch
- Image “lost” on modality causing re-imaging

The CQC guidance (2019) states that the term ‘equipment’ not only includes equipment that delivers radiation but also ancillary equipment that directly influences the dose to the individual. This can include, but is not limited to:

- Software
- Picture archiving and communication systems (PACS)
- Radiology information systems (RIS) or similar

If an Operator suspects that a piece of equipment has malfunctioned and exposed a person (patient, member of staff or member of the public) to a radiation dose greater than intended, an immediate investigation must be carried out as follows:

The Operator must inform the clinical imaging lead and RPS as soon as possible.

The RPS should liaise with the MPE and/or RPA to determine if the equipment should be taken out of action.

If appropriate, a notice should be placed on the piece of equipment informing other staff not to use the equipment and the equipment turned off.

15.3.3 Exposure technique

Consideration must be given to the use of imaging techniques that employ non-ionising radiation in preference to those that use ionising radiation. The diagnostic accuracy and relative waiting time for non-ionising techniques relative to clinical need should be given due attention.

Optimisation of exposures using beam collimation, correct selection of exposure factors and programmes, automatic exposure controls, dose sparing features and other limiting devices together with good radiographic technique is expected as normal practice.

The patient is positioned by an appropriately trained operator or student under direct supervision.

Diagnostic exposure factors are chosen by an appropriately trained operator, following guidance from the MPE, if needed. Where exposure parameters are pre-programmed, they should be checked before exposure to ensure they are applicable to that patient.

When new clinical techniques are introduced, it is particularly important that the relevant MPE should be involved in the optimisation of exposure.

15.3.4 Pause and Check

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

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

15.3.5 All incidents

If a patient is involved in an over-exposure then they, or their representative, should be informed as soon as possible. If you feel unable to do this, ask the most senior person present to assist. If the incident is not noticed until after the patient has left the premises, it may be more appropriate for the Referrer to speak to the patient. If moderate harm or greater has occurred, then this communication must follow the Employers Duty of Candour Process.

For a patient, or comforter and carer, if overexposure occurs, the MPE should also be informed as soon as possible, as should the Referrer and Clinical Imaging Lead.

For an overexposure of staff, student under supervision, or a member of the public, the RPS and RPA must be informed as soon as possible. The personal dosimeter for that person must be read immediately, or the RPA can estimate the dose if it is to a member of the general public or a member of staff that does not wear a dosimeter.

Staff involved must complete a significant events form (see section 14 Incident Reporting).

The RPA/MPE will consider whether the incident is reportable to the CQC, HSE or MHRA. They are responsible for this communication, and it must be done ASAP and, in any case, no longer than 2 weeks after the incident occurred.

15.3.6 Criteria for reporting incidents to the CQC

For a patient overexposure, the MPE will need to calculate the person's effective dose and decide whether the incident needs to be reported on to the CQC. The CQC revised its notification guidance and the criteria for notification applies to the total exposure from the incident.

In addition to this guidance, IR(ME)R Reg 8(4) requires that all 'clinically significant' accidental or unintended exposures are notified to the appropriate enforcing authority.

Table 5 p42 shows the criteria for a significant accidental or unintended exposure (SAUE) that must be notified to the CQC under IR(ME)R, and the related notification code: NB: It is not expected that any examination at HSU using plain film or fluoroscopy would ever impart an intended dose greater than 2.5mSv.

Notification code	Exposure category	Criteria for notification
Accidental exposure:		
1	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) ^c
Unintended exposure:		
2.1	Intended dose less than 0.3mSv	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) ^c
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	25 mSv or above
2.4	Intended dose more than 10mSv	2.5 or more times than intended
5	Foetal All modalities	Where there has been a failure in the procedure for making pregnancy enquiries and the resultant foetal dose is 1mGy or more
Complementary notification codes		
E	Equipment fault exposure (suffix as above)	
V	Voluntary notification (suffix as above)	
C	Clinically significant event (suffix as above)	

Table 5 IR(ME)R incident: notification codes, categories and criteria

15.3.7 Criteria for reporting incidents to the HSE/MHRA

Where members of the public or staff/students receive an over-exposure to ionising radiation, the incident must be reported to the HSE. The RPS and RPA will over-see this.

Over-exposures resulting from equipment faults before the equipment is put into clinical use, for example, for critical examination, should also be reported to the HSE.

Dose levels to staff are recorded in the Local Rules.

MHRA:

Where there are risks to individuals relating to medical devices, consideration should be made to reporting device and medicine-related incidents to the MHRA.

15.3.8 Incident learning and reporting

Refer to section 14 Incident Reporting p35.

16 AUDITS AND QUALITY CONTROL

16.1 PURPOSE

It is a requirement of IR(ME)R that employers include provision for carrying out clinical audit (Regulation 7) and dose audit (Schedule 3) as appropriate. Regulation 6 also required the employer to establish quality assurance programmes as set out in Schedule 2. The Employer's Procedures for exposures must include a procedure to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed.

This section sets out the audits to be undertaken by the HSU with respect to ionising imaging examinations.

16.2 RESPONSIBILITIES

16.2.1 Employer

Ensuring regular clinical audits as detailed below are periodically undertaken in a suitable timeframe. They may delegate this to the Practitioner or Operator.

16.2.2 Practitioner/Operator

Undertaking regular clinical audits and quality assurance programmes as delegated by the employer.

16.3 PROCEDURE

All procedures and protocols must be subjected to periodic audit to ensure that they are current, effective and appropriate. Any necessary improvements or amendments should be identified.

The findings of all audits will be documented and made available to the RPA/RPS/MPE and any other suitably interested party upon request.

Written records of audits must be kept to demonstrate the quality assurance procedures being followed. A report to the Radiation Protection Group should be submitted if there are persistent problems.

Staff must report any instance when they are aware procedures and protocols are not being followed and are not working as expected.

A list of suggested audits and their frequency are detailed in Table 6 p45 (below).

Audits will be reviewed at the Radiation Protection Group meeting.

Audit	Frequency	Responsible Person
Equipment Quality Assurance	Every 2 months as detailed in IRR 17 and requested by MPE. Or when there has been a change/repair to equipment, practice or policy. This may be undertaken more frequently as part of student training.	Employer, who may delegate this to an Operator
Dose audit (LDRLS)	Annually	MPE/Operator
Mandatory Staff Training	As per relevant institutional policy.	Employee/HR
Reject Analysis of Images	Annually. Reject rate for each view set at no more than 15% (to consider that HSU is a teaching institution)	Operator/MPE
Technical Evaluation of Image Quality	Every Year. 5% of all images reviewed (see section 11 Clinical and Technical Evaluation of Images p27)	Practitioner or Operator

Table 6 Suggested clinical audits and quality assurance programme

16.3.1 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 indirect supervision of an MPE.

Performance testing will also take place following any modification of equipment which might influence 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 Standard Operating Procedures (SoP) must be followed for all QA testing of all ionising imaging equipment

Results must be recorded in the Excel Sheet and any levels beyond the remedial level must be reported to the RPS and Clinical Imaging Lead immediately. If any results are beyond the suspension level, then the equipment must be taken out of use immediately, switched off, and a 'Do Not Use' sign placed on the control panel. Inform the RPS and clinical imaging lead immediately.

16.3.2 Dose Audit (Local DRL's)

Refer to section 9 Diagnostic Reference Levels (DRL's) Each room must have its own DRL and these should be compared to other local DRL's and National DRL's.

The data from the 'Record of Exposures' will be regularly transferred in to the 'DRL' excel sheet which will provide live updates of the count of each examination (per body part and view) and the 75% percentile DAP reading. The data transferred will not include patient identifying details.

The DRL sheet will be transferred annually to the MPE for them to calculate LDRL's for each body part and view. The MPE and Operator will review the DRL's and identify any which may have increased. An investigation into increased DRL's will be undertaken by the MPE/Operator paying attention to patient demographics, equipment, and techniques.

Any changes to clinical practice or the equipment, as well as any new national recommendations will be considered in reviewing the LDRLs and form part of the recommendations made.

16.3.3 Staff training

The employer may request the Continuing Professional Development (CPD) records of all Practitioners and Operators every 2 years. The Employer will keep a written record of visualisation of the CPD.

The Employer will also check that the Practitioners are professionally registered with an appropriate body as mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(a).

The employer will ensure that all staff members complete the relevant mandatory training as required.

16.3.4 Reject Analysis

When an image is deemed to fail the technical quality evaluation and requires a repeat (see section 11 Clinical and Technical Evaluation of Images), the Operator will record this on the 'Record of Exposures' excel sheet along with the reason for the repeat.

It is suggested that all rejected images are labelled as such and stored on PACS (not deleted from the workstation) as this is an aid for teaching.

Every year the reasons for rejected images will be examined for any trends.

The reject rate is set at 15% for each body area. If the reject rate is higher than the trends will be investigated and further training implemented for the Operators where necessary.

The reject analysis will be stored on the 'Reject Analysis' Excel sheet and made available to interested parties upon request.

16.3.5 Technical Evaluation of Image Quality

A yearly audit of technical image evaluation is suggested.

The Operator or Practitioner will select 5% of all images undertaken in the previous year and grade them according to the PACEMAN criteria (see section 11.2.4)

Particular attention must be placed on the visualisation of a marker (at source or electronic) on the image. The suggested target for this is 100%

The results must be recorded and distributed to all Operators and Practitioners and made available to other interested parties upon request.

16.3.6 Written Protocols and Standard Operating Procedures

Written protocols and SoPs will be reviewed every two years by the Radiation Protection Group, or when there is a significant change to practice, equipment, or procedures.

Operators and other staff will report to the RPS/MPE and clinical imaging lead any deviations or changes as soon as they arise.

16.3.7 Acting on audit findings

The data collected from audits will be collated and trends identified. Where the data are not as expected or are outside of tolerance, a review will be performed by an appropriate member of the Clinical Imaging or Medical Physics teams to identify a cause. Where practicable, changes will be implemented as soon as possible. If required, a further audit will be performed before the planned frequency to ensure the changes have led to compliance.

17 RESEARCH EXPOSURES AND NON-MEDICAL IMAGING

17.1 PURPOSE

This section satisfies the requirements under Schedule 1(h) of the IR(ME)R Employers Procedures and describes the policy and the procedure for research programmes.

All research projects using ionising radiation at HSU must comply with the National Research Ethics Committee (LREC) guidelines and have IRAS approval (including oversight by a medical radiation expert, usually an MPE). The HSU's research committee's written approval must be obtained before the project can commence.

Non-medical imaging exposures are those undertaken for insurance, administrative or legal purposes (such as suspected drug smugglers) where there is not expected to be any direct health benefit for the patient.

17.2 RESPONSIBILITIES

The responsibility for referring and justifying research exposures lies with the Principle Investigator

The responsibility for authorising research exposures lies with the named Practitioner under their scope of practice. The Practitioner must have reviewed the research protocol.

The Operator will be responsible for the practical aspects of the research exposure. They must be familiar with any changes to standard practice and adhere to the procedures for patient identification, consent, and optimisation of exposure factors and image quality.

17.2.1 MPE

Oversight of the ionising radiation aspect of the research or non-medical procedure including an estimation of the risk and benefits to the individual and society.

17.2.2 Referrer

Research studies or non-medical referrals must be identified as such on the request. Any such request must be made by a doctor or authorised non-medical referrer. The request must state the name of the research study, the type of examination required, and must be fully completed.

17.2.3 Practitioner

The Practitioner will take any nonmedical benefits to the patient into account when justifying the procedure, and will take particular account of the risks in relation to those benefits

17.2.4 Operator

Obtaining consent to undertake imaging from the patient or research participant and an explanation of the full risks and benefits. (NB: Informed consent for the research will be taken by the Principal Investigator or Chief Investigator, or suitably delegated person as detailed in the ethics application.

17.3 PROCEDURE

17.3.1 Research

It is the responsibility of the research lead to ensure the latest NRES (National Research Ethics Service) guidelines are followed. They will identify a suitable IRMER Practitioner who will liaise with an appropriate local Medical Physics Expert (MPE).

All research programmes must have approval from the relevant Ethics Committee before commencing.

Each research project involving exposure to individuals for whom no direct benefit is expected from the exposure will have a dose constraint applied on the advice of a suitable MPE. This dose constraint must not be exceeded.

Each research project involving exposure to individuals for whom a direct benefit is expected from the exposure will state a target level of dose on the advice of a suitable MPE. This target level of dose should be set at a level which it is anticipated will not be exceeded but may be exceeded if the clinical benefit of additional exposure outweighs the radiation detriment.

All volunteers must be screened to ensure suitability. Pregnant women and children should not normally be accepted as volunteers unless the project concerns their population group specifically.

Adults who lack the capacity to consent must be excluded as volunteers.

The risks of the exposure must be communicated to the volunteers by the research proposer or team member and confirmed by the Operator.

The Practitioner who authorises a research exposure must:

- Satisfy themselves that the subjects participate voluntarily
- Ensure that the subjects are informed in advance about the risks of exposure
- Where no direct medical benefit for the individual is expected from the exposure, ensure that the employer's dose constraint is adhered to

Where there is a direct benefit, plan a target for the dose to an individual volunteer.

Just as for standard medical radiation exposures, there should be a record of the exposure factors, to enable an estimate of the effective dose to the individual and to ensure compliance with the dose constraint.

In the event that the research is part of a multi-centre trial being led by a Chief Investigator from another centre, the local Practitioner is responsible for reviewing the trial protocol and main REC application and confirm in writing to the local Principal Investigator that the local site can adhere to the protocol, local patients are covered by the main Research Ethics Committee (REC) submission and any additional exposure is justified having regard to IRMER.

Similarly, the local MPE is responsible for reviewing the trial protocol and main REC application to confirm to the local Principal Investigator that the estimated ranges of doses made by the Lead MPE for the research are reasonable. A local dose constraint or target dose should be established, and this should be in line with the total research protocol dose estimated in the main REC application; concerns must be addressed with the Lead MPE for the research.

For local trials or studies which are not part of multi-centre research programmes, the procedure outlined above should be followed, where the local principal investigator and MPE have the additional responsibilities of the Chief Investigator and Lead MPE respectively.

The Radiation Protection Group must be informed of all research projects before approval through the LREC guidelines.

17.3.2 Non-medical referrals

Appropriate written protocols must be in place for every type of standard radiological practice, including non-medical exposures.

The Practitioner must authorise all non-medical referrals based on the non-medical benefit versus the risk to the individual person, or the procedure which is being requested.

Patient consent should be taken as per section 6 Correct Patient Identification. Imaging must not proceed if the person does not consent.

Pregnancy status must be established as per section 7 Pregnancy Enquiries. If pregnancy cannot be excluded, then the imaging must not proceed. Consult back to the Referrer.

Any additional projections or investigations, which may be required as a result of the initial investigation, must be medically justified.

18 EQUIPMENT INVENTORY

18.1 PURPOSE

A radiation equipment inventory will be kept by each Department, detailing for each unit:

- The type of equipment including the make and model
- Serial number(s) or other unique identifier
- The year of manufacture
- Date of installation / acceptance
- Any significant modifications carried out since installation.

18.2 RESPONSIBILITIES

Employer, who may delegate this to the Radiation Protection Group or Operators.

18.3 PROCEDURE

Updated whenever new equipment is procured (see section 15.3.1 Procurement of equipment)

19 REFERENCES

1. Ionising Radiation (Medical Exposure) Regulations 2017, SI 2017/1322 (Available from <https://www.legislation.gov.uk/uksi/2017/1322/contents/made> [accessed 13.7.21])
2. Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017, Department of Health and Social Care (2018) (Available from: www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance [Accessed 13.7.21])
3. Royal College of Radiologists. 2017. Making the best use of clinical radiology (iRefer) guidelines. 8th Edition. Online. Available from: <https://www.rcr.ac.uk/clinical-radiology/being-consultant/rcr-referral-guidelines/about-irefer> [accessed 13.7.21]
4. HSU. 2020. Imaging referral criteria guidelines 2020. V2. Issued 8.7.21 [Unpublished]

20 APPENDICES

21

Signature Sheet.

To be returned to Irix@aecc.ac.uk

This is to confirm that:

Name

Signature

Date

Has read and understood this document:

Health Sciences University

Employers Procedures

Ionising Radiation (Medical Exposure)
Regulations 2017

(IR(ME)R 17)