Leeds Teaching Hospitals NHS Trust

Radiology & MIS Clinical Services Unit

Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17)

EMPLOYER'S PROCEDURES

X-Ray, Fluoroscopy (including Radiology Theatres), CT, Mammography, DXA and Diagnostic Nuclear Medicine

Document:	**Employer's Procedures for Medical Exposures**	
Version:	8	
Approved by:	**Date:**	**Designation:**
Radiation Governance Group	04.09.2025	Chair, Radiation Governance Group
Authorised by:	**Date:**	**Designation:**
Trust Executive Directors	09.12.2025	Chief Medical Officer
Target audience:	All staff working within Clinical Radiology, or using their services, or equipment owned by them, and involved in the exposure of individuals to ionising radiation for medical exposures and non-medical imaging.	

Contents

Glossary

10-day rule
The first 10-days following the 1st day of menstruation.

28-day rule
The first 28-days following the 1st day of menstruation

Authorisation
The confirmation that the justification process has taken place. Authorisation guideline must be followed if an operator has authorised the exposure.

ARSAC
An abbreviation for the Administration of Radioactive Substances, Advisory Committee which approves the licensing of Employers, for each medical radiological installation which is undertaking the administration of radioactive substances to humans, and of individual practitioners.

Diagnostic reference level (DRL)
Radiation dose levels for typical diagnostic examination for typical examination on standard size adults and children.

Gillick competent
Children under the age of 16 can consent to their own treatment if they're believed to have enough intelligence, competence and understanding to fully appreciate what's involved in their treatment.

Glomerular Filtration Rate (GFR)
A Nuclear Medicine procedure which is a measure of how the kidneys are working

Inclusive pregnancy disclaimer (IPD)
Patient between 12 and 55 will be asked to confirm their gender (male, female, or intersex). If the patient replies "female" or "intersex", pregnancy enquiries will be asked.

Justification
The process of weighing up the potential benefits of the exposure against the risks of the radiation dose.

Medical Physics Expert (MPE)
A person having the knowledge and training to give advice on the application of physics to the diagnostic uses of ionising radiation, as defined in the IRME Regulations (2017).

Non-Medical imaging
Exposures that do not have a direct health benefit to the patient undergoing the exposure.

Operator
A person who is trained and entitled to carry out the practical aspects of an exposure.

Practitioner
A registered healthcare professional who is entitled to justify an individual exposure

Referrer
A registered healthcare professional who is entitled to refer patients for exposures in Radiology

Registered healthcare professional
A person who is a member of a professional regulated body mentioned in Section 25(3) of the National Health Serviced Reform and Health Care Professions Act 2022[1].

NOTE – Version control managed in Q-Pulse, all printed documents must be checked against Q-Pulse version to ensure that it is current.

1.0 Introduction

This document relates to the Ionising Radiation (Medical Exposure) Regulations 2017 and the Ionising Radiation (Medical Exposure) as Amended [2].

Under IR(ME)R 2017 regulation 6(1) the Trust must ensure that where appropriate, written procedures are in place in respect of those matters described in Schedule 2 of the regulations. This document outlines procedural standards that must be adopted within the Trust, or those using the Trust's services or equipment.

Other documents such as Trust policies, local department procedures and local rules may also need to be followed as part of compliance.

The Trust is committed to minimising risks to patients and ensuring that medical exposures are individually justified and optimised.

1.1 Scope

This document applies to all medical and non-medical exposures undertaken by the Radiology & MIS Clinical Service Unit (CSU) or by other CSUs which are using Radiology & MIS services or equipment owned by Radiology & MIS.

Separate Employer's Procedures have been developed to cover Radiotherapy, Dental Radiology, Cardiology, Brachytherapy and molecular Radiotherapy procedures.

2.0 Roles and Responsibilities

2.1 Chief Executive

The Chief Executive of Leeds Teaching Hospitals Trust (LTHT) has overall responsibility for ensuring that these Employer's Procedures are complied with.

2.2 Radiation Governance Group

The Radiation Governance Group (RGG) has delegated authority from the Quality and Safety Assurance Group (a sub-committee of LTHT Trust Board) to oversee and monitor Trust activities related to Radiation Protection and Medical Radiation Exposures.

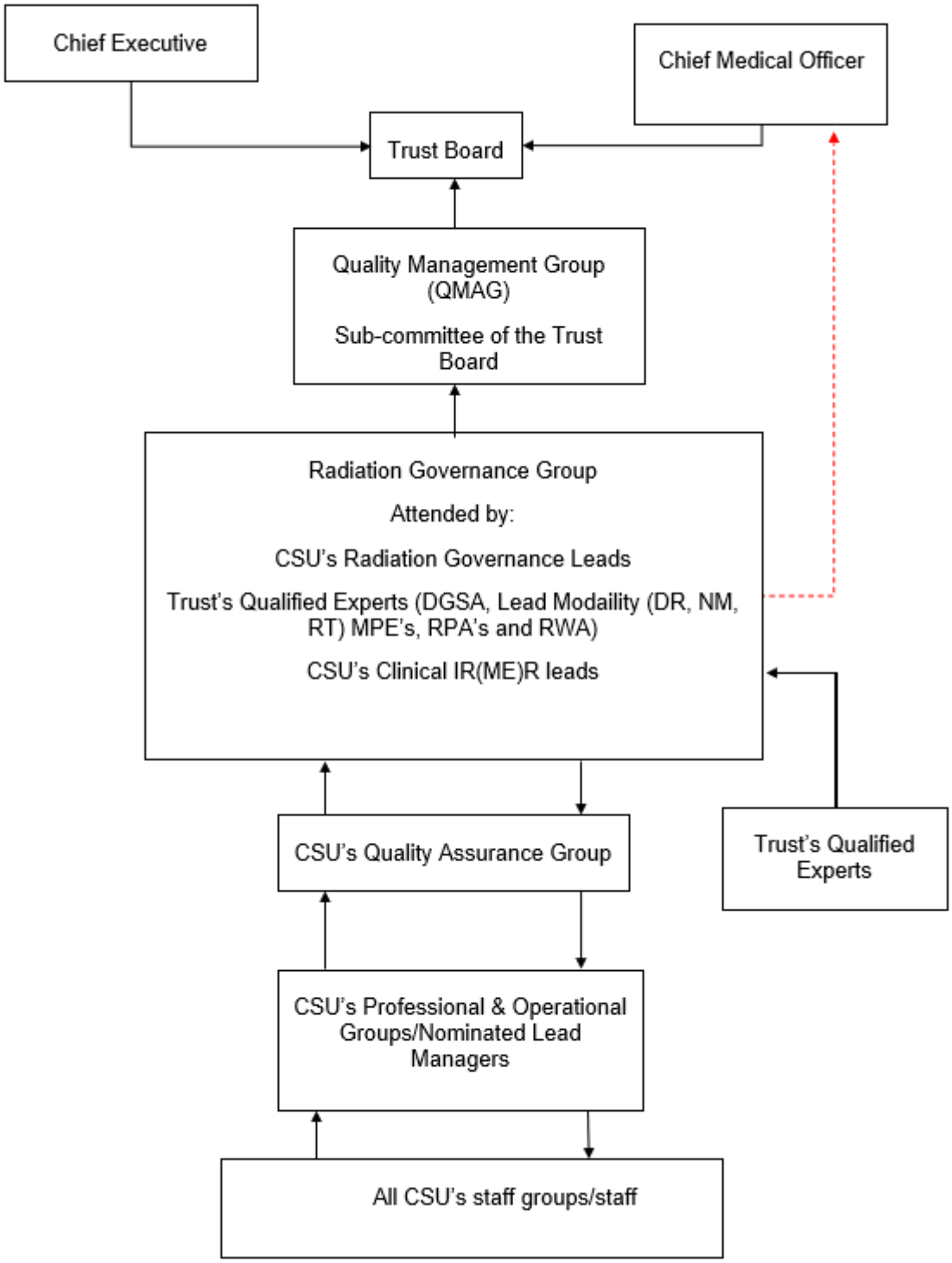
2.3 Clinical Director of Radiology

The Clinical Director (CD) of Radiology has responsibility for ensuring that these Employer's Procedures are complied with in the Radiology & MIS CSU.

2.4 Radiology Quality Assurance Group

The Radiology Quality Assurance Group (RQAG) has delegated authority from the CD of Radiology for ensuring that these Employer's Procedures remain relevant, effective and subject to regular review and audit.

RQAG may establish and delegate authority for compliance with specific aspects of the Employer's Procedures to other nominated groups within the Radiology & MIS CSU as described in this document.


Chief Executive
Chief Medical Officer
Trust Board
Quality Management Group (QMAG)
Sub-committee of the Trust Board
Radiation Governance Group
Attended by:
CSU's Radiation Governance Leads
Trust's Qualified Experts (DGSA, Lead Modaility (DR, NM, RT) MPE's, RPA's and RWA)
CSU's Clinical IR(ME)R leads
CSU's Quality Assurance Group
Trust's Qualified Experts
CSU's Professional & Operational Groups/Nominated Lead Managers
All CSU's staff groups/staff

3.0 Patient identification

Patient identification must be based on the Trust's "Positive Identification of Patients Policy[3]". Patient identification must only be undertaken by appropriately trained and entitled Operators.

Where possible, patient identification will be undertaken by the Operator who will be initiating the exposure. It is the responsibility of the Operator initiating the exposure to ensure that the patient has been correctly identified prior to the exposure taking place.

If more than one Operator is involved in the identification check, the Operator performing the identification must communicate clearly and verify the patient identification with the Operator who will be initiating the exposure.

The identification process must be led by open questions, e.g. "what is your full name?" and not "are you patient x?"

3.1 Mandatory three point identification check

The Operator must ask the patient all three following questions[4]:

- What is your full name?
- What is your date of birth?
- What is your address?

The Operator is responsible for checking the patient's responses against the patient identity information provided on the referral. If a patient has an LTHT identity (ID) wrist band, the Operator is also responsible for cross checking patient name and DOB against the wristband as well as with the patient directly.

In the event of mismatch, the Operator is responsible for contacting the clinical team and requesting further information/clarification to verify the patient identification.

If the patient's responses do not match the details on the request or there is any doubt about the identity of the patient then the exposure must not be undertaken. This should be appropriately documented in the patient's record on RIS or electronic patient records.

3.2 Additional Enquiries

As part of the identification process, the Operator will make additional enquiries designed to ensure that the patient is undergoing the correct examination at the correct time**.**

These enquires should confirm that:

- The clinical history corresponds to the requested examination.
- The examination requested (modality, body part, laterality) correspond to the patient's expectations about the examination.

For example, the Operator may ask the patient:

- What procedure/imaging are you expecting today?
- What area/side of the body are you expecting to be imaged?
- The Operator takes consent from the patient for the examination? E.g. "Are you happy for me to proceed".

When asking the questions, the Operator should be mindful that the patient may not be aware of the reason for their attendance or provisional diagnosis. For example, for a patient undergoing investigations for suspected cancer it may be appropriate to simply say "Can you tell me the type of test your doctor told you he was sending you for?"

The Operator is responsible for checking that the patient responses match the clinical information provided on the referral.

If the patient's responses do not match the details on the request or the appropriateness of the request then the exposure must not be undertaken.

3.3 Patients without capacity (including heavily sedated/unconscious)

For outpatients unable to positively identify themselves, the Operator must ask the legal guardian/escort to confirm the patient's name, date of birth and address prior to the examination taking place.

For inpatients and patients from the Emergency Department (ED), the Operator must cross reference the patient identification with the LTHT ID wrist band. **If no LTHT ID wrist band is present, the Operator must not proceed with the exposure.** The Operator must contact the relevant department and request that staff (who can confirm the patient identity) attend the Radiology department and affix a new ID wrist band.

The Operator should confirm that the clinical history matches the requested examination (modality, body part, laterality) with the legal guardian/ (nursing)escort.

3.4 Paediatric Patients

For paediatric patients, the Operator must ask the parent/legal guardian to confirm the patient's name, date of birth and address prior to the examination taking place.
The Operator should confirm with the parent/legal guardian that the clinical history matches the requested examination and the details of the requested examination (modality, body part, laterality).
If the paediatric patient is considered Gillick competent, the patient is allowed to confirm their own name, date of birth and address.

3.5 Patients/Parents/Guardians who require information in another language or have a sensory impairment

A range of additional tools (e.g. electronic translation) are available to assist Operators when communicating with patients/parents/legal guardians who have sensory impairments or who require information in another language. The Operator undertaking the examination is responsible for assessing the communication needs of the patient and ensuring that the patient identification process is performed using the most appropriate communication tool[5].

3.6 Anaesthetised Theatre Patients

If a patient is under general anaesthesia, the Operator must cross reference the patient identification with the LTHT ID wrist band or by confirming the patient details with the anaesthetic staff.
The Operator should confirm that the clinical history matches the requested examination (body part, laterality) with the clinical team.

3.7 Procedure if the address details do not match those on the request

For outpatients, the patient should be asked for their previous address. If the previous address agrees with the address on the referral only then RIS should be updated.

For inpatients - the ward should be contacted to confirm the patient's correct address and then RIS should be updated with the correct current address.

If the previous address doesn't match, the Operator should not proceed. The clinical team should be contacted to confirm the correct patient's details.

3.8 Updating the Patient's Record

Once changes to the patient's demographics have been confirmed, checking that the address is correct is essential before making any amendments. The Operator is responsible for recording this by updating RIS which will update the overall PAS.

The procedure on how to adjust patient's demographics is listed in the CRIS training manual[86].

3.9 Recording the Patient Identification Check

The Operator who initiates the exposure is responsible for ensuring that that the patient identification check has taken place and is recorded on RIS by ticking the appropriate box on the post processing screen.

In the event of a paper request, the Operator should record that they have positively identified the patient by annotating the paper request and then scanning this paper into RIS. For breast screening, this annotated paper request is filed at the breast screening unit.

3.10 Errors in Patient Identification

If at any stage of the process, the Operator realises or suspects that there has been an error in the identification of the patient, they are responsible for reporting the error to their Team Manager and recording the incident through the DATIX (14.5) incident reporting system. The Incident should be entered within 48 hours, after discovery.

4.0 Procedure to identify individuals entitled to act as Referrer or Practitioner or Operator within a specified scope of practice

4.1 Individuals entitled to act as Referrer for diagnostic exposures

A Referrer is a registered health care professional under the National Health Service Reform and Healthcare Professions Act 2002[1] who are entitled in accordance with these Employer's Procedures to refer individuals for an exposure to a Practitioner.

4.2 Entitlement

Referrals for diagnostic procedures involving the use of ionising radiation may be made by any registered medical or dental practitioner.

Referrals may also be accepted from national screening programmes where referral processes are in place and agreed.

As a large teaching and tertiary referral centre, it is not feasible for the Trust to maintain up to date lists of all medical and dental practitioners in hospitals and general practice who might be expected to refer for radiological investigations, nor is it practical for relevant staff to identify the signatures of all such persons. RIS contains a database of referrers, including their professional registration. If a referrer is not recognised by RIS, a procedure is in place to confirm the professional registration of the referrer[9][7].

With the exceptions outlined in the following section, all referrals from general practice, dental surgeries, private practices or from clinical teams working within hospitals must originate from a qualified medical or dental practitioner, be signed by this responsible clinician, and carry a clearly legible name of the Referrer. A paper request with an electronic signature will be accepted, but a professional registration number must be included.

The Trust will, as far as is possible, make it clear to referrers that this is our expectation. Any departure from this practice will represent a violation of the Regulations, and responsibility for this will rest with the medical or dental practitioner who is caring for the patient.

All Referrers are responsible for ensuring that the outcome from the referral, e.g. the report, is acted upon in a timely manner.

There are restrictions to the scope of practice for a GP. These restrictions are listed in local protocols[8] or restrictions are placed on electronic referral system (ICE).

4.3 Non-Medical Referrers

Other registered health care professionals, for example Radiographers, Nurse Practitioners, Midwives and Physiotherapists may be entitled to refer patients for radiological investigations with additional training and authorisation.

Non-Medical Referrers (NMRs) will only be entitled to refer under defined referral protocols which have already been agreed between Radiology & MIS and the relevant CSU or primary care practice and within a specific defined scope of practice which is then authorised by Radiology & MIS CSU.

4.3.1 NMR Protocol Development

Protocols must be developed in conjunction between the CSU and a named Consultant Radiologist. The protocol must be formally approved by the relevant Radiologist before being submitted to the RQAG for review and approval. Protocols require a review every 5 years.

4.3.2 NMR Training requirements

The Clinical Director (equivalent for GP) for the relevant CSU is responsible for certifying that the NMR is appropriately trained in:

- History taking.
- Physical examination.
- Clinical reasoning and decision making.

It is mandatory that all NMRs complete IR(ME)R training as part of the application process[9]. IR(ME)R training must be renewed every 3 years.

4.3.3 Scope of Practice

The scope of practice for the NMR will be defined and restricted to the protocol onto which they will be entitled to refer. Radiology and MIS CSU will send an authorisation letter to the NMR which is only valid for the agreed protocols and specific to the CSU sponsoring the application. It is the professional responsibility of the NMR, not to request an examination outside of their scope of practice. An escalation protocol is in place, when the NMR is working outside of their scope of practice[10].

4.3.4 Entitlement

Radiology & MIS will issue a letter of entitlement to the NMR. Entitlement can be withdrawn without notice if Radiology & MIS becomes aware that the NMR is:

- Referring outside of their agreed scope of practice.
- Demonstrating repeated poor referral practice.
- Failing to provide evidence of self-audit.
- Failing to undertake CPD.

4.3.5 Audit

As part of their entitlement, all NMRs agree to audit their practice and submit evidence of this to their CSU on a yearly basis.
Further guidance on the process for NMRs is available on Radiology's intranet site.
Radiology reserves the right to request the audit from the NMR.
Any common trends will be reported to RGG.

4.3.6 Self-request chest X-ray service

Appropriately trained Radiographers are acting as NMRs for this pathway. The patient registration form is reviewed by the Radiographer and the following criteria must be verified:

- Age 40+
- Leeds GP
- Symptom/s 3+ weeks
- No chest x-ray or scan in the last 3 months

The Radiographer will complete the patient registration form and upload on RIS.

Training records for the entitled referrers are held by the team managers.

4.3.7 Radiographers requesting MRI safety imaging

MRI Radiographers can request X-rays to confirm that the patient has no MRI contraindicated implants or foreign bodies. Full scope of practice, entitlement and training requirements are described in local SOP[11]

4.4 Making a radiology referral

All radiology referrals must be made on the electronic referral system or on a paper request. Paper referral must include the mandatory information from section 4.4.2.

4.4.1 Information required when making radiology referrals

It's the Referrer's legal responsibility to provide 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 if there is sufficient net benefit and therefore justify the exposure.

4.4.2 Mandatory Information

All referrals **must** include the following mandatory information:

- Accurate, up to date patient identification information.
- Full name.
- Date of birth.
- Address.
- Relevant clinical history/clinical findings on examination.
- Clinical diagnosis - or suspected clinical diagnosis.
- Requested examination.
- Information regarding pregnancy and breastfeeding (for patients between the age of 12 and 55 years old).
- Referrer contact details.
- Clearly legible name and signature or electronic identity via ICE or CRIS.
- Details of the staff group, surgery or clinical team.
- Patient Contact details.
- Non-Medical Referrers (NMR) must clearly indicate on the referral that the referral has been made by an NMR.
- Any pertinent risks such as
    - Allergy status
    - eGFR/renal failure
    - Infection status
    - High risk of falls
- Weight (for Paediatric nuclear medicine examinations and myocardial perfusion imaging on the Herceptin pathway).
- Any reasonable adjustments required by the patient

4.4.3 Additional information

- Mobility status (e.g. requires a hoist).
- Co-morbidities (where relevant).

- Medication (where relevant).
- Communication issues (i.e. non-English speaker).
- Carer or comforter requirements.
- Weight

An incomplete, incorrect or otherwise inadequate referral must be rejected.
In this circumstance the Practitioner's decision and rationale must be communicated to the Referrer as soon as is reasonably practicable, as per local protocol. The Referrer should be allowed the opportunity to improve and resubmit their referral.

Any Referrer making repeated inadequate referrals may have their entitlement removed by the Radiology Quality Assurance Group. The individual concerned and their line manager will be notified with the reason for their disentitlement and actions required for their entitlement as Referrer to be reconsidered.

4.5 Cancelling radiology referrals

The responsibility to cancel any requests that are no longer required rest with the Referrer. The Referrer should enter a cancellation request on ICE1[25]. The Referrer should contact the relevant department by phone, in addition to the request on ICE, if an urgent request requires cancelling. If ICE is unavailable to the referrer, the referrer must contact the department to cancel the referral.
Amendments are not possible on ICE. Send a cancellation request and submit a new referral.

4.6 Individuals entitled to act as Practitioner for diagnostic exposures

4.6.1 Role

A Practitioner is any registered health care professionals under the National Health Service Reform and Healthcare Professions Act 2002 who is entitled in accordance with these Employers Procedures to take responsibility for justifying and authorising exposures

When justifying the exposure the Practitioner must consider the following:

- Is the exposure likely to answer the clinical question?
- Will the outcome from the exposure affect the management of the patient?
- Has the clinical question been answered by previous imaging?
- Are other alternative imaging techniques (e.g. US) more appropriate to answer the question?
- Is the requested examination suitable for this patient (medical history, age, pregnancy status)
- What is the likely dose/risk from the exposure?
- How will any medication that the patient is taking affect the exposure?
- Potential exposure of carers and comforters?

4.6.2 Entitlement

All Consultant Radiologists and Radiology Specialist Registrars who have completed their FRCR part 1 examination are entitled by the CD of Radiology to act as a Practitioner and justify/authorise exposures within their scope of practice. Justification/authorisation must be documented on CRIS.

Consultant Radiologist working for external companies can be entitled as practitioner for LTHT. Consultant Radiologist are entitled by the CD of Radiology to act as a Practitioner and justify/authorise exposures within their scope of practice.

All ST1 Radiology trainees will only be entitled to act as Practitioners once they have received training on justification and authorisation and have been assessed as competent by a Consultant Radiologist.

Other appropriately qualified and trained registered health care professionals (e.g. Radiographers) may be entitled to act as a Practitioner for a defined procedure or range of procedures provided they have received the appropriate theoretical and practical training.

The Radiology Modality Lead Radiographer will hold records on these individuals including details of their training, their scope of practice and their entitlement.

For exposures involving the administration of radionuclides, the Practitioner must hold an IR(ME)R Licence for the specific procedure and follow guidance by Administration of Radioactive Substances Advisory Committee (ARSAC)[13]. IRMER Licence holders are listed on in a separate SOP[14].

All Practitioners are required to take part in appropriate continuing professional development relevant to their role.

4.6.3 Authorisation guidelines

Authorisation guidelines must be approved by a named Practitioner. The Practitioner that approved the authorisation guidelines takes responsibility for the justification of each exposure that is authorised under these guidelines.

4.7 Individuals entitled to act as Operator for diagnostic exposures

4.7.1 Role

Operator means any person who carries out any practical aspect associated with the procedure of a medical exposure. Some examples of the practical aspects are:

- Patient identification.
- Checking pregnancy or breastfeeding status.
- Authorisation of the exposure under authorisation guidelines.
- Selecting the exposure factors.
- Initiating the exposure.
- Contrast administration.
- Dispensing/administration of a radiopharmaceutical.
- Image manipulation and transfer to ensure the image(s) reaches its correct and intended destination to be acted upon in a timely fashion.
- Recording the factors relevant to patient dose.
- Clinical image evaluation.
- Equipment quality control checks.

The Operator is responsible for all the practical aspects that they perform.

4.7.2 Entitlement

The following categories of employees working within Radiology & MIS CSU, including honorary employees, are entitled by the Clinical Directory of Radiology or relevant Radiology Lead Radiographer to act as Operators for diagnostic exposures within their scope of practice.

- Radiologists.
- Radiographers.
- Assistant Practitioners.
- Clinical Technologists.

Other appropriately qualified and trained health care professionals may be entitled to act as Operators within an agreed scope of practice by the relevant Radiology Modality Manager provided they have received the appropriate theoretical and practical training.

The necessary training to be entitled to act as an Operator in each modality will be prescribed and documented by the Radiology Modality Lead Radiographer and records of the individual's, training and scope of Practice will be held by the relevant Radiology Modality Manager.

4.7.3 Authorisation

Appropriately trained Operators are entitled to authorise exposures according to the authorisation guidelines approved by the named practitioner. Any exposures that fall outside of the criteria of the authorisation guideline, should be justified by a Practitioner.

4.7.4 Students/Apprentices

Any students, apprentices, who undertake any Operator functions, will do so **only under the supervision of an entitled Operator**. In these circumstances, the supervising Operator will retain responsibility for ensuring that the practical aspect is performed correctly.

4.7.5 Operators from other CSUs

Other appropriately qualified and trained health care professionals may be entitled to act as Operators for a defined scope of practice provided they have received the appropriate theoretical and practical training. These individuals will be entitled by the Clinical Director (or nominated deputy) of the relevant CSU. Details of such individuals, the training received and the scope of their practice will be documented and held by the relevant CSU.

All Operators are required to take part in appropriate continuing professional development relevant to their role under IR(ME)R 2017.

4.7.6 Agency Staff /Application specialists

Agency staff will only be entitled to undertake any Operator functions after they have been assessed as competent following local induction and training. Local induction

and training documentation should be stored in the personal file/training folder of the agency staff.

Application specialists will only be entitled to undertake Operator tasks under the direct supervision of an entitled LTHT Operator.

4.7.7 MPE

MPE are appointed in accordance with the Trust Ionising Radiation Safety Policy[15].

5.0 Making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast feeding

(Note that for ease of following this procedure "individuals of childbearing potential" will be referred to as patients in this section).

5.1 Responsibilities

The Operator is responsible for ensuring that the pregnancy enquiries are made according to this procedure prior to undertaking an exposure. This should be done via the inclusive pregnancy disclaimer (IPD) forms which include the following questions:

1. Which sex were you registered as at birth? (if female/intersex, proceed to question 2)
2. Are you or might you be pregnant?
3. When was the first day of your last menstrual period?
4. Additional assurance if outside of the 10 day rule.

Note that although the Referrer should indicate on the request whether there is any potential for the patient to be pregnant or breastfeeding, this information must not be solely relied upon when the patient attends for the examination.

The process for making pregnancy enquiries is illustrated in the flowchart in SOP[16]

5.2 Scope

This procedure covers to all patients aged 12-55 years inclusive.

Pregnancy enquiries should be made for:

- All interventional procedures
- All procedures involving the administration of radioactive substances.
- All diagnostic X-ray examinations where the primary beam falls between the diaphragm and knees, with the following exceptions
    - Categories 1 and 2, it **is not** necessary to make enquiries, even if the primary beam irradiates the abdomen or pelvis.
    - Categories 3, 4 and 5, it **is** necessary to make enquiries, even if the primary beam does not irradiate the abdomen or pelvis.

Dose and risk categories for typical diagnostic X-ray examinations are provided in table 1.

Breastfeeding enquiries should be made for nuclear medicine procedures.

Table 1

	Examination	Typical foetal dose range (mGy)	Risk of childhood cancer per examination	Category
XR	Skull, Teeth, Chest	0.001 – 0.01	<1 in 1 million	**1**
XR	Cervical / thoracic spine			
XR	Mammography			
CT	Head, Neck			
CT	Pulmonary angiogram	0.01 – 0.1	1 in 1 million to 1 in 100,000	**2**
CT	Calcium scoring			
CT	Coronary angio (prospective)			
DXA	Bone density*	0.1 – 1.0	1 in 100,000 to 1 in 10,000	**3**
XR	Barium swallow, meal			
XR	Abdomen, Pelvis, Hip			
CT	Thorax (including liver)			
QCT	Lumbar spine			
XR	Barium enema, IVU	1.0 – 10	1 in 10,000 to 1 in 1,000	**4**
XR	Lumbar spine			
CT	Abdomen, Lumbar spine			
NM	Nuclear medicine procedures (all except those listed in Cat. 5)			
CT	Pelvis (Abdo/Pelvis, CAP)	10 – 50	1 in 1,000 to 1 in 200	**5**
IR	All interventional procedures			
NM	Nuclear medicine procedures: • Bone scans • MIBG • Tektrotyd • Liver/spleen • GI bleed			

- PET-CT
- Meckel's
- 1-day MPS
- Scan with a potential CT scan of the pelvis/abdomen

*DXA examinations fall in Category 1, but IPD is completed for medical reasons.

5.3 Special considerations

In some cases, at the operator's discretion, it may be necessary to take additional steps to ensure that the patient is in an environment where they feel able to discuss the possibility of pregnancy.

If there are any concerns regarding safeguarding, follow Trust guidance on the intranet.

5.4 Examinations in categories 1 and 2

Pregnancy questioning is not required.

5.5 Examinations in categories 3, 4 and 5

5.5.1 Patient states that they are not pregnant

- If the examination is in category 3 or 4, the operator should document the response and proceed with the examination.
  See table 2 all examinations included in category 3 and 4.
  If the examination is in category 5, the operator should ask additional questions to exclude pregnancy.
  See table 2 all examinations included in category 5. The full list of questions is available in SOP RAD_EP11.
  1. If pregnancy can be excluded based on these additional checks, the operator should document the response on RIS system and proceed with the examination.
  2. If pregnancy cannot be excluded, the operator should follow the steps described in section 5.5.4.

Table 2

Examination	Category
X-RAY (INC. DENTAL) & DIAGNOSTIC FLUORO Any examination where primary beam is not between the diaphragm & the knees **MAMMO** All mammography examinations **CT** All CT where the scan range is **not** between the diaphragm and the knees	**1 & 2** **(no questioning required)**
DXA* All DXA **X-RAY & DIAGNOSTIC FLUOROSCOPY** All examinations where the primary beam **is** between the diaphragm and the knees. **CT** Any other CT which is not in Categories 1,2 or 5. i.e. where scan range **is** between the diaphragm and the knees, but the uterus **is not** in the scan range. **NUCLEAR MEDICINE** All except those in Category 5	**3 & 4** **(low foetal dose procedures)**
CT Any scan of the pelvis, abdomen/pelvis or chest/abdomen/pelvis where the uterus is in the scan range **INTERVENTIONAL RADIOLOGY** All interventional procedures **NUCLEAR MEDICINE** • Bone scans • MIBG • Tektrotyd • Liver/spleen • GI bleed • PET-CT • Meckel's • 1-day MPS • Any scan with a potential CT of the abdomen/pelvis	**5** **(high foetal dose procedures)**

*DXA examinations fall in Category 1, but IPD is completed for medical reasons.

5.5.2 Patient states that they are or are likely to be pregnant

The operator should document the response in the patient's RIS record and pass the request to the practitioner for a decision as to whether the examination should proceed.

5.5.3 Patient unable / unwilling to confirm pregnancy status

The operator should ask the patient for the date of the first day of their last menstrual period (LMP.)

- **Examination in category 3 or 4 (low dose)**
  - If it is 28 days or fewer since the first day of their last menstrual period, the operator should reassure the patient that the risk to an unborn child from the examination is minimal. If the patient consents, their response, consent and LMP should be documented on the RIS system, and the operator should proceed with the examination.
  - If it is more than 28 days since the first day of their last menstrual period, the patient should be treated as probably pregnant (see Section 5.5.4) and the operator should pass the request to the practitioner for a decision as to whether the examination should proceed. Section B of the IPD should be completed and documented on the RIS system.

- **Examination in category 5 (high dose)**
  - If it is 10 days or fewer since the first day of their last menstrual period, the operator should reassure the patient that the risk to an unborn child from the examination is minimal. If the patient consents, the response should be documented, and the operator should proceed with the examination.
  - If it is more than 10 days since the first day of their last menstrual period, the patient should be treated as probably pregnant (see Section 5.5.4) and the operator should pass the request to the practitioner for a decision as to whether the examination should proceed. Section B of the IPD should be completed and documented on the RIS system.

5.5.4 Patient definitely or probably pregnant

If pregnancy is established or likely, then the justification for the examination should be reviewed by the relevant Practitioner (who may wish to discuss the case with the Referrer). This review should consider:

- The clinical benefit to the mother from the examination may also be of indirect benefit to the foetus
- Delaying an essential procedure until later in pregnancy may present a greater risk of harm to the foetus

If it is decided to postpone the examination, then the patient should be asked to telephone the department on the first day of their next menstrual period to arrange an appointment within the next 28 days (Categories 3 and 4) or the next 10 days (Category 5).

If after review, it is decided that the examination is justified and is to be undertaken, the name of the Practitioner and Referrer making the decision should be clearly documented in the patient's RIS record. The Practitioner must document the decision on RIS and justify the exposure to the foetus. The discussion with the patient and their consent to the examination should be documented on section B of the IPD and saved on CRIS.

The foetal dose should be kept to a minimum consistent with the diagnostic purpose. This can be achieved by minimising the number of views and the absorbed dose per view. Protecting the patient's lower abdomen with lead aprons is not recommended, as advised by the MPE.

The Operator conducting the examination is responsible for ensuring that all relevant exposure factors (DAP, Screening time, DLP, etc.) are recorded on the patient's RIS record.

5.6 Patient lacks capacity / capability to respond

The operator should document this and pass the request on to the practitioner for a decision as to whether to proceed.

5.7 Emergency procedures

In emergency cases, an attempt to establish the patient's pregnancy status should be made if this will not delay the procedure.

If a decision to scan the patient is taken without confirming pregnancy status or where the patient is known to be pregnant then this decision should be discussed with the (acute) Radiologist and documented by the Radiologist on the RIS system.

5.8 Anaesthetised patients CT

Due to the general anaesthetic a pregnancy test must be performed. The results of the pregnancy test must be available before the start of the general anaesthetic procedure. Pregnancy status must be recorded on the Paediatric questionnaire and signed by the patient or parent/guardian

5.9 Nuclear medicine patients

The only routine occasion where a known pregnant patient would have a nuclear medicine examination is in the case of suspected pulmonary embolism (PE), where a modified lower-dose protocol for lung perfusion imaging may be performed according to the departmental procedure. If pregnancy cannot be excluded by the patient, the ward should perform a pregnancy test.

It is the Referrer's responsibility to discuss the risks and benefits with the patient. IPD section B should be filled in by the patient, before proceeding with the administration.

If a known pregnant patient requires any other nuclear medicine examination, the referrer needs to have a prior discussion with an IR(ME)R Practitioner licence holder[14] and the MPE.

5.10 Breastfeeding enquiries

Patients attending for nuclear medicine procedures should be asked in addition to the pregnancy enquiry, whether they are or have recently been breastfeeding.

If yes, then the advice given in the ARSAC Notes for Guidance (section 7.17-7.37)[13] will be followed taking further advice from a Medical Physics Expert (MPE) as necessary.

- Written instruction must be given to the patient.
- Wherever possible, at least one feed should be expressed and appropriately stored in advance of the administration.
- The infant should be breastfed just before the administration.
- At the time of the next feed or 3 hours post administration (whichever is soonest), the breastfeeding patient should express as much milk as possible - this milk should be discarded and alternatives used instead'
- If advice regarding breast feeding is given, this should be recorded on the Nuclear Medicines procedure record[17] and the patient's RIS entry for that specific procedure.

5.11 Inadvertent foetal exposure5.11 Inadvertent foetal exposures

If an inadvertent foetal exposure does occur, either because of a failure to follow these procedures or because the patient when asked denies pregnancy, either deliberately or in ignorance of their pregnancy status, it must be investigated as a radiation incident as soon as it is identified. Any member of staff who becomes aware of an inadvertent foetal exposure should report it to the relevant Modality Lead Radiographer, Medical Physics Expert and submit a DATIX (14.5).

An investigation into the circumstances of the incident will be completed by the Radiology Modality Lead Radiographer and MPE. The MPE will provide an estimate of the foetal dose and risk and advise as to whether the incident is CQC reportable. Reporting to the CQC must not be delayed and the Practitioner and Referrer should also be notified that the incident has occurred. Where a notification has been made, the completed investigation must be provided to the CQC within the designated timeframe (14.5). Where applicable, the Trust's Duty of Candour procedure would be invoked.

5.12 Communication to the patient

Posters are displayed in departments to increase awareness of the risks of radiation in early pregnancy these ask patients to notify a member of staff if they think they may be pregnant. Risk of radiation is described in patient information leaflets and appointment letters.

Know pregnant patients should not have their pelvis/abdomen covered with a lead aprons, as this could cause additional exposures or higher doses. Patient should be informed that best practice is not to use shielding[33].

6.0 To ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed

6.1 Written Procedures and Protocols

RQAG has delegated responsibility from the triumvirate team for ensuring that all written procedures and protocols including authorisation guidelines remain relevant, effective and appropriate.

Where applicable, responsibility for designing and implementing quality assurance processes has been delegated to modality specific protocol groups (i.e. Plain Film or CT Protocol Group). These protocol groups are responsible for ensuring that all procedures and protocols are:

- Quality assured.
- Communicated to all relevant staff groups.

New documentation will be uploaded to the quality management system, after approval from RQAG.

6.1.1 Examination protocols (exposure charts)

The modality specific protocol groups and/or relevant Team Managers have delegated authority to ensure that any examination protocols are:

- Optimised.
- Quality assured.
- Communicated to all relevant staff groups.

In addition, where examination protocols (exposure charts) are programmed into the equipment, the specific protocol groups and/or relevant Team Managers have delegated authority to ensure that:

- Only authorised users can change examination protocols.
- Authorised users have appropriate training.
- Examination protocols are backed up.
- Processes are in place to minimise the risk of examination protocols being changed during service visits.

These groups/individuals are also responsible for providing assurance to RQAG that the quality assurance processes are being followed.

All staff must report any instances when they are aware that procedures and protocols are not being followed or working as expected to their Team Manager.

6.2 Diagnostic X-ray Equipment

RQAG has delegated responsibility from the triumvirate team for ensuring that a quality assurance programme for equipment is implemented and maintained. RQAG has delegated authority for the equipment quality assurance programme to the Radiology Equipment QA Group.

The Radiology Equipment QA Group has responsibility for ensuring that:

- All X-ray and nuclear medicine equipment are subjected to regular quality assurance testing.

- Testing before it is first used clinically.
- Testing after any maintenance procedure which is capable of affecting its performance.
- All radiographer QA protocols are quality assured, evidence based and effective.
- All staff that who perform QA are appropriately trained[18].
- MPE input is sought on the definition and performance of the QA testing (including acceptance).
- The Radiology Equipment QA group is responsible for providing assurance to RQAG that the QA programme for equipment is being followed.

The Operator performing the QA is responsible for acting on the results. If any of the QA is outside of tolerance, the Operator should report this as per protocol[18].

Diagnostic X-ray equipment that requires a service by the manufacturer should be handed over by the Radiology & MIS staff and the handover document[20] completed. The service engineer will hand the equipment back to Radiology staff. Radiology staff are responsible for any QA, before returning the diagnostic X-ray equipment back to clinical use.

6.3 Nuclear Medicine Equipment

The equipment used in Nuclear Medicine, i.e. dose calibrators, gamma counters, intraoperative gamma probes, gamma cameras and PET scanners are subject to regular quality assurance testing performed by both Medical Physics and Radiology testing protocols have been developed in accordance with both the manufacturers and relevant professional bodies recommendations (e.g. IPEM Reports 85, 108 & 111, UK Gamma Probe Working Group and NPL GPG93). This includes daily tests such as consistency checks of dose calibrators before use and daily flood field uniformity tests of gamma cameras. Daily checks are also performed on all gamma cameras or PET scanners with hybrid CT capabilities.
The daily quality control of gamma counters is performed before any samples are counted. Daily quality is usually performed on set days of the week.

More detailed quality control testing and calibration is performed at longer intervals or following repair and maintenance as necessary. The procedures are part of the Medical Physics and Clinical Engineering registered ISO 9001:2015 Quality Management System.
Results of quality assurance measurements are reviewed by Medical Physics and issues are discussed at the Nuclear Medicine Team Meetings.

The Operator performing the QA is responsible for acting on the results. If any of the QA is outside of tolerance, the Operator should report to the duty physicist and the team manager.

Equipment that requires a service by the manufacturer should be handed over by the medical physics department and the appropriate handover document[20] filled in. It is the responsibility of the Medical Physics department to hand the equipment over for clinical use.

7.0 The assessment of patient dose and administered activity

The Operator who initiates the exposure is responsible for ensuring that the factors relevant to patient dose are documented at the end of every examination in RIS.

7.1 Diagnostic X-ray procedures

For general radiographic and fluoroscopic procedures, the Dose Area Product (DAP) must be recorded in RIS at the end of the examination if available, kVp, mAs and screening time (for fluoroscopy procedures) should also be recorded. For older equipment where DAP is not available, the kVp, mAs and screening time (for fluoroscopic procedures) must be recorded.

For CT examinations, including SPECT-CT and PET-CT, the Dose Length Product (DLP) must be recorded.

To assist with patient dose surveys and establishing diagnostic reference levels, Operators should record any additional, patient specific metrics as requested by Radiological Physics.

7.2 Diagnostic Nuclear Medicine

For all examinations involving the administration of radioactive substances including PET-CT and SPECT-CT, a record in the RIS system must be made of:

- The radiopharmaceutical.
- The administered activity.
- The units of administered activity, in MBq.
- CT DLP for all CT's performed as part of a SPECT/CT or PET/CT hybrid imaging examination.

The RIS system will give an alert if the administered activity is over the ARSAC limit. If the administered activity is over the ARSAC limit, the Team Manager and the MPE should be informed. The incident should be recorded on the DATIX reporting system (14.5).

7.3 Procedure to ensure that the correct radiopharmaceutical is identified

In compliance with the LTHT Injectable Medicine Code, the radiopharmaceutical is checked by both the Operator and a 2nd checker. The Operator and the 2nd checker should check the referral, vetting, radiopharmaceutical, dose, expiry, batch numbers and patient identification. The Operator and 2nd checker's identification details are recorded on the Nuclear Medicines procedure record[17] and on the administration section on RIS. Further details are in the relevant NM standard operating procedure. Oral administrations are exempt from the second check procedure.

8.0 Diagnostic reference levels

8.1 Diagnostic X-ray

The Trust has adopted Local Diagnostic Reference Levels (LDRLs) for a set of common examinations. These LDRLs are based on audits of local dose data

undertaken by Medical Physics. The frequency of local dose audits is determined by the typical dose and risk levels within a clinical area and the process for conducting these audits is as described in the Medical Physics and Clinical Engineering ISO9001:2015 Quality Management System with reference to IPEM Report 88 "Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations".
Where LDRLs are not available, the current UK National DRLs have been adopted - these can be found on the government website[22].
For paediatrics, where specific LDRLs are not available, the current European DRLs[23] have been adopted.

8.1.1 Process for DRL audit

The MPEs will review the results from local audits and make any recommendations for the establishment of local DRLs to the RQAG. If the suggested local DRLs are acceptable they will be formally adopted by the Trust and these will also be reported to the Trust Radiation Governance Group. Records of all patient dose audit results should be kept by Radiology and made available to the local users.

8.2 Diagnostic Nuclear Medicine procedures

The current DRLs for established Nuclear Medicine diagnostic procedures have been adopted from those published in the guidance notes from the ARSAC[13]. Where applicable local DRLs based on the ARSAC DRL or lower have been developed and these are given in the appropriate diagnostic protocol. Administered activities must not exceed these values without prior written justification from the appropriate Practitioner on an individual patient basis. A tolerance of ±10% of the local DRL is allowed, but the administered activity should not be consistently greater than the DRL. The GFR procedure is using a local DRL. The local DRL is approved by the MPE and the Radiopharmacy department.

8.2.1 Process for DRL audit

The administered activity on RIS is audited every month, by the Medical Physics department. Medical Physics will create a list of every examination outside of the tolerance of ±10% of the local DRL. Weight based examinations can only be audited if weight has been recorded. The list is reviewed by a radiographer or clinical technologist and corrected if needed.

8.3 Hybrid Imaging (SPECT and PET-CT)

The CT MPE has created local DRLs for the CT component of selected SPECT-CT examinations.

8.4 Communication of DRLs to Operators

Radiology & MIS will maintain an up-to-date list of DRLs in use and ensure that the list is communicated to Operators.

8.5 Process if DRLs are being exceeded

An incident should be reported on DATIX for any overexposure, following the procedure in 14.5.
Where local doses are found to consistently exceed the relevant DRL, an investigation should be undertaken by Radiology and an MPE into the reasons for the high doses

and to determine what action can be taken to reduce doses to an acceptable level, consistent with the intended purpose of the examination.
Records of any investigations into high doses, and the actions taken as a result must be kept by Radiology.

An incident should be input into DATIX for examinations if the images are not diagnostic and the patient is underexposed.

9.0 Research approval and responsibilities

9.1 Local IRMER Approval and Referrals for Research Exposures

Studies involving research exposures must not be carried out at Leeds Teaching Hospitals without first being granted Local IRMER Approval.
Studies will not be considered for Local IRMER Approval unless:

- The study has all relevant national approvals (e.g. research ethics committee approval, ARSAC approval, Health Research Authority (HRA) approval).
- The local radiation experts are assured that the individuals will participate voluntarily, having been informed in advance about the risk from associated radiation exposures.

Local IRMER Approval is granted according to procedures which are issued as part of the Medical Physics and Clinical Engineering ISO9001:2015 registered Quality Management System.

Referrals for research exposures[24] will be carried out in line with the requirements of referrals for all radiological examinations, as described in 4.4, with additional responsibilities described below.

9.2 Responsibilities

9.2.1 Research study teams

- Seeking Local IRMER Approval for all studies involving research exposures.
- Informing the local radiation experts of the research exposures which are required by the study protocol, including indicating which of these are considered to be standard of care for the participant group.
- Providing the local radiation experts with access to all study documentation relevant to their review.
- When referring for research exposures, providing all relevant information in order to allow identification of the trial which the referral concerns.
- The sequence number must be provided on the referral.
- Keeping accurate records relating to research exposures for all trial participants, detailing the number and type of research exposures which they have received, according to the relevant R&I procedures.
- Ensure Radiology capacity approval and IRMER approved exposures for diagnostic imaging correspond with each other and there are no variations in approved number of requests/exposures.

9.2.2 Principal Investigator

- Ensuring that their studies are carried out in accordance with all research governance requirements and regulations, including IRMER17.
- Ensuring that participants take place voluntarily.
- Ensuring that participants are fully informed of all radiation risks associated with the study prior to giving their consent to take part.
- Ensuring participants are screened to ensure that they fit the inclusion criteria for the trial before being consented onto the trial (i.e. pregnant women and children should not normally be allowed to participate in research trials involving radiation unless the research trial is specific to these groups).

- Ensuring that participants do not receive a radiation dose which is over and above that which is described in the Local IRMER Approval.
- Ensuring that all referrals for research exposures are carried out in line with the requirements of referrals, as described elsewhere in 4.4. Additionally, it must be clear that the referral is for a research exposure and must contain relevant information to enable identification of the trial which the referral concerns.
- Ensuring that the outcome from a research exposure is acted upon in a timely fashion.
- To indicate on the formal request to Radiology the sequential number of which the requested exposure is within the IRMER approved number of exposures for the research trial

9.2.3 MPE

- Advising on compliance with IRMER17 in relation to research exposures.
- Reviewing study documentation and setting dose constraints / target doses, within their scope of practice, according to the work and technical instructions which are issued as part of the Medical Physics and Clinical Engineering ISO9001:2015 registered Quality Management System.
- Ensuring that ARSAC licences are in place for all administrations of radioactive substances which are to be carried out as part of a research study.
- Communicating any potential issues to the relevant research study team.

9.2.4 Clinical Radiation Expert /Practitioners

- Justifying research exposures to ionising radiation within their scope of practice, in line with the general responsibilities for Practitioners, as outlined in 4.5.
- Reviewing referrals for research exposures to ensure that participants will not exceed any relevant dose constraint if the referral is accepted and justified.
- Communicating any potential issues to the relevant research study team.
- ARSAC licence holders are responsible for ensuring that they hold the appropriate Practitioner licences for research administrations of radioactive substances which are to take place under their licence.

9.2.5 Operators

- Ensuring that, when undertaking any practical aspects of research exposures, they act in line with the general responsibilities placed on Operators, as described in 4.6.
- Contacting the Referrer prior to performing the exposure, in the event that there is a query relating to a referral for a research exposure.
- Ensuring any specific examination protocols required for the trial are utilised, as necessary.

10.0 Patient information Nuclear Medicine

Where appropriate, patients undergoing investigation or treatment using radioactive substances (or their representatives) will be given written information to tell them what to do to minimise the radiation dose to themselves and others. This information should be available during the consent process.

The relevant information will be drawn up with advice from the MPE and Radiation Protection Adviser (RPA).

This is implemented in practice via the Nuclear Medicine patient appointment letters and Nuclear Medicine protocols:

- Information leaflet/appointment letters outline the rationale for undergoing the test, what the test involves and steps to minimise patient radiation dose.
- Risk of exposure poster are available in the departments.
- The protocol document includes procedures for Patient Preparation, Ward Patients and Restrictions & Aftercare. This provides instruction to the Operator to discuss test risks/benefits with the patient, or parent in the case of children; to ensure that the examination is optimised and patient dose is minimised.
- Verbal information delivery/checks are captured on the form Nuclear Medicine Procedure Record[17] which is scanned and stored on the patient's RIS record.
- If an adult patient (age 16 and above) lacks capacity to consent (within the meaning of the Mental Capacity Act 2005), a Consent Form 4 should be filled out by the referrer.
- If a paediatric patient (age 16 and below) lacks capacity to consent (within the meaning of the Mental Capacity Act 2005), the parent/legal guardian should consent for the patient.

11.0 Patient information Radiology

Information about the risk and benefits associated with radiation dose from the exposure is provided for patients where practicable. This information is given to the patient via posters, leaflets and verbally by staff as appropriate to the situation and modality. This information should be available during the consent process.

This information is provided in the following ways:

- For some pre-booked examinations (e.g. Fluoroscopy and CT) information is provided in leaflets which are sent out to patients with their appointment letter.
- For walk in patients, information posters are displayed in relevant waiting areas[25,26].
- Information on radiation doses, benefits and risks is also available on the UK Health Security Agency website.
- If a patient is unsure of the benefit of the exposure or expresses any concerns about the radiation dose and risk, this should be initially discussed with the Operator undertaking the procedure. If the patient is still concerned, they will be referred to a more senior colleague and/or Practitioner who will provide further advice after consulting with the appropriate MPE. If specific advice is issued to the patient by the Operator performing the examination, they are then responsible for ensuring that a record of the conversation is recorded on RIS.

11.1 Paediatric patients

Information posters specifically designed to provide information to parents/guardians on the benefits/risks from paediatric exposures are on display in paediatric waiting areas or in patient leaflets.

11.2 Patients/Parents/Guardians who require information in another language or have a sensory impairment

A range of additional tools (e.g. electronic translation) is available to provide information to patients/parents/guardians who have sensory impairments or who require information in another language. The Operator undertaking the examination is responsible for assessing the communication needs of the patient/parent/guardian and ensuring that the information is provided in the most appropriate format.

11.3 Access to MPE Advice

If required MPE advice can be obtained by ringing:

Radiological Physics (DR enquires) – 26432
Nuclear Medicine Duty Physicist – 80-6531
leedsth-tr.RadiationProtection@nhs.net
leedsth-tr.nmphysics@nhs.net

12.0 Clinical evaluation

All exposures (i.e. images) will be evaluated by an entitled Operator who has appropriate training and experience. A proportion of the studies are auto-reported according to agreed pathways (12.3).

NOTE – Version control managed in Q-Pulse, all printed documents must be checked against Q-Pulse version to ensure that it is current.

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The evaluation of the exposures (images) within radiology i.e. the report, will be recorded in Enterprise Imaging (EI), NBSS and/or RIS which links to the other electronic clinical systems in the Trust or in the community.

Only those entitled to verify an examination will have access to and be able to issue a report in RIS.

In certain specific circumstances, (e.g. Theatre procedures) staff from other CSUs are entitled as Operators to record the evaluation from the exposure performed by Radiology staff. These exposures will have an Auto-report on RIS.

12.1 Yorkshire Imaging Collaborative

Registered healthcare professionals from other Trusts within the Yorkshire Imaging Collaborative (YIC) with the appropriate training, qualifications and experience will be entitled to act as Operators and will be able to provide clinical evaluations on images generated by LTHT. The scope of practice, training, qualifications and experience required to undertake this role will be formally agreed between LTHT's Clinical Director of Radiology and the Clinical Directors of the respective participating YIC Trusts. Only those individuals who meet the agreed criteria (training, qualifications and experience) and agree to only provide clinical evaluations on images within their scope of practice will be allowed access to the shared reporting IT system. In addition, as part of the shared reporting arrangements, all participating YIC Trusts have agreed to provide the training records of any Operators on request. (subject to approval from IG)

12.2 External reporting CT

Registered healthcare professionals from external companies with the appropriate training, qualifications and experience can be entitled to act as Operators and will be able to provide clinical evaluations on images generated by LTHT. The Operators have been approved by the speciality lead Radiologist (e.g. GUONC lead).

12.3 Auto-reporting

Pre-agreed examinations and/or specific have an auto-report on RIS. The relevant CSU is responsible for ensuring that a clinical evaluation is undertaken, and the results are acted upon.

In these circumstances, the CD of the relevant CSU is responsible for:

- Ensuring that all Operators performing evaluations are appropriately trained.
- Ensuring that all training records are up-to-date and stored.
- Ensuring that all Operators are entitled and their scope of practice clearly defined.
- Specifying where the record of the evaluation should be recorded (i.e. patient's notes).

- Ensuring that audits are undertaken to provide assurance that an evaluation for each exposure is undertaken and recorded.

13.0 Clinical audit

Clinical audit is the systematic evaluation of the patient pathway or components thereof, against good practice standards and implementing change / modifying practice where required, to facilitate continuous improvement.13.1 Elements of clinical audit

To maintain an effective clinical audit programme across the clinical pathway, the Trust has developed a strategy which provides for due consideration of structure, process, and outcome, which are defined below:

- Structure.
  - The organisational attributes of the patient care setting, including material resources (e.g. facilities and equipment), staffing and organisational structure.
- Process
  - The practical elements of care provision, such as referrer, practitioner, and operator activities in the context of their contribution to diagnosis and treatment.
- Outcome
  - The effect of the clinical pathway on the health status of individual patients and populations.

13.2 Scope and depth of audit

Clinical audit undertaken throughout radiology is of varying scope, comprising:

- Comprehensive audit, addressing the entirety of the patient pathway from referral to follow up.
- Partial audit focusing on specific critical parts of the pathway.

Clinical audit includes both audit of compliance with the IR(ME)R17 regulations as well as audit to evaluate and improve service quality and patient experience.

13.3 Practical implementation

Table 2 outlines the clinical audit programme, detailing audits and responsible groups/committees. Audits may also be undertaken on an ad-hoc basis, in response to a specific concern, improvement idea etc. or in response to incidents or a change in equipment / process / newly published guidelines.

Audits will be undertaken in accordance with the methodology outlined in RAD_EP12. Results will be reported to the responsible group / committee along with recommendations and an action plan, as required. The group / committee will be responsible for implementation of the action plan and evaluation of the effectiveness of these actions.

ble	Audit	Responsibility
Structure	Organisation / management structure Allocation of responsibilities Staffing Education and training Premises and equipment	RQAG Management meetings Service review meetings
Process	Referral process / quality of referrals Justification / authorisation process Availability and quality of examination and treatment guidelines. Patient identification. Reliability of information transfer systems. Clinical image quality (reject analysis)	RQAG, local modality meetings, audit meetings, equipment QA meeting
	Patient dose audit (routine)	RQAG
	Analysis of types and causes of incidents of accidental or unintended exposure.	RQAG, local modality meetings
	Optimisation, including: • clinical image quality (reject analysis) • comparison of patient dose with national / international accepted practice	Protocol groups / optimisation teams, local modality meetings
Outcome	Examination and treatment-specific practices, e.g. • interval cancer rates in breast screening • outcomes of self-request chest X-ray service	REALM meetings Clinical teams

13.4 Record keeping

"Structure" and "process" audits will be recorded in the minutes, and associated documentation, of the relevant meetings. "Outcome" audits presented at the REALM meetings. Results are documented on the Radiology drive, Radiology quality management system or Trust audit system.

NOTE – Version control managed in Q-Pulse, all printed documents must be checked against Q-Pulse version to ensure that it is current.

14.0 Reducing the Magnitude of Unintended Exposures

14.1 Equipment procurement & specification

Managers with responsibilities for equipment procurement must involve the appropriate MPE when considering the purchase of any equipment used in relation to medical exposures. The MPE must be involved in the specification of the equipment and any tendering and pre-purchase evaluation. As part of this process Medical Physics will review the Medical and Scientific Equipment (MSE) purchase request forms to ensure that equipment necessary for compliance with the regulations are included in the purchase, e.g. personal protective equipment (PPE), table skirts, ceiling mounted protective screens, radiation, and contamination monitoring equipment.

The provision of appropriate training for relevant staff must be arranged and included as part of the tender process. All equipment which may affect the radiation dose received by individuals undergoing medical exposures is subject to acceptance testing by Medical Physics with appropriate MPE input.

Appropriate Operator manuals which include instructions on the safe use of equipment and recommendations for keeping medical exposures As Low As Reasonably Practicable (ALARP) Consistent With the Intended Purpose (CWIP) must be provided as the part of the procurement.

14.2 Equipment maintenance

Equipment is maintained in accordance with manufacturers' instructions and servicing requirements. There are service contracts in place with the manufacturer, their agents or a suitable third party for the servicing of all equipment used for medical exposures.

Equipment used for medical exposures showing signs of any fault, damage or failure is immediately withdrawn from clinical use by clinical staff. Medical Physics, and where appropriate, Clinical Engineering should be informed. Clear signs that this equipment is out of action are placed on the console by the Operator and are not removed until the equipment is returned to clinical use.

The equipment and controlled area handover form[20] is completed on handover to and back from the service engineer. Following return of the equipment to the trust, the form will be reviewed by the Team Manager and if there are concerns that the work carried out may have affected the radiation dose that a patient could receive, Medical Physics must be contacted for advice on what testing is to be carried out before returning the equipment into clinical use.

14.3 Medical Exposures

All ionising radiation exposures are justified by a Practitioner and where appropriate non ionising modalities are considered and substituted.

Patient identification procedures are followed prior to any exposure being made.

14.3.1 X-ray procedures

Exposures are performed in accordance with imaging protocols which include details of the exposure factors (specific for the diagnostic X-ray equipment), to be used to optimise the patient dose for adults and paediatrics.

Where relevant, pregnancy checks are made at the same time as the patient identity checks.

The patient positioning, exposure factors and AEC selection are checked before making exposures.

Appropriate quality assurance is carried out on all diagnostic X-ray equipment.

Pause and Check posters must be displayed in the examination room or control room.

14.3.2 Diagnostic Nuclear Medicine procedures

Administered activities are based on a local DRL and scaled appropriately for paediatric patients. The radiopharmaceutical and activity to be administered are checked against the authorised referral prior to administration.

Dose calibrators are checked for consistency prior to use each day to ensure that the measured activity is accurate.

The clinical protocols require questions regarding pregnancy and breast feeding to reduce the risk of unintentional exposure of an unborn or breastfeeding child. They also describe where advice and restrictions are necessary following the administration.

Nuclear Medicine scanning equipment is checked each day prior to radioactivity being administered to ensure that procedures can be completed following exposure.

Pause and Check posters must be displayed in the examination room or injection room.

14.4 Training

All new members of staff receive the appropriate level of training as described in the Radiology mentorship/training documents on procedures and equipment training.

All Operators are qualified and adequately trained, in accordance with schedule 3 of IR(ME)R, for their roles and their mentoring training records are held by Team Managers with a copy placed in individuals' personal files. Students, Radiography Apprentices and Assistant practitioners work under direct and in-direct supervision as appropriate. Additional training is provided following any system updates or replacements.

Records of equipment training are recorded for on MELVIS each individual and any on-going training requirements are reviewed at annual appraisal.

14.5 Incident Reporting

All incidents involving radiation are investigated in accordance with the Trust's current investigation of incidents policy/procedure[27] and Radiology SOP[28,29]. Medical Physics

has created a Radiation incident flowchart[30] for each modality, to differentiate between lower risk and higher risk incidents.

For lower risk incidents, Medical Physics has created a Lifetime Cancer Risk chart[31], which can be used in when reviewing incidents in DATIX.

For higher risk incidents, a modality specific Radiation Incident Proforma is completed documenting all relevant exposure factors and DAP/DLP and forwarded to the Radiation Protection generic email address for a radiation dose and risk assessment to be completed.

All significant unintended or accidental exposures are reported using the LTHT DATIX incident reporting system and the relevant Team Manager informed. The "radiation incident" tab is used on DATIX so that Medical Physics are informed via an auto-generated email from the system.

All exposures deemed to be clinically significant accidental or unintended exposures are reported to the IR(ME)R Inspectorate at the CQC within 2 weeks of discovering the incident. The investigation report must be sent to the CQC 12 weeks after discovering the incident.

An investigation must be undertaken by the relevant CSU into the cause of the incident and remedial action undertaken where necessary. The investigation report must confirm the corrective measures adopted and be sent to Medical Physics within the specified timescale for review and sending to CQC.

Where applicable, the Trust's Duty of Candour procedure is invoked.

Radiation incidents are discussed at the monthly RQAG meeting and any learning points are communicated to all staff.

Medical Physics and Radiology maintain a record of notified radiation incidents and provide a summary of incidents and analysis of their causes to the RQAG meetings. In addition, an annual summary report identifying trends in incidents and lessons learned is presented to the RGG as part of the annual MPE report.

15.0 Clinically significant unintended or accidental exposure

15.1 Definition of Clinically Significant Accidental or Unintended Exposures (CSAUE)

For stochastic effects such as cancer induction, a CSAUE is defined as an accidental or unintended exposure which results in a 0.1% (1 in 1000) or greater lifetime radiation induced cancer risk[31].

This definition is applicable to adults, paediatric and foetal exposures (where the pregnancy was not known about at the time of the exposure).

For deterministic effects such as erythema and epilation a CSAUE is defined as an **unjustified** dose of radiation greater than:

- 0.5Gy to the lens of the eye.
- 0.5Gy to the heart or brain.
- 5Gy (including backscatter) to the skin.
- 50mGy to the thyroid.
- Psychological harm
    - In rare circumstances, an accidental or unintended exposure may be a CSAUE if it affects the individual's quality of life to a level that requires intervention or treatment.

It should be noted that justified exposures where it is known in advance (or becomes apparent during a procedure) that an adverse outcome may occur are **not** CSAUE. For example, a Practitioner may make the decision to continue to expose the patient past the point at which a skin reaction (erythema) may occur as they feel that this risk is justified in the context of the patient's clinical condition. Although this would not be a CSAUE as the exposure is justified, the Practitioner would still be required to document this decision. For IR procedures a template is available in Enterprise Imaging (EI), to document this decision.

Other incidents which would not be classified as CSAUEs would be incidents where a pathology has not been detected on an X-ray leading to failures in the correct management of the patient (further pain and suffering, etc.) Although this is an incident which would require further investigation and may trigger a requirement for duty of candour as the exposure was justified, performed correctly and there was no additional dose to the patient this is not a classified as a CSAUE under IR(ME)R[32].

15.2 Incident Notification & Investigation

The process described in section 14.5 details the actions required for incident reporting and investigation of a CSAUE.

16.0 Non-medical exposures

Non-medical imaging exposures 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". (IR(ME)R17)

Any non-medical imaging exposure must be justified by an appropriate Practitioner or authorised by an Operator (4.7.3), taking into account any detriment to the individual's health, financial or other benefit to the individual and/or the benefit to society as a whole. Where possible, a dose constraint should be applied such that the individual does not exceed any statutory dose limit for a member of the public. This includes exposures received by carers and comforters of persons undergoing medical exposures.

Any non-medical imaging exposure may only be taken with the express consent of the individual who is to be exposed. Consent for exposures for immigration/emigration purposes will be assumed if the relevant forms have been signed by the individual.

In all other cases, an appropriate consent form signed by the individual must be seen by the Practitioner or Operator who is authorising the exposure.

There are seven main types of non-medical imaging exposure identified. Radiology & MIS CSU will devise, maintain and keep one or more protocols for each type of exposure

- Radiological health assessment for employment purposes
- Radiological health assessment for immigration/emigration purposes.
- Radiological health assessment for insurance purposes.
- Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing etc.
- Radiological age assessments (to confirm age of patient in situations where there is doubt or uncertainty).
- Use of ionising radiation for the identification of concealed objects within the human body.
- Radiological health assessment for transplant donors.

17.0 Carers and comforters

17.1 Definition

Carers and comforters are individuals who are knowingly and willingly exposed to ionising radiation through support and comfort of those undergoing a medical exposure or non-medical imaging, for example parents, relatives, or friends.

Carers and comforters are not LTHT nursing staff, AHP, doctors, external nursing home support workers or prison officers. These individuals are providing support to the patient as part of their employment and are "holders".

When it is necessary for someone to support a patient they should preferably be a parent, guardian, escort, or someone who is not normally occupationally exposed to ionising radiation. Ordinarily no member of Radiology staff should support a patient, except in an emergency.

17.2 Providing Information for carers and comforters

The carer and comforter must receive a full explanation of the risks and benefits associated with their role. This information can be given verbally or in the format of posters and leaflets approved by the relevant MPE.

It is the responsibility of the Operator initiating the exposure to ensure that risks and benefits have been clearly communicated to the carer and comforter. The Operator must also give clear instructions during the exposure to ensure that their doses are As Low As Reasonably Practicable (ALARP).

17.3 Justification/authorisation

The exposure of the carer and comforter requires separate justification/authorisation to the justification/authorisation of the medical exposure of the patient.

As well as the normal considerations when justifying an exposure, when considering the justification of the exposure of a carers or comforters, the Practitioner must give consideration to:

- Any likely health benefits to the patient.
- Reduce patient anxiety and distress.
- No delay in diagnosis and therefore patient management.
- Higher likelihood of patient compliance with higher probability of successful examination reducing the need for a repeat.
- Any possible benefits to the carer or comforter.
- Psychological benefit from knowledge that the patient is receiving appropriate medical attention.
- The detriment that the exposure may cause.
- What is the likely dose/risk from that exposure.

This justification must be undertaken by an entitled Practitioner or authorised by an entitled Operator working under authorisation guidelines written by a Practitioner.

17.4 Dose constraint for carers and comforters for all diagnostic X-ray procedures

Carers and comforters may be required to assist in the patient's examination for the following reasons:

- To reduce patient anxiety and distress.
- To aid patient positioning and immobilisation.

The Operator will assess the examination and look at alterative actions to prevent a comforter or carer from being exposed to radiation. These will include:

- Use of distraction aids.
- Use of immobilisation aids and techniques.

To keep the dose to a carer and comforter to a minimum the Operator should:

- Ensure the carer and comforter is not pregnant.
- Provide the carer and comforter with the appropriate lead apron (and other protective clothing if appropriate).
- Ensure the carer and comforter is not in the primary beam.
- Provide a full explanation of what the carer and comforter is required to do and answer any questions they may have.
- Record the carer and comforter details according to SOP.

The risk assessment for carers and comforters in plain film and fluoroscopy has demonstrated that provided they are wearing the appropriate lead protection and following directions from staff they are unlikely to receive a dose greater than 0.3 mSv. Consequently, a dose constraint of 0.3mSv has been adopted for carers and comforters involved in X-ray procedures.

The risk assessment for carers and comforters in CT has demonstrated that provided they are wearing the appropriate lead protection and following directions from staff they are unlikely to receive a dose greater than 1mSv. Consequently, a dose constraint of 1mSv has been adopted for carers and comforters involved in X-ray procedures.

17.5 Dose constraint for carers and comforters for diagnostic Nuclear Medicine procedures

Patients having a procedure involving the administration of radioactive substances will remain radioactive after they leave the department and therefore consideration is given to the exposure of those who come into contact with them afterwards.

For the majority of cases where individuals around the patient are able to comply with standard precautions resultant doses will be below the public dose constraint (i.e. 0.3 mSv).

However, certain procedures have been identified as having the potential to give doses higher than this to those in close prolonged contact with the patient as a result of providing support, particularly if the patient requires such support during the uptake period i.e. the time between administration and scan.

The carer and comforters will be authorised/justified before the patient is injected with the radioactive tracer

In circumstances where individuals are likely to receive more than 1mSv, or 5mSv for MIBG scans, the Operator must discuss with the IR(ME)R practitioner licence holder and the MPE before proceeding with the examination.

The dose constraint adopted for carers and comforters for most diagnostic Nuclear Medicine procedures will be 1mSv and 5 mSv for MIBG procedures. Advice will be given to ensure that doses to carers and comforters are kept to a minimum and below the dose constraint.

To keep the dose to a carer and comforter to a minimum the Operator must:

- Where appropriate provide the carer and comforter with PPE e.g. gloves and plastic apron.
- Provide an explanation of what the carer and comforter must do to minimise their radiation dose (e.g. hand washing and contact patterns) and answer any questions they may have.
- Records of previous carer and comforter attendances are reviewed to ensure the same person does not regularly perform this role.
- Record the carer and comforter details and the estimated dose locally.

Individual radiation risk assessments will be completed for specific situations where the generic ones are inappropriate, for example;

- An individual frequently acting as a carer and comforter.
- A minor caring for a parent/adult.
- The only parent/guardian able to attend a paediatric appointment are pregnant. The patient information leaflet requests that these individuals contact the department prior to the appointment.
- All therapeutic administrations.

The RPA/MPE will advise on the risk assessments and the setting of appropriate individual dose constraints.

Reference

1. National Health Service Reform and Health Care Professions Act 2002 (legislation.gov.uk)

https://www.legislation.gov.uk/ukpga/2002/17/section/25C

2. Ionising Radiation (Medical Exposure) Regulations 2017 and the Ionising Radiation (Medical Exposure) Amendment Regulations 2018

https://www.cqc.org.uk/guidance-providers/ionising-radiation/ionising-radiation-medical-exposure-regulations-irmer

3. Positive Identification of Patients Policy

https://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=528

4. Positive Patient Identification

RAD_EP2

5. Patient Information Leaflets Radiology
6. Patient resources - Leeds Teaching Hospitals NHS TrustCRIS training manual

https://intranet.leedsth.nhs.uk/wp-content/uploads/2022/09/CRIS-Training-Manual-v1.3.pdf

7. Unrecognised referrers on CRIS

AD_SOP_AT1

8. NM Governance document

NM_RP_IRMER_EP4

9. NMR application process

RAD_EP3

10. Escalation process NMR

RAD_EP7

11. Requesting Plain Film X-rays by MRI Radiographers for Confirmation of MRI safety (non-medical referrers)

MRI_SOP6

12. Requesting a cancellation of a Radiology Exam: Clinicians

NOTE – Version control managed in Q-Pulse, all printed documents must be checked against Q-Pulse version to ensure that it is current.

RIT_SOP1

13. Guidance by Administration of Radioactive Substances Advisory Committee (ARSAC)

https://www.gov.uk/government/publications/arsac-notes-for-guidance

14. IR(ME)R licence holder nuclear medicine

NM_RP_IRMER_EP1

15. Ionising Radiation Safety policy

https://nww.lhp.leedsth.nhs.uk/policies/ref.asp?ref=PC044

16. Pregnancy flow chart

RAD_EP1

17. Nuclear medicine procedure record

\\Trust.leedsth.nhs.uk\Data\Department\radiol\RADIOLOGY DOCUMENT LIBRARY\Nuclear Medicine\FullNMProcedureRecordJan2020.pdf

18. QA training record

X:\radiol\QA CROSS CITY GROUP\14. QA Team\QA Training Record..xlsx

19. Reporting flowchart QA

X-RP_IRMER_QA1

20. Handover form equipment

RAD_EP5

21. SOP Administration of Medicines NM

NM standard operating procedure

22. UK National DRLs

https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl

23. European Guidelines on DRLs for Paediatric Imaging

http://www.eurosafeimaging.org/wp/wp-content/uploads/2014/02/European-Guidelines-on-DRLs-for-Paediatric-Imaging_Revised_18-July-2016_clean.pdf

24. HRA definition of research exposure

https://www.myresearchproject.org.uk/help/hlpradiation.aspx

25. Plain film Adult information

https://flipbooks.leedsth.nhs.uk/LN004548.pdf

26. Plain film Paediatric information

https://flipbooks.leedsth.nhs.uk/LN004546.pdf

27. Trust incident reporting procedure

https://nww.lhp.leedsth.nhs.uk/policies/ref.asp?ref=PR080

28. Reporting Radiation incidents

RAD_RP4

29. Handling Radiation incidents

RAD_RP5

30. Radiation incident flowchart

RAD_RP2

31. Lifetime cancer risk chart

RAD_RP3

32. Significant accidental and unintended exposures under IR(ME)R

Notify us about an exposure - Care Quality Commission

33. BIR report Guidance on using shielding on patients for diagnostic radiology application

final_patient_shielding_guidance.pdf