Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Please Note: This policy is currently under review and is still fit for purpose.

Employer's Procedures under IR[ME]R 2017

This procedural document supersedes Employer's Procedures under IR(ME)R 2017 PAT/PS 22 v.1

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Amendment Form

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Version 2	29 March 2021	• Amending document to reflect practice • Reviewed against latest CQC SAUE guidance	Jane Davies Miss Sara Elliott Mr Giles Morrison
Version 1	7 January 2019	This is a new procedural document, please read in full.	Mr Giles Morrison, Dr Duncan White, Mr Peter Thompson, Ms Jane Davies.

Contents

1. INTRODUCTION

This document is applicable to the Ionising Radiation (Medical Exposure) Regulations 2017 and the Ionising Radiation (Medical Exposure) Amendment Regulations 2018. These Regulations address the radiation protection of persons undergoing medical exposures that fall into the following categories:

- as part of their own medical diagnosis or treatment,
- as part of health screening programmes
- as part of research,
- as asymptomatic individuals,
- as those undergoing non-medical imaging using medical radiological equipment
- as carers and comforters of persons undergoing medical exposures.

The employer must ensure, where appropriate, that written departmental protocols are in place for every type of standard radiological practice coming within these Regulations. Under IR[ME]R 2017 regulation 6(1) the Trust must ensure that written procedures are in place in respect of those matters described in Schedule 2 of the regulations.

The following Trust wide procedures are concerned with the establishment of general non-specific procedures, protocols and a quality assurance programme. Departmental procedures that are in compliance with Trust Employer's Procedures are also required. These are fully detailed separate documents that are used by staff working at a departmental level. Some typical departmental procedures are referenced within this document.

2. PURPOSE

This document is a platform for the delivery advice for the implementation and response to the Ionising Radiation (Medical Exposure) Regulations 2017. It specifies procedural standards that must be adopted within the Trust. It also provides further information on education, training and matters of legislative compliance. The Trust Board is committed to minimising risks to patients, ensuring that medical exposures are individually justified and optimised, i.e. that a medical exposure will be of net benefit to the individual or society, as appropriate.

3. DUTIES AND RESPONSIBILITIES

The responsibility for compliance with IR(ME)R 2017 lies with DBTH as the **Employing Authority**. Refer to CORP/HSFS 21 - Ionising and Non-Ionising Radiations Safety Policy - for details of the Trust's management organisation and a full list of duty holders under these and any other related regulations. That policy also includes the Terms of Reference for the Radiation Safety Committee and the Clinical Governance Sub Committee (Radiation) in Appendix 7 and 8, the duties of the Medical Physics Expert (MPE) in Appendix 4, and the Management Framework for radiation protection in Appendix 10.

4. EP 1 (schedule 2 (a))

Employer's procedure to identify correctly the individual to be exposed to ionising radiation

This procedure follows the Trusts Patient Identification Policy PAT/PS 7. Section 8 of that document referrers directly to medical imaging.

1. It is the ultimate responsibility of the healthcare professional acting as the 'operator', according to the definitions in the Ionising Radiation (Medical Exposure) Regulations 2017, to ensure that the correct patient is being examined or treated against the requested procedure.

2. If the operator cannot satisfy themselves as to the identity of the patient they must not proceed with the examination/treatment. All identification procedures and outcomes must be fully documented on the RIS system.

3. The patient must be asked to give their full name, date of birth and address. An open style of question must be used e.g. 'Please can you tell me your name, date of birth and address?' These details must be checked for agreement against the patient's referral.

4. In theatre situations the patient identification is confirmed by Theatre staff prior to being anaesthetised according to operating theatre procedures. A member of this team identifies the patient prior to the medical exposure. This must be documented on the request.

5. If the patient is unconscious or unable to communicate in confirming their identity, the operator must:

    - Check the patient's identity bracelet against those details given on the request.

    - If a wrist band is not worn, or the patient is from in-patients, Out-Patients or the Emergency Department, confirmation of identity must be sought from a member of staff/relative/carer **who knows the patient**. In this case the name of the informant must be recorded on RIS.

    - Any other method of confirming the identity of the patient must be recorded i.e. 'Written Communication' or 'Sign Language'.

    - If there are language difficulties that have not previously been identified to the department (needing the services of a translator) then the referrer must have checked the identity of the patient and confirmation must be sought from them.

6. Children too young to identify themselves must be accompanied by a parent /guardian /member of staff and should be identified by the carer. Patients with Learning difficulties or who are unable to communicate due to mental illness can be identified by a responsible adult who knows or cares for them. In this case the name of the informant must be recorded on RIS.

7. If the patient cannot be identified by name then they will be identified by their unit number, (Unknown patient, GU Medicine clinics, Majax patients) which can be an Emergency department number or other department identity number.

8. An unidentified or confused patient in the Emergency Department will be provided with a wristband, which gives the Unit number and patient's name if known. This can then be used to confirm identity.

9. All images taken on patients of unknown name will have the unit number as the ID label identifier.

5. EP 2 (schedule 2 (b))

Employer's procedure to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice

Only those named in the **Lists of Approved Personnel** are allowed to act as referrers, practitioners or operators. These lists are held in the relevant Medical Imaging modality Department Procedure.

5.1 Referrer

'Referrer' means a registered medical or dental practitioner or other state registered health professional who is entitled to refer individuals for medical exposure to a practitioner. Medical students are not authorised to refer patients for medical exposures. Certain other healthcare professionals may refer particular categories of patients under a specified scope of practice in line with *Trust Policy for the Referral of Imaging Examinations by Qualified Non-Medical Healthcare Professionals PAT/T1.*

For the purposes of the Ionising Radiation (Medical Exposure) Regulations, the Referrer is defined as the person who completed the referral form.

5.2 Practitioner

1. 'Practitioner' means a registered medical or dental practitioner or other state registered healthcare professional that is entitled in accordance with the Employer's Procedures to take responsibility for a medical exposure.

2. Radiologists with FRCR, DMRD or equivalent will be considered qualified, and may be practitioners in any diagnostic medical exposure except nuclear medicine.

3. Only those consultants who hold a current ARSAC certificate or Practitioner Licence for the relevant investigation or treatment, and for the site at which the administration is to be carried out, can act as a practitioner for Nuclear Medicine procedures.

4. Clinical Scientists and Technologists who have undergone specialist training may act as Practitioners for x-ray examinations following Nuclear Medicine investigations.

6. Dental surgeons may be practitioners solely for intra oral radiography. These Dental Surgeons must be members of their professional body, dental radiology must have been a component of their initial training, or they must have attended post training dental radiology courses, which included in either case a radiation protection component.

5.3 Operator

'Operator' means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects[1] have been allocated, medical physics experts, medical physics staff and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training.

Operators must have adequate theoretical and practical training relevant to their scope of practice, and in radiation safety. This includes medical physics staff who maintain or calibrate radiation dispensing or generating equipment.

[1] See section 20 (DEFINITIONS) for a full definition of the term "Practical aspects".

6. EP 3 (schedule 2 (c))

Employer's procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast-feeding

6.1 Minimise Radiation Exposure to a Possible Foetus

It is the policy of Doncaster and Bassetlaw Teaching Hospitals to make enquiry of pregnancy status for all individuals of childbearing potential prior to exposure to ionising radiation.

This procedure applies to –

a) Examinations or treatment involving administration of any radiopharmaceutical

b) Examinations using ionising radiation where there is exposure above the knee and below the diaphragm on individuals of childbearing potential

6.2 Considerations

1. Referrers must consider the possibility of pregnancy when assessing the requirement for examinations involving administration of radiopharmaceuticals or other use of ionising radiation. This must be documented in the radiology referral. Final responsibility lies with the operator initiating the exposure or administering the radiopharmaceutical to ensure that pregnancy status is checked.

2. An explanation of the requirement for checking pregnancy status must be given to the patient. The enquiry and response must be documented on the radiology examination record, treatment record or radiopharmaceutical administration record.

3. Pregnancy status will be checked with all patients who are potentially capable of bearing children (nominally 12-55 years but some patients may fall outside this range).

4. The question must be posed with care as it may offend or embarrass some individuals. If in any doubt as to the sensitivity with which the question should be posed, it is recommended that staff seek advice from senior colleagues.

5. In cases where there are communication difficulties due to language, hearing or sensory impairment an interpreter must be used to aid communication with the patient. The use of an interpreter must be documented as per departmental procedure.

The 10 day rule applies to high-dose procedures, defined as those resulting in tens of mGy to the uterus (i.e. dose to uterus is greater than 10 mGy) this includes but is not limited to the following examinations::

- High resolution diagnostic CT of the abdomen/pelvis
- Barium/water-soluble contrast enemas
- Small bowel enemas
- Barium/water-soluble contrast follow-through examinations
- Hysterosalpinograms
- Herniograms
- Coronary Angiograms
- Aortagrams
- Cystograms
- Intravenous urograms
- Gastric band adjustments
- ERCPs
- Any interventional radiology procedure where abdominal/pelvic irradiation occurs
- Iodine 131 therapy

The 10-day rule need not be applied where there is no possibility of pregnancy.

The 28 rule will be applied to all other examinations between the diaphragm and the knee that involve exposure to ionising radiation.

6.3 Operators Responsibilities (No Possibility of Pregnancy)

If the patient has answered “No” to the possibility of pregnancy the examination may proceed. The pregnancy record will be updated, stamped or written on and signed by the patient and the Radiographer/MTO/Physicist. All signed forms will be stored in the RIS system.

6.4 Operator’s Responsibilities (Possibility of Pregnancy)

If the period is late and/or there is a possibility of pregnancy

- OPD/GP patients for non-urgent requests will be given an appointment following their next period.

OPD, Emergency Department, and GP patients for urgent requests will undergo a pregnancy test in line with departmental specific procedures prior to the examination taking place if this is

feasible. The results will be recorded as per department specific procedures. The operator will comply with the request only when they are satisfied that:

a. reasonable steps have been taken to exclude pregnancy

and

b. the examination cannot be delayed (see 6.5)

6.5 Operator's Responsibilities (Definite Pregnancy)

a. If the examination being requested is a Nuclear Medicine Lung Scan specifically for exclusion of pulmonary embolism *where the pregnancy was known at the time of the request*, it may only proceed if they were authorised in the knowledge that the patient is pregnant.

b. In all other cases, where the pregnancy was known *at the time of the referral*, the referring clinician must consider:
   1. the risks and benefits of the examination to both patient and foetus
   2. the possibility of delaying the examination until after delivery
   3. using imaging modalities that do not use ionising radiation

and, taking advice from a Radiologist, must discuss the risks and benefits of all scenarios with the patient. Where the examination needs to proceed using ionising radiation, the discussion with the patient must be documented within the referral clinical history and written informed consent obtained. As per local modality protocol, prior to undertaking the examination, the operator and the patient must sign to confirm this. This will be recorded on the RIS system.

c. Where the definite pregnancy has come to light as part of the checks undertaken within Radiology and was either not known at the time of referral or not mentioned within the referral clinical history, the patient will be sent back to the referring clinician for re-assessment as per b. above. The referring clinician must generate a new imaging request as part of this process.

6.6 Major Trauma and Life-threatening situations

In the case of major trauma and life threatening delays in care, the LMP rules will not be applied. The patient will be asked if there is a possibility of pregnancy:

- If there is no possibility of pregnancy then the scan will go ahead.
- If there is a possibility of pregnancy, the supervising Radiologist will be informed. The risks to both the patient and foetus will be explained to the patient, so that they can make an informed decision to proceed or not.
- In either case, the operator and patient (if able) must sign relevant local documents

If the patient is unable to answer or give consent due to their medical condition, the referring clinician will take the responsibility for consent. This must be documented both on the referral and within the RIS system.

6.7 Breast-Feeding

Enquiries must be made prior to administration of a radiopharmaceutical to determine whether the patient is breast-feeding. It is the responsibility of the operator administering the radiopharmaceutical to ensure that the enquiry is made and recorded on the Radiopharmaceutical Administration Record.

If the patient is breast-feeding then the Departmental Specific Procedures for Breast-feeding Patients should be followed (Nuclear Medicine only).

7. EP 4 (schedule 2 (d))

Employer's procedures to ensure that quality assurance programmes in respect of written procedures, written protocols and equipment are followed

1. All procedures and protocols will be reviewed locally at two yearly intervals in order to ensure that they are effective, appropriate and include any amendments deemed to be required. Those that have a direct impact on radiation dose and procedure outcome must be authorised by the relevant Medical Physics Expert (MPE) via the Radiation Group

2. Equipment QA programmes are the responsibility of the MPE and the local clinical team and will be reviewed in line with national guidance at least annually. QA reports from each modality lead will be submitted to the Radiation Safety Committee on an annual basis.

3. Amendments of procedures at intervals of less than one year are not precluded should this be necessary.

4. Modality Leads will co-ordinate the process of creating department level controlled documents within their area of responsibility.

5. Procedures and programmes must be reviewed by one of the following:

    a. Medical Physics Experts (MPE)
    b. Clinical Director for Medical Imaging
    c. Imaging Services Managers
    d. Modality Leads of Departments
    e. Clinical Governance Sub-Group (Radiation)

    Review and possible amendments will take place every two years or

    - after any incident which may affect radiation dose
    - prior to the implementation of new legislation and/or guidance notes from official bodies
    - following a review of Trust policies
    - prior to the introduction of any new patient investigations

6. The primary responsibility for reviewing Employer's Procedures (EPs) rests with the Clinical Governance Sub Committee (Radiation). They should be ratified by the Trust's Radiation Safety Committee. The EP review team will be formed from –

    - Imaging Services Managers
    - Radiation Protection IR(ME)R Lead
    - Clinical Governance Lead
    - RPAs and MPEs for Diagnostic Radiology and Nuclear Medicine

7. The Trust Radiation Safety Committee is responsible for ensuring that all quality assurance programmes are followed.

8. EP 5 (schedule 2 (e))

Employer's procedure for the assessment of patient dose and administered activity

8.1 Diagnostic Radioisotope Procedures

The identity of the radiopharmaceutical must be confirmed from the label on the vial shield before proceeding.

For diagnostic procedures, administered activities should be within 10% of the diagnostic reference level (DRL) specified in the study protocol (or the adjusted DRL in the case of a child or an obese / emaciated adult). Variation or exceptions to this are covered in the relevant imaging departmental protocol.

The responsibility for ensuring that the correct radiopharmaceutical and activity is administered rests with the operator administering that radiopharmaceutical.

Full details of the procedure for drawing up and establishing the activity to be administered are given in "**RP28: Departmental Procedure for Sub-Dispensing and Administration of Tc-99m radiopharmaceuticals" and "RP29: Departmental Procedure for Sub-Dispensing and Administration of non-Tc-99m radiopharmaceuticals".**

8.2 Therapeutic Radioisotope Procedures

For therapy procedures, administered activities should be within 10% of that prescribed.
The full details of the administration of the patient dose will be recorded on the **"Request for Radioiodine Therapy and Supplementary Consent Form".**

Therapy doses must always be checked by two people prior to the administration of the dose, at least one of which must be an approved operator. This will involve checking the activity, reference date and expiry date of the radiopharmaceutical all of which can be found on the label attached to dose container.

The activity of the therapy dose will be checked using an assay calibrator, with a second competent person being used to verify the assay. The measured activity, the date and time will be written on the label of the container. The initials of both the operator and the person responsible for checking the dose will be written on the label on the side of the tin.

The label on the lead pot will be kept and attached to the treatment planning form.

8.3 Radiological Procedures

The Practitioner justifying an exposure should have an extensive knowledge of the radiation risks and dosimetry of the given examination and should be aware of their responsibility in keeping patient dose to a minimum.

The Practitioner should follow a checklist prior to justifying an exposure:-

- Has a named, identified, referrer requested the examination?
- Does the examination comply with Employer's Procedures and local technique protocols?
- Are the clinical details appropriate to the examination requested?
- Have previous attendances and outcomes been considered?
- Have age, gender, and period data been taken into account?
- How urgent is the examination?

For general x-ray, suggested exposure factors will be displayed in each x-ray room.

Deviation from the suggested exposure factors which results in an exposure being given which is outside the national diagnostic reference levels or outside the local reference levels must be logged. If there is no obvious explanation for a high dose being recorded this must be reported to the radiation lead or to a radiation protection supervisor. Local investigation procedures, as detailed in the Local Rules, will be followed.

Exposure factors are taken to mean any parameter that may be used to estimate the patient radiation exposure. A Medical Physics Expert will be required to derive some of these parameters and will be required in all cases to derive effective doses should these be required.

- In radiography the generator factors and focus to patient skin distance will determine the skin entrance dose.
- In fluoroscopy the factors are ever changing so a physical measure of dose area product is used.
- In CT estimates of dose are made using standard phantoms.

In diagnostic radiology the relevant parameters (exposure factors, DAP) shall be recorded on the image DICOM header. The "factors" shall constitute sufficient details to estimate the dose, it is implicit the examination has followed standard protocols

Routinely, only factors relevant to patient dose shall be recorded. Commonly recorded data will include:

- direct measurements with dose area product meters where these are fitted
- a dose area product calculation made by the equipment based on actual factors and field sizes
- calculated entrance skin dose using known factors kV, mAs and distance, plus calibration data for the output of the x-ray tube and standard backscatter factors
- calculated mean glandular dose for mammography examinations using known factors kV, mAs and distance plus calibration data for the output of the x-ray tube and standard conversion factors (undertaken 6 monthly). Plus actual doses taken from a sample of 50 women (undertaken 12 monthly),

- calculated dose length product, CTDi and number of slices for CT examinations using set factors plus calibration data on a phantom,
- calculated dose width product for panoramic dental examinations using set factors and calibration data.

In all cases the calibration data for the X-ray tube or calibration of the DAP will be made available following a survey of the radiological equipment by an approved member of the medical physics staff. This calibration must be done after installation of new equipment and at least annually subsequently. Re-calibration may also be required following major repairs or replacements of equipment unless routine QA measurements indicate no change in radiation output.

The patient dose data of whichever origin will be recorded on RIS, even if it is recorded or derivable from data automatically recorded elsewhere. This data shall be some or all of the following as relevant:-

- DAP meter reading, exposure factors (kV, mAs, and focus to skin entrance distance).
- For fluoroscopy – screening time, dose, air kerma (where available).
- For CT - DLP and CTDi (vol).
- mammography exposure parameters such as: KV, mAs, Thickness, Compression Force, Entrance dose and Glandular dose (recorded at the time of exposure, on all individual images taken)

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 qualified and approved medical physics expert.

9. EP 6 (schedule 2 (f))

Employer's procedure for the use and review of Diagnostic Reference Levels (DRLs)

'Diagnostic Reference Levels' means dose levels in medical radio diagnostic practices or, in the case of radioactive medicinal products, levels of activity for typical examinations for groups of standard-sized patients for broadly defined types of equipment:

9.1 Radiological Procedures

Every 3 years an audit of patient doses will be made of all standard procedures and analysed for derivation of reference dose, to audit and compare levels against the set reference dose, and to revise as necessary.

Doses will be calculated from recorded factors on imaging records to check compliance with reference levels.

Diagnostic reference levels have been set for all diagnostic X-Ray equipment within the DBTH NHS Foundation Trust and are held within individual imaging room folders.

Any dose which exceeds the recommended reference level will be documented within Datix and reported to the local RPS. The local RPS will investigate and the incident will be reported to RPA and the Clinical Governance Sub-Group (Radiation) following investigation.

9.2 Nuclear Medicine

In the event of a patient receiving an activity that is much higher than intended or otherwise incorrect, then reference must be made to the departmental specific procedure for deviations from prescribed dose.

Administered activities must be periodically reviewed against relevant DRLs. This is the responsibility of the MPE. The MPE also takes responsibility for the review of study protocols in relation to DRLs and other aspects of optimisation.

10. EP 7 (schedule 2 (g))

Employer's Procedure for the exposure of individuals participating in medical research programmes

1. Most but not all research studies must have a national rather than local research ethics committee approval and a written examination protocol. In the case of nuclear medicine they must also have ARSAC authorisation and must comply with all requirements under the Environmental Permitting Regulations where relevant. A list of all current research programmes satisfying these conditions are held in an electronic database as part of the Trust's Research Management System.

2. Nuclear Medicine protocols must be agreed with the ARSAC licence holder, who will also be the practitioner for any research study for which they have ARSAC authorisation.

3. Dose constraints and targets must be set in the planning of any research study from which the participating individual is not expected to receive a direct medical benefit. Such dose constraints and targets should be set after consultation between the Practitioner and Medical Physics Expert

4. Target doses for individuals undergoing experimental procedures will be consistent with the relevant DRL or prescribed activity given in the relevant routine study protocol.

5. Prior to the exposure of patients or other persons participating in research programmes, it is the responsibility of the research co-ordinator for the particular research study being undertaken to ensure that:

    - the individuals concerned participate voluntarily in the research programme;
    - the individuals concerned are informed in advance about the risk of the exposure.

    The risks associated with the exposure should be established after consultation between the Practitioner, the relevant Radiation Protection Adviser and Medical Physics Expert

    It is the responsibility of the research co-ordinator to ensure that confirmation of these checks is documented on the request.

6. Research studies 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 in all other respects described in EP1. The responsibility for justification rests with the practitioner.

    Persons selected to participate in the study must comply with the age range and clinical condition (or normal control) approved for the study.

The number of exposures received by an individual and the number of patients participating in the study must not exceed those approved for the study.

7. The operator will not perform an exposure unless there is a written protocol detailing a current national research ethics approval, in line with the Trust's Research Governance policy CORP/COMM 14. In the case of nuclear medicine, it is also necessary to confirm that ARSAC authorisation is in place prior to the administration. These checks are performed by interrogation of the Research Management System.

8. Where all conditions relating to exposures for the purposes of Medical Research are satisfied, the investigation should continue in accordance with the appropriate Employer's Procedures, Departmental Procedures and protocols.

11. EP 8 (schedule 2 (h))

Employer's procedure for the provision of written instructions and information to patients undergoing treatment or diagnosis with radioactive substances

11.1 Nuclear Medicine

In certain situations it is necessary to issue patients with written instructions and advice before they leave the department. The procedure to be followed may differ depending on whether the patient is returning to their own home or returning to a care / nursing home or hospital ward. Standard written instruction cards are used to provide the necessary information to the patient, in addition to the verbal explanation given by the operator.

11.2 Patients Leaving Hospital and Returning Home:

1. Before a patient leaves hospital, following the administration of a radiopharmaceutical, the operator must check with the relevant study protocol to see if an instruction card is required. It is the responsibility of the operator administering the radiopharmaceutical to ensure that an instruction card and radiation protection advice is given to the patient if required by the study protocol. Both verbal and written advice must be provided.

2. In cases where the dose is adjusted upward from the DRL, it may become necessary for an instruction letter to be issued and radiation protection advice given even though this is not specified for the standard DRL. Specific details of these restrictions can be found within the departmental protocols relating to this modality.

3. Where the patient is a child who lacks the capacity to consent, written instructions should be given to the person with parental responsibility for the child.

4. Where the patient is an adult who lacks the capacity to consent, written instructions will normally be given to a close relative or the adult who is taking care of the patient. In cases where it is not clear who should receive written instructions, the practitioner must be consulted before the patient leaves the department.

5. If written instructions are given to someone other than the person receiving the radiopharmaceutical, the reason for this must be recorded together with the name of the person receiving the advice and their relationship to the patient.

11.3 Radioiodine Therapy Patients (In-Patients or returning to Nursing/Care Homes)

1. It is unlikely that a therapy patient will be either treated as an in-patient or that they will return to a nursing / care home following treatment. The above situations are normally excluded by the practitioner during the justification process.

2. The operator must also comply with procedures to assist nursing homes receiving radioactive patients to comply with IRR 2017 in terms of registration with the HSE, risk assessment, precautions for staff, the control of waste and appointment of a RPA.

3. The patient's home circumstances will be discussed during the interview along with the precautions they will need to take after the therapy and any other information relevant to their treatment. Any issues raised will be discussed and explained during the interview. (Please see the departmental protocol, **"A Procedure for Radioiodine Therapy – Consent, Administration and Pre-Therapy Interview"**.)

12. EP 9 (schedule 2 (i))

Employer's procedure to provide 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.

Information detailing the risks associated with the dose associated with exposure to ionising radiation will be provided to patients by one or more of the following methods:

1. posters displayed in relevant waiting areas.

2. verbal explanation of the radiation risks by the operator

3. opportunity to ask questions of the operator immediately prior to the examination

In the case of radioiodine therapy, the benefits and risks are discussed in detail during the clinic discussions with the medical teams at the time of referral and again during a pre therapy interview prior to the therapy commencing. Continued consent is confirmed prior to administration of radioiodine.

Where the patient is unsure of the benefit of exposure to radiation and the operator or radiologist is unable to gain consent for their investigation to continue, the patient should be advised to undertake further discussion with their referring clinician. The examination will be paused until the patient is satisfied.

13. EP 10 (schedule 2 (j))

Employer's procedure for the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose

To ensure that an examination, once completed, has an outcome that is noted within the patient's record on ICE:

1. All diagnostic medical exposures will have a clinical evaluation by an operator designated to carry out this function. All evaluations are recorded on the trust Radiology Information System (RIS) which also exports them to the trust-wide information system ICE.

2. Examination of patients will only be carried out when clinically justified.

3. For Interventional Radiology Procedures (therapeutic) the operator affecting the procedure must make a report, even though they may not be in a position to report on the therapeutic benefits gained at the time of the procedure.

4. When a referrer asks for "no report", it is the responsibility of that referrer acting as an operator to interpret and evaluate the examination and make reference to it in the patient's notes. All relevant staff should be aware of their responsibilities under IR(ME)R legislation. The system used to generate the referral will indicate the referrer is aware of these responsibilities, and their signature, whether hand-written or electronic, will validate this.

13.1 Nuclear Medicine Examinations – Imaging Tests

5. For imaging tests requiring both technical and medical reports, an operator will write a technical report and, where necessary, request views in addition to those specified in the relevant imaging protocol.
6. For all imaging studies requiring a medical report, the referral information together with acquired and processed images should be assigned to an appropriate Consultant Radiologist or reporting nuclear medicine radiographer/technologist. The images are available on PACS once the operator has sent them electronically.

13.2 Radionuclide Therapy

7. In the case of patients undergoing radionuclide therapy, a record of the administered activity and the date of administration are reported in the RIS system. The clinical outcome of the therapy is assessed at follow up visits by the medical team caring for the patient, and will be recorded in the patient's notes.

14. EP 11 (schedule 2 (k))

Employer's procedure to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable

1. Operators will be trained to undertake safely all aspects of a medical exposure, and this training will include radiation protection and the correct use of equipment.

2. Operators will be aware of all relevant procedures and protocols and will follow these in the order given in the relevant departmental procedures.

3. While the observance of procedures and protocols is intended to ensure that patient exposure is kept to the minimum consistent with diagnostic or therapeutic outcome, operators are themselves responsible for the practical aspects of the exposure and so must exercise vigilance at all times.

4. Where errors do occur staff must report the incident in line with the Trust incident reporting policy via Datix, ensuring that they have recorded the data required to facilitate investigation of the incident in line with relevant local procedures.

15. EP 12 (schedule 2 (l))

Employer's procedure to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure

Definition of accidental and unintended, as written in "Significant accidental and unintended exposures under IR(ME)R: Guidance for employers and duty-holders", CQC, June 2019:

> **Accidental exposure:** an individual has received an exposure in error when no exposure of any kind was intended.
>
> **Unintended exposure:** 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, radiopharmaceutical or timing of exposure. These can happen for many reasons including procedural, systematic or human error, or equipment malfunction. The latter includes software, PACS and RIS systems, and PPE.

A clinically significant exposure is defined as one which exceeds a dose of 1mSv, a maladministration of radiopharmaceutical, or a therapeutic underexposure greater than 10% deviation from the prescribed dose

1. Where an accidental or unintended exposure occurs staff must report the incident in line with the Trust incident reporting policy, ensuring that they have recorded the data required on DATIX to facilitate investigation of the incident. This includes a request for a dose report by Radiology Physics staff. The operator will also be required to complete a reflective statement detailing the nature of the incident and what learning has taken place to reduce the likelihood of future incidents.

2. Where the dose meets the trigger factors detailed in MGTI, PM77 and SAUE guidance, the incident may be reportable to the Chief Executive, the Divisional Governance Lead, the Trust's Serious Incident Group and/or to the CQC IR[ME]R Inspectorate. The incident will be reported as a Serious Incident when the incident's Handler selects "Serious Incident" on DATIX.

3. The referring clinician will be made aware of the dose report via the Datix system and governance processes and the information retained in the patient's medical record.

4. The patient will be informed at the time of the incident where possible and offered a meeting to discuss the dose report and any concerns if required. This process will be managed by the modality lead in liaison with the division's Clinical Governance Sub Committee (Radiation) in line with the Trust's "Being Open and Duty of Candour Policy" CORP/RISK 14.

5. In the event of an Incident that involves Ionising and Non-Ionising Radiation it will need to be reported on DATIX, using the Category "**Radiation**" and Sub-Category that corresponds to

the legislation that may have been breached, i.e. "(IR[ME]R), Patient Exposed to Unintended Radiation Dose". Any Near-Misses can be filtered out by using the appropriate Sub-Category.

6. Any reported radiation incidents will be investigated on DATIX and discussed with the RPA/MPE, who will then be asked to issue a dose report. The incident will be reported to the Trust's monthly Clinical Governance Sub Committee (Radiation) for further consideration.

7. The management team will discuss any reported serious IR(ME)R-related adverse incidents at the Trust's Radiation Safety Committee. Meetings are scheduled every six months. The above committees will be responsible for reporting the incident to CQC IR(ME)R Inspectorate.

16. EP 13 (schedule 2 (m))

Employer's procedure to be observed in the case of non-medical imaging exposures

'Non-medical imaging exposure' means any deliberate exposure of humans for imaging purposes where the primary intension of the exposure is not to bring a health benefit to the individual being exposed;

1. The request must specify that the investigation is a non-medical examination.

2. Nuclear Medicine procedures for non-medical purposes will only be carried out if the circumstances have been discussed with an ARSAC certificate or license holder either employed by the Trust or with whom special arrangements have been made. The investigation must be **individually justified** by the ARSAC holder acting as practitioner.

3. All other procedures for non-medical reasons will only be carried out if the circumstances have been discussed with a Consultant Radiologist employed by the Trust, or by a pre-determined protocol. This will be on an individual patient basis, or exceptionally for groups of workers being referred by the same clinician for the same examination. In the latter case the circumstances must be reviewed on a regular basis or at least annually with justification being re-evaluated at each review. The individual patient or group generic justification will only be in respect of one referrer.

4. Requests for the examination of children where physical abuse is suspected and the results of the exposure may contribute to the prevention of future abuse are not classified as non-medical examinations.

5. If the practitioner is in any doubt as to the value of a non-medical exposure requested of them, they should seek further information from the referrer in order to inform the justification process.

6. Any non-medical imaging procedure must be reported by a Radiologist and where coincidental findings are noted that require medical attention, the practitioner is responsible for ensuring the subject is referred to the appropriate care pathway.

17. EP 14 (schedule 2(n))

Employer's procedure to establish appropriate dose constraints and guidance for the exposure of carers and comforters

- In accordance with the Ionising Radiations Regulations 2017 (IRR2017) (Regulation 8), risk assessments determine the circumstances in which friends or family of patients undergoing a medical exposure may be exposed to ionising radiation as a result of the support and care of that patient.
- The risk assessments form the basis of written procedures which restrict so far as is reasonably practicable the doses received by the supporter and carer.
- Where the exposure of the supporter/carer occurs on DBTH premises, these procedures are contained in the **Local Rules** and local modality procedures**,** as required by IRR2017 (Regulation 9(4))
- Where exposure of the supporter/carer occurs following departure of the patient from DBTH premises, these procedures will be in the form of 'written instructions' issued to the patient or responsible person in accordance with EP9.
- Compliance with the written procedures will ensure in the majority of circumstances that the effective dose of the supporter and carer is less than 1mSv per annum. In a limited number of defined circumstances, the effective dose of the supporter and carer will be restricted to less than 1 or 3 mSv/procedure, ensuring compliance with the member of public dose limit of 5 mSv in 5 consecutive calendar years. (IRR 2017 ACOP guidance paragraphs 231-232 and schedule 3 part 6).

Examinations performed in main x-ray rooms do not expose a supporter/carer to effective doses that exceed limits defined within IRR2017 and thus will not require a "carers and comforters" designation, *unless* the supporter/carer is integral to the production of images (i.e. they hold the patient in a specific position)

The following procedures have specific "carers and comforters" designation:

1. Paediatric micturating cystograms
2. Skeletal surveys for Suspected Physical Abuse
3. Paediatric Skeletal surveys for pathological abnormalities
4. Video swallows for Speech and Language Therapy purposes

These examinations have been assessed for scatter dose by the RPA and have been deemed to fall within the dose constraints of IRR2017.

Within CT and Interventional Radiology, where high dose procedures are undertaken, a supporter/carer will not be allowed within the controlled area when radiation exposures are made and thus will never be a designated a 'carer and comforter'.

Those present as part of their job role (e.g. prison officers or certain nursing staff) cannot be designated 'carers and comforters' and are covered by IRR17, Local Rules and local procedures.

18. PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

19. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

19.1 The MPEs are responsible for providing the advice and information regarding any changes in legislation that is used during the periodic review of the policy. Monitoring of this document will be the responsibility the members of the Trust's Radiation safety Committee. Monitoring as specified below!

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Monitoring Current IRMER legislation for amendments and changes.	MPE and Clinical Governance Group	Every two years or when deemed appropriate by the MPE	Change in Policy reported to RSC Group
IRMER Update Training.	Operational management teams and clinical governance group.	Read through procedures every year plus theoretical training every three years.	Reviewed as part of PDA
Compliance with IRMER legislation and its associated procedures. (Nuclear Medicine)	RPA/MPE inspection report	Every year	Annual inspection and reporting.

Clinical Audit. (i.e. systematic examination or review of medical radiological procedures – Refer to full definition below.)	Radiographers, Physicists etc	Every three years	Results reported to clinical governance (radiation) group and RSC.
QC reports. (All Modality leads)	Radiographers and Physicists	Biannual	Results reported to clinical governance (radiation) group and RSC.

20. DEFINITIONS

The following definitions are for terms that are found within this document:

"Accidental exposure" means an exposure of an individual as a result of an accident;

"Adequate training" means training which satisfies the requirements of Schedule 3 and the Expression "adequately trained" is to be construed accordingly;

"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 exposure;

"Clinical audit" means 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;

"Diagnostic reference levels" means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized individuals or standard phantoms for broadly defined types of equipment;

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

"Employer" means any person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, those exposures described in regulation 3 or practical aspects, at a given radiological installation;

"Employer's procedures" means the procedures established by an employer pursuant to regulation 6(1);

"Equipment" means equipment which—

(a) Delivers ionising radiation to a person undergoing exposure; or
(b) Which directly controls or influences the extent of such exposure;

"Evaluation" means interpretation of the outcome and implications of, and of the information resulting from, an exposure;

"Interventional radiology" means the use of X-ray imaging techniques to facilitate the Introduction and guidance of devices in the body for diagnostic or treatment purposes;

"Ionising radiation" means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less or a frequency of 3 × 1015 hertz or more capable of producing ions directly or indirectly;

"Licensing Authority"—

(a) For the purpose of licensing any practitioner in respect of the administration of radioactive substances means the Secretary of State;

"Medical exposure" means an exposure coming within any of paragraphs (a) to (e) of regulation 3;

"Medical physics expert" means 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;

"Medical radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;

"Medical radiological procedure" means any procedure giving rise to a medical exposure;

"Non-medical imaging exposure" means 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;

"Operator" means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects have been allocated, medical physics experts and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training;

"Patient dose" means the dose concerning patients or other individuals undergoing exposures to which these Regulations apply;

"Practical aspect" means the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, clinical evaluation and image processing;

"Practitioner" means a registered health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual exposure;

"Quality assurance" means all those 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 and quality control is a part of quality assurance;

"Quality control" means 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;

"Radioactive substance" means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;

"Radiodiagnostic" means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic Radiology using ionising radiation, and dental radiology;

"Radiological installation" means a facility where exposures to which these Regulations apply are performed;

"Radiotherapeutic" means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;

"Referrer" means a registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for exposure to a practitioner;

"Registered health care professional" means 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**);

"Relevant enforcing authority" means— in England, the Care Quality Commission);

"Unintended exposure" means any exposure to ionising radiation which is significantly different from the exposure intended for a given purpose.

21. ACCOUNTABILITY FRAMEWORK

- The Chief Executive and the Trust's Board of Directors
- The Trust's Clinical Governance and Quality Committee.
- The Trust's Radiation Safety Committee
- General Managers
- Departmental Business/Service managers
- MPEs
- Modality Leads

22. EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (Please see Appendix 1).

23. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Ionising and Non-Ionising Radiations Safety Policy - **CORP/HSFS 21**
Medical Equipment Training Policy - **CORP/RISK 2**
Risk Identification, Assessment and Management Policy – **CORP/RISK 30**
Trust Policy for the Referral of Imaging Examinations by Qualified Non-Medical Healthcare Professionals - **PAT/T 1**
Fair Treatment for All Policy – **CORP/EMP 4**
Equality Analysis Policy – **CORP/EMP 27**
Research Governance Policy – **CORP/COMM 14**
Patient Identification Policy **- PAT/PS 7**
Being Open, Saying Sorry and Duty of Candour Policy - **CORP/RISK 14**
Mental Capacity Act 2005 Policy and Guidance, including Deprivation of Liberty Safeguards (DoLS) – **PAT/PA 19.**

24. DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website:
https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

25. REFERENCES

1. The Ionising Radiation [Medical Exposure} Regulations 2017
2. The Ionising Radiation [Medical Exposure} Amendment Regulations 2018
3. The Ionising Radiation Regulation 2017
4. PM77, Equipment used in Connection with Medical Exposure 3rd Edition – HSE
5. Department of Constitutional Affairs
   Mental Capacity Act (2005): Code of Practice, 2007
   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

APPENDIX 1 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division/Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
PAT/PS 22 V.2 – Employer's Procedures under IR[ME]R 2017	Clinical Specialities	Sara Elliott	Existing	15/01/2021

1) Who is responsible for this policy? Clinical Specialities – Medical Imaging

2) Describe the purpose of the service / function / policy / project/ strategy? Trust-Wide – IRMER 2017 - Employers Procedures

3) Are there any associated objectives? Yes

4) What factors contribute or detract from achieving intended outcomes? None

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No

- **If yes, please describe current or planned activities to address the impact**

6) Is there any scope for new measures which would promote equality? No

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4

Date for next review: December 2022

Checked by: Jaz Sawhney, Clinical Director in Medical Imaging **Date:** 15.01.2021