Division of Cancer, Diagnostics & Support Services

Imaging Business Unit

University Hospitals of Derby and Burton NHS Foundation Trust

Imaging Department Protocol: Employers Procedures to meet the requirement of Schedule 2 of the Ionising Radiation (Medical Exposures) Regulations

This document sets out the procedures in place to meet the requirements of Schedule 2 of (IRMER), as required by regulation 6(1) of the Ionising Radiation Medical Exposures Regulations (IRMER) with regard to diagnostic imaging examinations including Interventional Radiology.

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Version / Amendment History	**Version**	**Date**	**Author & Role**	**Reason**
	1.0	April 2020	Mike Barnard Clinical Manager – Compliance	To record the procedures in place within a single document and revise the procedures to be compliant with current regulatory requirements and best practice guidelines.
	1.2	June 2020	Mike Barnard Clinical Manager – Compliance	To reflect new Trust Radiation Safety Policy regarding the communication of Radiation Risks to patients and address feedback from the Medical Physics Expert and representative Operators and Practitioners
	1.3	June 2021	Emma Lawson Superintendent: Ionising Radiation Protection	Annual review. Updated name of Suspected Physical Abuse policy. Included requirement of Comforters and Carers to wear lead aprons in CT, omitted in previous draft. Formatting of flow chart in section c updated.
	1.4	November 2021	Emma Lawson Superintendent: Ionising Radiation Protection	Updated pregnancy check exceptions to include personalised care plans.
	1.5	October 2022	Emma Lawson Superintendent: Ionising Radiation Protection	Updated to include advice for pregnancy checking for patients undergoing fertility treatment. Updated Clinical Director signatures. Changes to procedures A, B, J, L and N in accordance with QSI findings.

Intended Recipients – Essential to Role (Copy Holder in QPulse): Radiologists, Radiographers and other Imaging Business Unit staff designated as Practitioner or Operator for these examinations.	**Intended Recipients – For Awareness / Reference** Other Imaging Business Unit staff All Trust and external staff designated as referrers for these examinations
Communication: The document will be distributed to all Radiologists, Radiographers and other staff designated as Practitioner or Operator for these examinations via QPulse. These staff are required to acknowledge that they have received, understood and will comply with the document via QPulse.	**Training:** All Practitioners and Operators will be trained on these procedures. All referrers will be informed of the procedures and instructed regarding them.
To be Read in Conjunction with: Trust Policy and Procedures for Ionising Radiation Safety. Other Employers procedures	
Groups & Stakeholders Consulted Practitioners and Operators Radiation Protection Advisor(s) and Medical Physics Expert(s)	**Equality Impact Risk Assessment** **Stage 1:** Completed **Stage 2:** N/A
Approving Group: Imaging PQRS	
Authorising Group: Trust Radiation Protection Committee	
Approving Imaging BU Manager	 David Tipper (General Manager)
Approving Imaging BU Senior Manager	 Dr Rathy Kirke (Clinical Director)  Dr Rajeev Singh (Clinical Director)

Approving Trust Manager	 Penny Owens (Divisional Director – AHP's and Chair of the Trust Radiation Protection Group)	
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Uncontrolled when printed. Staff should consult the electronic master copy for the definitive version This document remains in force until replaced or withdrawn.		

Contents

1. Introduction

All Imaging Business Unit staff undertaking examinations involving the exposure of patients to ionising radiation **must** comply with these procedures. Similar procedures are in place for Imaging Business Unit staff conducting examinations in Nuclear Medicine and the Breast Unit.

The Ionising Radiation (Medical Exposures) Regulations address the radiation protection of persons undergoing exposures to ionising radiation 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 Ionising Radiation (Medical Exposure) Regulations require that employers must ensure, where appropriate, that written departmental protocols are in place for every type of standard radiological practice coming within these Regulations. This document sets out the procedures in place to meet the requirements of Schedule 2 of (IRMER), as required by regulation 6(1).

In addition, general non-specific procedures, protocols and quality assurance programmes are required under IRMER.

2. Purpose

To set out procedures Imaging Business Unit staff **must** follow in order to ensure appropriate radiation protection for patients; and others covered by IRMER.

To meet the Trusts duty to provide written procedures under IRMER.

3. Duties and Responsibilities

The responsibility for compliance with IRMER lies with the Trust Board as the Employing Authority.

In addition to the Trust, IRMER defines 3 types of Duty Holders; Referrers, Operators and Practitioners. The responsibilities of these duty holders are described in the regulations and the Trust Ionising Radiation Safety Policy

Please see the Ionising Radiations Safety Policy for details of the Trust's management organisation and a list of staff with managerial responsibility under

IRMER and any other related regulations. Terms of reference for the Radiation Protection Group and its Sub-Groups are linked to the Trust Ionising Radiation Safety Policy.

3.1 Mental Capacity:

Sometimes it will be necessary to image patients who are lacking in capacity, as defined by the Mental Capacity Act, and so unable to cooperate with the employer's procedures.

It is not the role of Imaging staff to make a formal assessment of the mental capacity of patients. This is the role of the referrer, who should include information regarding mental capacity issues in the referral, and make appropriate arrangements for the safe conduct of the examination.

When a patient arrives for an examination without previous mention of mental capacity issues and the operator has concerns that the patient does not have capacity to give appropriate consent; this should be discussed with the referrer. Where such issues cannot be resolved in a timely manner, examinations should be delayed.

4. Procedures required by Schedule 2 of IRMER

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

1. All requests must contain sufficient details to allow the person attending for examination to be confirmed as the person for whom the referral was made. Typically (as a minimum name, date of birth and address) this will be the patient's name, date of birth and address as well as other identifiers such as hospital and NHS number. Requests not containing sufficient information to identify the patient will be rejected.

2. It is the responsibility of the Radiographer / Radiologist / Assistant Practitioner or other healthcare professional making the exposure to ensure that the patient referred is the person being examined.

3. The Operator must confirm the patient's identity in accordance with the Trust Policy for Positive Patient Identification. This requires at least 3 separate points of the patient's identifying information to be checked against the information provided in the referral.

   The patient must be asked to give their full name, address and date of birth. 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 against the request card / electronic referral / print out from CRIS.

   Closed questions, including the answer; e.g. *'Are you Mr Joe Bloggs?' 'Is your address 123, Hospital Way, Madeuptown?* **must not** be used.

   This check **must** be made in the examination room prior to exposure and not in the waiting room.

   Where the examination / procedure requires a 'stop moment' to be performed the identity check should form part of this process

4. If the patient is unable to cooperate with a verbal identity check:

   - For Inpatients and Emergency Department Patients:

     The details on the patient's identity bracelet must be checked against those given on the request.

     If the patient is escorted by a member of staff from the ward / department they have been referred from, the staff member should be asked to confirm the patient's identity as a supplementary error reduction measure. If the patient is not escorted, but is accompanied by a friend / relative / carer from outside UHDB, they should be asked to confirm the patient's identity as a supplementary risk reduction measure. Any such check should be fully documented in CRIS.

If a patient identity bracelet is not present for reasons other than clinical considerations, ward staff must be contacted and informed that the procedure cannot go ahead unless an identification bracelet is in place. This is the responsibility of the registered health professional caring for the patient.
If an identity bracelet cannot be worn for clinical reasons, e.g. the patient has swollen limbs or intravenous lines attached, then it is the responsibility of the ward staff to identify the patient to the Operator. The method used to identify the patient must be fully documented in CRIS, including the name and designation of any ward / department staff involved.

- For Out-Patients: Confirmation of identity must be sought from a member of staff / relative / carer who knows the patient. This must be fully documented in CRIS, including the name of the person confirming the patient's identity and their relationship / designation. Occasionally, outpatients may be provided with a patient identity bracelet. In such circumstances, this may be used to identify the patient, as for inpatients and ED patients.

- Any other method of confirming the identity of the patient must be recorded in CRIS by the Operator; i.e. 'Written Communication', 'Interpreter' or 'Sign Language'. The interpreter must use an active process e.g. what is your name, DOB etc.

- Older Children may identify themselves for plain film X-ray examinations. Children too young to identify themselves; and those attending for CT, fluoroscopy or examinations requiring the use of contrast agents or adjuvant drugs; must be accompanied by a parent, guardian or member of staff who knows and can identify the child. This must be fully documented in CRIS by the Operator, including the name of the person confirming the patient's identity and their relationship / designation.

- In theatre and similar situations, if the operator was not present at the start of the procedure, the patient's wristband should be checked if this is possible without interfering with the aseptic field / surgical procedure.

  Alternatively, a surgeon, anaesthetist, nurse or ODP must confirm that the patient was correctly identified during the WHO Checklist / Stop moment prior to being anaesthetised.

  In such cases the method of identification must be documented in CRIS by the Operator, including the name of the person identifying the patient.

- If a patient is unable to communicate, or has significantly impaired communication; and cannot confirm their own identity even with appropriate support, confirmation of identity must be sought from a member of staff / relative / carer who knows the patient.
  - This may be appropriate due to conditions such as dementia, head injury, learning difficulties or intoxication.
  - Where an examination can be safely rearranged with support in place to allow patients to identify themselves, this should happen. E.g. The

patient is accompanied by specialist support staff or patient has access to their communication aids.

The process used to identify the patient must be fully documented in CRIS, including the name of the person confirming the patient's identity and their relationship / designation.

- If the patient cannot be identified by name then they will be identified by a hospital number, and unknown male 1 / unknown female 1, etc. This temporary identity will be updated, or merged with any pre-existing records, when the patient's identity is established. Such patients must have a wristband to allow identification against these temporary details.

5. The Operator making the exposure must satisfy themselves that all requirements have been carried out before doing so.

6. If the Operator cannot satisfy themselves as to the identity of the patient they should not proceed with the examination. Significant discrepancy between the information provided by the patient and the identification information provided in the request must be resolved. This is typically done by contacting the referring team / location. Referrers have a responsibility to assist in resolving such queries in a timely manner. Examinations will be delayed until discrepancies are resolved. All identification procedures and outcomes must be fully documented in CRIS.

   In the case of common discrepancies such as changes to family name or address, Operators can proceed with requests as long as the patient confirms the details provided in the referral via a positive patient identification process.

   - Following an identity check where the patient provides details different to those in the referral:
     - The Operator should tell the patient that the information provided does not match that in the referral and ask if the information has changed without disclosing the information in the referral:

       E.g. 'I'm sorry, the address I have for you is different, please could you tell me your previous addresses'.

       E.g. 'I'm sorry, the name I have for you is different, please could you tell me if you have been known by a different name'.

   Where patients cannot provide the information supplied in the referral, the referrer should be contacted and asked to resolve the discrepancy before the examination takes place.

   Where there are multiple discrepancies or where information not usually subject to change, such as date of birth, is incorrect further checks must be made. These may include checks in other electronic systems as well as checks with the referrer.

The nature of any discrepancy and how it was resolved, must be documented in CRIS.

Where discrepancies are resolved, Imaging staff must update electronic systems as soon as is practicable.

7. All Imaging staff must make checks between the referral, patient and any healthcare records they select during the conduct of an examination; to ensure that physical or electronic healthcare records used during the examination process are those belonging to the patient referred for examination.

   For example:
   - Checks between the referral and the patient details when selecting from the modality worklist.
   - Checks between the patient and referral when attending the patient on CRIS
   - Checks between the referral and patient details when selecting a record from CRIS or PACS.

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

Referrers, Practitioners and Operators are duty holders under IRMER.

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.

- Practitioners must be adequately trained, please see schedule 3 of IRMER. Typically training will consist of:

    - Core academic / professional qualifications:
        - Radiologists with FRCR or equivalent will be considered qualified and may be practitioners in any diagnostic medical exposures.
        - Specific training on the role of the practitioner and procedures which must be followed at University Hospitals of Derby and Burton.

- Specialist Radiology Trainees are not considered qualified to act as practitioners until they have full FRCR.

- Radiographers who are state registered and have undertaken specialist post-graduate training may be entitled by the Trust to act as Practitioner for a specified range of examinations; providing they can demonstrate the depth of medical knowledge required to assess the risks and benefits to patients during Justification.

- Academic qualifications will be checked on appointment and state registration will be checked periodically as part of Trust Human Resources processes. Training records will be kept by the Business Unit.
  The individual practitioner should undertake relevant CPD and keep copies of their training records. A check on CPD activity will be made at annual appraisal and a summary kept as part of the appraisal record. Practitioners must keep adequate records of their CPD.

- A practitioner must justify all as being in the patients best interests; i.e. that the benefits of the examination outweigh the risks.

    - The Clinical Director, as Lead Practitioner, may issue protocols allowing operators to authorise examinations meeting specified criteria without direct reference to a Practitioner.

- The Clinical Director of the Imaging Business Unit will entitle all practitioners, in writing, and provide a list of their duties, a copy of which will be kept in personnel files / in QPulse.

- A register of Practitioners for diagnostic radiographic / fluoroscopic or computerised tomography (CT) examinations is kept by the Imaging Medical Staffing Administrator and is available to all Imaging staff via QPulse.

- For a list of IRMER training requirements for Practitioners see Appendix 3.

Referrer

2. "Referrer" means a registered medical or dental practitioner, or other state registered health professional who is specifically entitled to refer individuals for medical exposure to a practitioner. Referrers are typically:

    - Referrers must be adequately trained, please see schedule 3 of IRMER. Typically training will consist of:

        - Core academic / professional qualifications. Qualified doctors / dentists included on the GMC / GDC register are considered qualified to act as referrers.
        - Specific training on the role of the referrer and procedures which must be followed at University Hospitals of Derby and Burton.

    - Medical students are not authorised to refer patients for medical exposures.

    - Certain other healthcare professionals may act as non-medical referrers under Trust procedures. These staff must be appropriately trained and authorised to refer by both the referring location and the department receiving the referrals. Non-medical referrers practice within an agreed protocol and extension of their core scope of practice. Typically, they may refer particular categories of patients for a limited range of examinations.

    - Referrers must provide:

        - Sufficient information to positively identify the patient being referred.

        - Sufficient clinical information to allow the Practitioner to Justify the request.

        - Other information relevant to the safe conduct of the examination.

        - Where practicable, the referrer must provide the patient with an explanation of the examination including risks and benefits.

    - Referrers typically:
        - Are UHDB employees, including Doctors in Training.
        - Or practice in Southern Derbyshire
        - Or practice in South East Staffordshire

- Other suitably qualified healthcare professionals may act as referrers upon application.

- All Referrers are registered in Trust / linked electronic systems. These records include the addresses of all locations from which they can make referrals.

- All Referrers registered in Trust / linked electronic systems are authorised referrers and requests for diagnostic radiographic / fluoroscopic or computerised tomography (CT) examinations may be accepted subject to Justification. In addition, a register of approved non-medical referrers is kept by the Imaging Compliance Team and is available to staff, including via QPulse.

- State registration numbers are used as unique identifiers in Trust IT systems. Checks on state registration will be made prior to adding referrers to Trust electronic systems.
    - For medical and dental staff these checks are made by the IT department.
    - For non-medical staff, the imaging compliance team administer the authorisation process, including checks on training and registration.

- Trust referrers will receive instruction in their role at induction and periodically thereafter.

- For a list of IRMER training requirements for Referrers see Appendix 3.

Operator

3. "Operator" means any person who carries out any practical aspect associated with the procedure of a medical exposure including those to whom practical aspects have been delegated.

- Operators must be adequately trained, please see schedule 3 of IRMER. Typically training will consist of:

    - Core academic / professional qualifications.
        - Qualified Radiographers included on the HCPC register are considered qualified to act as operator.
        - Radiologists with FRCR or equivalent will be considered qualified to act as operator.
        - Specialist Trainees in Radiology (Registrars) are considered qualified to act as operators after passing FRCR part 1. Prior to this they may undertake all aspects of the role under direct supervision providing they have completed training on the equipment.
    - Specific training on the role of the Operator and procedures which must be followed at University Hospitals of Derby and Burton.

    - Specific training in the safe use of any radiation equipment used as part of their role.

- Students are not authorised to act as Operators for medical exposures although they may undertake all aspects of the role under direct supervision providing they have completed training on the equipment.

- Certain other healthcare professionals may act as operators under Trust procedures. These staff must be appropriately trained and authorised to act as operator by both the location where exposures will occur and the department owning the equipment. Such operators practice with an agreed protocol and extension of their core scope of practice.

- Academic qualifications will be checked on appointment by the Human Resources or Medical Staffing Department as appropriate. State registration will be checked periodically, as part of Trust Human Resources processes and by Imaging Managers.

- Training records will be kept by the Business Unit. The individual operator should undertake relevant CPD and keep copies of their training records. See above for practitioner CPD.

- The Clinical Director of the Imaging Business Unit will entitle all operators, in writing, and provide a list of their duties. This process will be administered by the Imaging Compliance and Management Support Teams. Records will be kept in personal files / in QPulse.

- A register of Operators within the Imaging Business Unit is kept by the Imaging Management Support Team and is available to staff, including via QPulse. This is reviewed annually by:
    - Clinical Managers review the register of Operators
    - The Clinical Director reviews the register of Practitioners

- Medical Physics Experts (MPE's) are also operators under IRMER. The head of Radiation Physics of Nottingham University Hospitals NHS Trust can provide a list of MPE's and their training upon request. All MPE's are formally appointed according to the Radiation Safety Policy.

- For a list of IRMER training requirements for Operators see Appendix 3.

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

1. Enquiries regarding the pregnancy status of all individuals of childbearing capacity must be made prior to diagnostic radiographic, fluoroscopic or computerised tomography (CT) examinations of areas above the knee and below the diaphragm.

   Do not ask the patient if the criteria above are not met, e.g. CT head, dental x-rays, chest x-ray, knee x-ray, etc.

1.1 Exclusions:

The patient's pregnancy status may be disregarded in the following circumstances:

- Trauma in unconscious patient, or those otherwise without capacity, where it is not safe or appropriate to delay the examination; including during emergency surgery on patients who have not regained consciousness.
- Unexpected requirement for Imaging on sedated or anaesthetised patients: e.g. during surgical procedures when an instrument or swab is lost; or in the event of a surgical complication such as a perforated ureter.
- Where the Operator is requested to perform an examination on a sedated or anaesthetised patient whose pregnancy status has not been established by the referrer prior to sedation / anaesthesia; and it is not safe or appropriate to delay the examination. In such circumstances the Operator may proceed with the exposure but must report this as an incident on the Trust DATIX incident reporting system.
- In exceptional circumstances where there is a UHDB Personalised Care Plan in place for a patient the Operator may proceed for the specific imaging examinations listed in the Care Plan as Authorised by the Clinical Director, as Lead Practitioner, in the Care Plan. A reference to the specific Care Plan should be provided as part of the referral by the referrer when making the request to allow the Operator to Authorise the examination

2. Referrers must consider the possibility of pregnancy when assessing the requirement for examinations involving exposure of areas above the knee and below the diaphragm to ionising radiation; as pregnancy is highly relevant to both the Justification and conduct of the examination.

   a. Referrers should indicate on the request that there is no possibility of pregnancy if relevant e.g. Total Abdominal Hysterectomy etc.

   b. For patients who are known to be pregnant, Referrers must indicate why an examination involving exposure of the area above the knee and below the diaphragm is required during pregnancy. Such requests

must include the stage of gestation and confirm that the patient is willing to consent to the examination.

c. If the referrer is aware that the patient is a transgender man or gender non-conforming individual of child bearing potential aged between 12 and 55 years, they should inform the patient of the need to disclose any possibility of pregnancy and seek the patients consent to include relevant information in the referral.

    i. It is recognised that under the GRA 2004 this is protected information which cannot be disclosed without the patients consent. If the patient refuses consent to include relevant information in the referral the referrer must inform them that they will have sole responsibility for the protection of any fetus.

    ii. If the patient consents the patients childbearing capacity and / or pregnancy status, should be clearly indicated in the referral.

d. Where the referrer is unaware of the possibility of pregnancy due to the patient being an unidentified transgender man or gender non-conforming individual where the Patient has not consented to the information being shared the patient has sole responsibility for protection of the fetus.

e. When the patient will be sedated or anaesthetised during a procedure expected to involve radiation exposure to the abdomen, pelvis or upper femora in an individual of childbearing capacity it is the referrer's responsibility to check the possibility of pregnancy:
    - If the patient can exclude pregnancy this should be stated in the referral for Imaging.
    - If the patient cannot exclude pregnancy the referrer must arrange the examination date so that it will fall within 10 days of the start of a the patient's menstrual period. This should be stated in the referral.
    - Where the patient is pregnant, or cannot exclude pregnancy and it is not appropriate for the examination to be booked within 10 days of the start of the patient's menstrual period; the referrer must discuss the request with a Practitioner for Justification. Please see section 8c below.

3. Examinations by prior appointment.

When an examination is arranged by prior appointment efforts will be made to ensure that persons of childbearing capacity are aware of the need to avoid exposure to x-rays during pregnancy and ensure the patient does not attend inappropriately:

- Letters and patient information leaflets instruct the patient to contact the department if there is any possibility of pregnancy.

- Where appointments are made by telephone, patients meeting the criteria in section 4, below, are asked about possible pregnancy during the appointment booking process.

4. The operator initiating the exposure is ultimately responsible for ensuring that pregnancy status is / has been checked when:

   a. The referral indicates the patient is female and aged between 12 and 55 years; or outside this age range where a possibility of pregnancy is suspected by the operator or indicated in the referral.
   b. The referral indicates that the patient is a transgender man or gender non-conforming individual of child bearing potential aged between 12 and 55 years; or outside this age where a possibility of pregnancy is suspected by the operator or indicated in the referral.

   - Operators will not make routine enquires regarding pregnancy of patients who appear male unless the request indicates they are female or of childbearing potential. Where the Practitioner or Operator is unaware of the possibility of pregnancy due to the individual being a gender non-conforming individual, unidentified transgender man or transgender man who has not consented to this information being shared by the referrer; the patient has sole responsibility for protection of the fetus.

   - Operators cannot make meaningful enquiries regarding pregnancy of anaesthetised or sedated patients. The referral should indicate that the patient is not pregnant, the procedure is being performed within 10 days of the start of the patient's menstrual period or that the referral has been Justified by a named Radiologist. Any request not meeting these criteria should be reported as an incident on the Trust DATIX system. Where a patient is sedated or anaesthetised at the time of exposure the referrer has sole responsibility for the protection of the fetus.

   - When an examination has been justified in the knowledge that the patient is pregnant, Checks on Pregnancy status are not required, but the Operator must check that the patient has been provided with information about the risk from radiation to the fetus and consents to the examination. The examination may then proceed.

5. An explanation of the requirement for checking pregnancy status must be given to the patient before the check is made.

   E.g. '*Before we can perform your x-ray examination I am legally required to ask if you are, or may be, pregnant'*.

   If further explanation is required: '*The use of X-rays poses risks to fetus, including unlikely but significant risks such as developmental abnormalities'.*

6. Patients should be asked if they are, or may be pregnant.

This must be done in a way appropriate to the individual.

Examples of appropriate wording include:

- *'Is there any chance that you could be pregnant?'*
- *'Radiation may harm the unborn child, are you or could you be pregnant?*

This should be done in private, in the examination room where practicable; with care and sensitivity, as it may offend or embarrass some individuals.

- For examinations requiring 'preparation' such as abdominal and pelvic CT, the check on pregnancy should be made prior to starting the 'preparation'.

- Particular sensitivity is required when making pregnancy checks on children. The Operator needs to be particularly aware of patient confidentiality when children are accompanied by parents or guardians.
  - Younger children should be asked if they have started their menstrual periods. If no, this should be recorded on CRIS and the examination may proceed without further checks.
  - Older children will normally be willing to have their examination alone, so allowing a confidential check to be made.
  - Where a parent or guardian will be present, the Operator must explain that there is a legal requirement to make the check on all patients of child bearing capacity between 12 and 55 years of age prior to making the check on pregnancy.

7. The enquiry and response must be documented within the Imaging record in CRIS. The patient should be asked to sign the relevant section of the request card / examination record / sticker to confirm the enquiry has been made, and this should be scanned into CRIS.

Statement from CRIS printouts / stickers used for Hand written referrals:

Pregnancy Check – Examinations of the abdomen, pelvis, lower spine or hips in patients with child bearing capacity:

I understand that X-Rays should be avoided whenever possible during pregnancy. I confirm that to the best of my knowledge I am not pregnant and am not actively trying for a family.

Signature:

Date:

8. When patients are undergoing fertility treatment and have had embryo transfer, they should be regarded as being pregnant unless disproved by a pregnancy test at the interval set by the fertility treatment provider.

9. Actions following pregnancy check:

    a. If the patient indicates they are not pregnant, the examination may proceed. Operators and Practitioners may accept a negative result from a recent pregnancy test as confirming the patient is not pregnant unless they have reason to believe this is not the case. Please see section 9, below.

    b. If the Patient is definitely pregnant the examination must be discussed with a Practitioner for a Justification decision with due consideration of optimisation / reduction of dose. If a practitioner justifies exposure, they will act as the IRMER practitioner for the examination. The patient must be provided with risk information and their consent to the examination should be recorded.

    c. If the Patient cannot rule out pregnancy: <u>High dose examinations</u>.

        Where practicable, non-urgent examinations should be delayed until pregnancy can be ruled out, e.g. the patient starts a menstrual period.

        Where delaying the examination is not practicable and a recent pregnancy test result is not available, the Operator must check the date of the patients last menstrual period. If this is within 10 days, the examination may proceed. If this is more than 10 days or the patient is uncertain, the procedure for patients who are pregnant should be followed.

        High Dose Procedures are:
        - Any fluoroscopy of the abdomen and pelvis including
            - Fluoroscopy or Angiography with a mobile image intensifier in theatre
            - Fluoroscopy during endoscopic procedures
            - Fluoroscopy during spinal / pain treatments or surgery
            - Barium / Contrast Follow Through
            - Barium / Contrast Enema
            - Herniography
        - Abdominal or Pelvic CT
        - Abdominal or Pelvic Interventional Radiology Procedures

    d. If the Patient cannot rule out pregnancy: <u>Low dose examinations.</u>

        Where practicable, non-urgent examinations should be delayed until pregnancy can be ruled out, e.g. the patient starts a menstrual period.

Where delaying the examination is not practicable, the Operator must check if the patient's menstrual cycle is regular and their period is not overdue. If the patient's period is overdue or the patient is uncertain, the procedure for patients who are pregnant should be followed.

Examinations not listed as high dose, in section c, above, are considered low dose.

e. 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. Ideally this will be a trained medical interpreter provided by the Trust, but Trust policy allows the use of others in certain circumstances. Please see Trust Policy and Procedures for Chaperoning.

The use of an interpreter, including if this is a Trust or informal interpreter must be documented on CRIS.

f. It is the referrer's responsibility identify that a patient they are referring for does not have capacity and so is unable to confirm their pregnancy status, or consent to the examination. The referral for such patients must mention their lack of capacity and the arrangements the referrer has put in place to allow the examination to proceed, e.g. arranging a pregnancy test.

If the referral does not identify that the patient lacks capacity, but the Radiographer feels the patient does not have the capacity to consent to the examination, including confirming their pregnancy status; the examination may not proceed and the referral should be returned to the referrer.

10. If the examination is delayed due to the patients pregnancy status, or the patient declines the examination, the Operator must inform the Referrer and this this documented on CRIS.

- When a non-urgent examination is postponed until after the patient's pregnancy status has been established the patient must be informed of the arrangements for rebooking the examination. In most cases this will involve the patient contacting the relevant department to rearrange their examination when their pregnancy status has been clarified, e.g. by the start of a menstrual period.

- Pregnancy testing.
    - Pregnancy tests are not 100% accurate in excluding early pregnancy.
    - The Imaging department does not provide or undertake pregnancy tests.
    - Operators and Practitioners will utilise the results of pregnancy tests performed in other areas of the Trust or elsewhere.

11. In addition to the above procedures, departments where diagnostic radiographic / fluoroscopic or computerised tomography (CT) examinations are performed must

take measures to raise the awareness of the effects of ionising radiation with individuals capable of childbearing or breastfeeding. Within the Imaging Business Unit, these must include:

a. Posters informing persons of child bearing potential that they must inform the Operator if they are, or may be, pregnant.
b. Written information on the risks and benefits of imaging examinations provided to all patients upon attendance. This includes the risks of radiation exposure in pregnancy.
c. Procedure specific information leaflets sent to patients with appointment letters and available to others on the internet. These include the risks of radiation exposure in pregnancy.

Protocol Steps - Summary

Examinations arranged by appointment

A procedure to ensure pregnancy is identified prior to attendance:

Letters and Patient information leaflets instruct the patient to contact the department if there is any possibility of pregnancy.

Where appointments are made by telephone the patient should be asked during the booking process.

Examinations not requiring an appointment

It is not possible to check for pregnancy prior to the patient attending the Imaging department

Pre-examination check

The check should be performed in an appropriate location, to ensure that the Patient's privacy is maintained and that they feel able to disclose a possible pregnancy.

The risk of radiation during pregnancy should be explained to all patients identified as having child bearing potential.

Non–emergency Examination

Low dose procedures:

- If the patient's period is not overdue, the examination may proceed.
- If the patient's period is overdue, or their periods are not regular, follow the procedure for patients "definitely or probably pregnant".

High dose procedures:

- If the procedure date is within 10 days of the start of the patient's menstrual period the examination may proceed.
- If the procedure date is more than 10 days since the start of the patient's menstrual period, follow the procedure for patients "definitely or probably pregnant".

Patient indicates they are pregnant or they may be pregnant.

Patient should be asked for the date of the first day of their last menstrual period (LMP)

Patient indicates they are not pregnant

Emergency Examination

Examination is covered by exclusion in the employer's procedure and a pregnancy check is not required

Patient signs declaration and this is scanned into CRIS

Request passed to a Practitioner for Justification

Will decide if request can proceed (and provide an appropriate examination protocol) or should be delayed or cancelled.

Outcome of Justification recorded in CRIS

Request Justified

Patient informed of risks and is happy to proceed

Examination Proceeds

Patient informed of risks and is not happy to proceed

Examination does not Proceed
Referrer informed
Documented in CRIS

Request not Justified

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

1. All procedure and protocol documents relating to the use of ionising radiation must be approved by the Trust via the process set out in the Trust Radiation Safety Policy.

   All Imaging procedure and protocol documents will be managed on the Business Unit's QPulse system. This includes. Schedule 2 IRMER procedures, Referral guidelines, authorisation guidelines, examination protocols, exposure charts.

   This will include:
   a. Annual review by key stakeholders including:
      - The relevant Medical Physics Expert (MPE)
      - Clinical Manager(s)
      - Representatives of staff groups following the procedure, E.g. Consultants, Radiographers, Technologists, Assistant Practitioner, Nurses etc.

2. Documents and procedures will be amended as necessary following significant changes to practice or national guidance, independently of the annual review programme.

3. Documents will be distributed to imaging staff electronically via the QPulse system.
   - Key staff will be identified as reviewers.
   - Where a document is directly relevant to their practice, staff will be designated as copyholders, receive a copy via the system and required to electronically sign (acknowledge) the document.
   - Other staff will have access to documents via the QPulse system and will be notified of changes to relevant documents via the system.

4. The Imaging Compliance Team undertake audit of compliance with procedural documents, including employers procedures, as part of the departments Quality Management System.

   Audits of employer's procedures will be undertaken at least once per year. The results of these audits will be reported to the Imaging PQRS meeting with exception reporting to the Trust Radiation Protection Group.

   Clinical Managers and Heads of Service are responsible for addressing non-compliance by non-medical staff.

   The Clinical Director and Assistant Clinical Director for Governance are responsible for addressing non-compliance by medical staff.

5. The Medical Physics Expert will also independently audit compliance with policies and procedures annually.

6. Equipment QA programmes will be reviewed periodically in line with national guidance and are the responsibility of the Clinical Manager / Head of Service. This review must include consultation with the MPE and covers the following:
    - The QA protocols, including the review / setting of appropriate remedial and suspension levels. These must be in line with IPEM guidance (Report 91) or lower:
        - Typical remedial levels are baseline +/- 20%
        - Typical suspension levels are baseline +/- 50%
    - Handover process (modified AXREM)
    - Keeping QA records
    - Calibration of QA instruments and records
    - Staff training (in QA and handover),
    - A check on the accuracy of the records of their equipment on the Imaging Business Unit equipment inventory
    - Equipment Maintenance
    - Patient dose monitoring and records

    Responsible Clinical Managers / Head of Service:
    - Donna Leary – CT
    - Mark Prince – Plain Film / Fluoroscopy / Interventional Radiology at Derby Sites
    - Adam Bowes - Plain Film / Fluoroscopy / Interventional Radiology at Burton Sites
    - Lee Chlechowicz - Plain Film at Community Sites
    - Ruth Green – Breast Imaging
    - Dudley Ibbett – Nuclear Medicine

7. Management of Equipment QA:
    - QA Schedules are issued and audited annually by the Imaging Compliance Team (with advice from the MPE).
    - The person conducting the level A QA test is responsible for ensuring that test results are documented appropriately and that any result outside of remedial or action levels are escalated to the Superintendent or Clinical manager as appropriate.
    - Superintendent Radiographers are responsible for ensuring Level A tests are done on schedule and when necessary following maintenance work; ensuring that the results are evaluated and that any action necessary is taken, including removing equipment from clinical use where appropriate.
    - Clinical Managers are responsible for ensuring that Medical Physics Testing (commissioning, acceptance testing, critical examination and post maintenance testing) are performed when required; and Level B tests are performed on schedule. Clinical Managers are responsible for ensuring that there is appropriate handover of equipment from / to Trust employees and for the oversight of both Level A and Level B tests including the completion of any action required

e. Employer's procedure for the assessment of patient dose

1. The following methods of recording dose recording must be used by the operator making the exposure for each patient examination.

    - Plain film radiography – Dose Area Product (DAP).
    - For dental radiography – Dose Area Product (DAP) where available; or exposure factors (kVp and mAS)
        E.g. Dental Equipment in:
        RDH Emergency Department X-ray records DAP
        Kings Treatment X-ray department does not and Operators must record kVp and mAS

    - Fluoroscopy – Dose Area Product (DAP) and 'screening' time.

    - CT - Dose Length Product (DLP)

- Interventional – Dose Area Product (DAP), 'screening' time and Air Kerma.

These factors must be recorded by the operator making the exposure for all examinations.

Dose may also be recorded by the radiation equipment via DICOM and transferred to PACS and Dosewatch.

The Operator must ensure that the dose is recorded on CRIS and Dosewatch (usually sent automatically). Where equipment requires information to be sent to Dosewatch manually, Operators must be made aware.

If a patients dose is much higher or lower than expected for the patient size or procedure this must be reported by the person making the exposure to the Superintendent / senior Radiographer on duty in the area or Radiation Protection Supervisor. If it is thought that there has been an accidental or unintended exposure this should be reported via DATIX and the MPE informed.

2. Calibration of equipment.

    - Dose measurement features e.g. DAP, DLP etc., must be calibrated equipment by an approved member of the medical physics staff.

    - Calibration must be done after installation of new equipment and where appropriate on an annual basis subsequently. Re-calibration may also be required following major repairs or replacements of equipment. Please see the handover procedure for details.

f. Procedure for the use and review of Diagnostic Reference Levels (DRLs)

'Diagnostic Reference Levels' are typical levels of does received by standard sized patients undergoing a specific examination on a broadly defined type of diagnostic radiology equipment.

1. Local Diagnostic Reference Levels will be established as follows:
    - Local Diagnostic Reference Levels (LDRL's) will be calculated from patient dose records collected automatically via the dosewatch system.
    - These will be benchmarked against any national DRL available and local DRL's from other Trusts, where available.
    - They will be agreed at the relevant medical exposure committee (MEC) following consideration of any national DRL and with advice from the relevant MPE. LDRL's will be ratified by the Imaging PQRS Committee and signed off by the Clinical Director and General Manager.
    - LDRL's are distributed to Operators via Imaging's QPulse system.
    - LDRL's are displayed in each examination room and are available to staff via Imaging's QPulse system.

2. The Clinical Manager for each area of service will ensure that a dose audit, comparing patient doses to the LDRLs, is conducted for each room / piece of radiation equipment at intervals of no more than 3 years.
        - The advice of the MPE must be sought on dose assessment and audit outcomes.
        - Audits of Paediatrics doses must be conducted.
        - Records of dose audits will be kept by the Compliance Team on QPulse.

3. If Dose audit demonstrates a LDRL or NDRL is consistently exceeded, this will be reviewed by the MEC who will recommend action to the Clinical Manager, General Manager and Clinical Director.
    - National DRL's are issued via the government website: https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl

4. Upon completing an examination, Operators need to decide if the dose is higher or lower than they would expect for a patient of this size.

    If the patients dose is above a DRL and this is consistent with the patient size or procedure then no action should be taken. Where no reason for this is readily identifiable, this should be regarded as an incident and investigated.

g. Procedure for the exposure of individuals participating in medical research programmes

1. All requests to undertake research studies received by the Imaging Business Unit will be passed to the appropriate MPE for review; and will not be accepted until advice that they meet regulatory requirements is received.

2. All research studies must be approved via the Trust research ethics process.

3. All research studies must have a written examination protocol. A list of all current research programmes satisfying these conditions are held in an electronic database as part of the Trust Research Management System.

4. 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 and documented in the research protocol.

5. Target doses for individuals undergoing experimental procedures will be consistent with the relevant DRL given in the relevant routine study protocol. The risks associated with the exposure should be established after consultation between the Practitioner, the relevant Radiation Protection Adviser and Medical Physics Expert

6. 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.

7. Research studies should be identified as such on the request. Any such request must be made by a doctor or authorised non-medical referrer. Requests must meet the normally expected standards to allow justification, as well as any containing any additional information to allow the request to be performed in accordance with the relevant research protocol

8. In most cases, patients participating in research studies are referred for Imaging as part of the normal care pathway for their condition. In such cases referrals are justified and performed on the basis of the clinical indications for the examination. However:
    - Examination protocols may vary from those normally used, in line with the relevant research protocol.
    - The timing of examination appointments will be adjusted to comply with the relevant research protocol.

9. Where examinations are requested for research studies which are not part of ‘normal care’:

- Requests will be directed to the Clinical Trials Radiographer or Consultant acting as Practitioner at UHDB for the research.
- The Practitioner will Justify the examination; determine the scan protocol required and when the examination should be performed.
- The Clinical Trials Radiographer will liaise with the Trial Coordinator and Imaging Appointments Team to ensure the examination is performed appropriately.

i. Employers procedure to ensure that, wherever practicable and prior to exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure.

The Trust takes a graduated approach to providing patients with information on the risks associated with exposure to ionising radiation as part of diagnostic Imaging.

1. There are three main steps in the medical exposure process where information on the risks and benefits can be provided:

1.1 Referral
When making referrals for examinations involving their patient being exposed to ionising radiation Referrers must be mindful of the following:

- They have a responsibility to discuss the risks and benefits of all proposed examinations and treatments with their patients in order to allow them to make informed decisions regarding their care.
- They are best placed to discuss alternatives to proposed examinations, including those not involving the use of ionising radiation and the option of not having any diagnostic tests, with patients.
- Exposure to ionising radiation represents a material risk to patients, which referrers should discuss with them when appropriate.

It is recognised that this is not practicable in all circumstances. However it is expected that, where appropriate, the referrer will discuss the risks of the radiation exposure with patients in the following circumstances:

- All GP and primary care requests
- All inpatient and ED requests
- All outpatient requests except those made prior to the patient's initial clinic attendance.

The Clinical Director of the Imaging Business Unit Group will periodically write to referrers reminding them of these responsibilities.

1.2 When examinations are arranged by appointment:

When an examination is arranged by appointment, patients are:

- Sent / given an examination specific patient information leaflet, which includes the risks and benefits, enclosed with their appointment letter.
- Informed that such a leaflet is available on the Trust's website when an appointment is arranged verbally by telephone.

1.3 When the patient attends for examination

- For low dose examinations, such as plain film X-Ray examinations, dental examinations and Bone Densitometry, this will be via written information.

- Posters displayed in waiting areas providing information on the risks of X-ray examinations, that these are outweighed by the benefit from the information obtained and that all requests are checked to ensure this is the case.
- Leaflets including information on the risks and benefits of the exposure to Radiation are available to patients in waiting areas.

- For medium dose examinations, such as diagnostic fluoroscopy and CT scans, this will be via:
  - Posters displayed in waiting areas providing information on the risks of X-ray examinations, that these are outweighed by the benefit from the information obtained and that all requests are checked to ensure this is the case.
  - Leaflets including information on the risks and benefits of the exposure to Radiation are available to patients in waiting areas.
  - As part of their explanation of the examination to the patient, Operators will enquire if they have any questions on the risks and benefits. Such enquires may be omitted when inappropriate, e.g. CT scans following suspected stroke, major trauma, etc.

- For high dose examinations, such as interventional procedures, the referrer and / or Practitioner will discuss the risk with the patient, where appropriate.

  Where formal; documented consent is required for a procedure; the risk from ionising radiation will be included in the documented discussion of risks from the procedure recorded on the consent form and will be checked by the Practitioner during part 2 of the consent process.

2. Superintendent Radiographers must ensure that appropriate posters are displayed in their area, that appropriate supplies of leaflets are available in their area, and that the processes associated with these are followed.

3. Written information will be translated into other languages upon request. This may be via the provision of written information in the desired language, or a verbal translation provided by the Trust's interpreter service in person or on the telephone.

4. When patients are unconscious, or lack capacity, information on the risks and benefits of the examination will be provided to any accompanying relative, or carer acting as their representative, by the means described in section 1, above. When unaccompanied it is not practicable to provide such information.

5. When the patient is a child the information will be provided to the child and / or their accompanying parent / guardian by the methods described above:
   - Information will be provided to older children and any accompanying parent or guardian using age appropriate language.
   - Information will be provided to the parents or guardians of young children via the means described above. It is not practicable to provide information

on risks and benefits to small children who are not accompanied by a parent or guardian.

6. Where the patient is unsure of the benefit of exposure to radiation:
    - The Operator should provide further information:
        - Explaining that the risks from diagnostic exposure to radiation are small compared to the benefits and to other common risks.
        - Explaining that the referrer has made the request for the examination after considering the risks and benefits to the patient and that the information will help the clinical team provide the patient with the best care and treatment.
        - Explaining that the request has been reviewed by the Imaging Department who agree that the benefits outweigh the risks

    - If the patient still does not wish to proceed with the examination due to concerns over the risk, the Operator should:
        - In hours, the Operator should discuss this with a Practitioner, who will either speak to the patient or decide that the examination will be cancelled and arrange for the referrer to be informed that the patient has declined to be examined due to concerns over the risk from Radiation
            - Where an examination is cancelled because the patient has declined to be examined due to concerns over the risk from Radiation, the referrer must be informed and the reason for the cancellation recorded on CRIS
        - Out of hours, the Operator should postpone the examination, inform the referrer and document this on CRIS.

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 healthcare record:

1. All diagnostic radiographic / fluoroscopic or computerised tomography (CT) examinations will have a clinical evaluation by an Operator designated to carry out this function.

    - In most cases this will take the form of an Imaging report issued by a Radiologist or reporting Radiographer. This is stored in CRIS and transferred to other electronic systems including PACS, Trust Patient management systems and external systems in primary care.
    - In some cases the Imaging report will be provided via a teleradiology service. In all cases when such services are used:
        - The staff issuing the reports is a fully qualified Radiologists on the GMC specialist register.
        - The staff issuing reports on behalf of UHDB are individually selected by the Imaging BU Clinical Director.
        - A defined proportion of reports are audited for accuracy.
        - A process for the communication of reports is in place including mechanisms for referrers to discuss findings and for the escalation of Critical Urgent and Significant Unexpected findings.

    - In other cases the responsibility to provide a documented evaluation has been transferred to the referrer. Examinations where the documented evaluation will not be provided by the Imaging Business Unit:
        - Are documented in the 'Reporting Agreement' which indicates who is responsible for providing the evaluation.
        - Will be auto-reported on CRIS. This auto report will indicate who will provide the report and where in the patient's healthcare record it can be found.

2. The Imaging Business Unit has audit systems in place within CRIS to ensure that all examinations are reported either as:
    - A report containing a clinical evaluation of the images resulting from exposure to ionising radiation during diagnostic radiographic / fluoroscopic or computerised tomography (CT) examinations.
    - An auto-report indicating who will provide a clinical evaluation of the images and where this can be found, if not in the notes.
    - KPI's for reporting turnaround times ae set by the Business Unit and monitored via the weekly Imaging Waiting list meeting utilising a Qlickview dashboard updated twice daily. Where these are not met, arrangements to address any backlog are put in place on a weekly basis. These include:
        - Outsourcing reporting to teleradiology companies

- Insourcing arrangements with Imaging department to undertake additional reporting activity
- The planning of reporters working patterns to address existing backlogs or those anticipated based on the examinations booked in the coming week.
- Imaging trackers are in post to ensure that examinations are appropriately prioritised for reporting based on referral type and factors such as when the result is required for outpatient clinics.

3. The Trust Radiation Protection Group audits compliance with the Reporting Agreement. A sample of examinations covered by the reporting agreement is selected for each area responsible for the clinical evaluation of Images. These are distributed to the relevant Business Units who must confirm that a clinical evaluation is present in the patient's healthcare record.

4. A record of the dose-area product (DAP) reading is recorded on CRIS by the Operator. Where the DAP is not available, the exposure factors (cumulative mAs and highest kVp) must be recorded.

k. Employers procedure to ensure the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable

Procedures to reduce the probability and magnitude of accidental or unintended exposures are made up of a number of elements:

- Procedures are in place for the management and quality assurance testing of equipment to ensure that it is functioning correctly and any issues which might contribute to accidental or unintended exposure are identified and addressed as soon as is practicable.

- Risk assessments are conducted, as required by IRR, for every type of examination in every location in which it is performed.

- Procedures are in place to ensure the safe and appropriate conduct of examinations including checks on the identity of the person attending for examination, the examination to be performed and its timing.

- Operators are trained on the safe use of the equipment they use and in the appropriate conduct of the examinations they perform.

- All incidents involving ionising radiation, including near misses, must be reported in accordance with the Trust policy for Incident Reporting, Analysis, Investigation and Learning.

- Learning from incident investigations is shared within the Imaging Team and with others when appropriate.

Procedure:

1. Operators and Practitioners are trained to undertake safely all aspects of a medical exposure. This training includes radiation protection, and the correct use of equipment.

2. Procedures for the safe use of ionising radiation in diagnostic radiographic / fluoroscopic or computerised tomography (CT) examinations are in place. Operators and Practitioners receive training in these to ensure they are aware of all relevant procedures and protocols and will follow these.

3. The Imaging Compliance team audit compliance with these procedures to ensure they are followed.

4. While the observance of the framework of IRMER procedures and protocols is intended to ensure that patient exposure is kept to the minimum consistent with the intended diagnostic outcome, errors resulting in accidental exposure may occur. In order to minimise the likelihood of such errors, Operators make checks with the patient to establish, as far as is practicable that the necessary and correct examination is being performed at the correct time.

The required checks are outlined in the Imaging Business Units PATIENTCheck protocol (Appendix 1). When the Operator identifies a significant discrepancy between the referral and the information provided by the patient; this must be resolved before the examination can proceed. This might be by contacting the referrer, referring team, or referring location for clarification; or clarification from the patient's healthcare record.

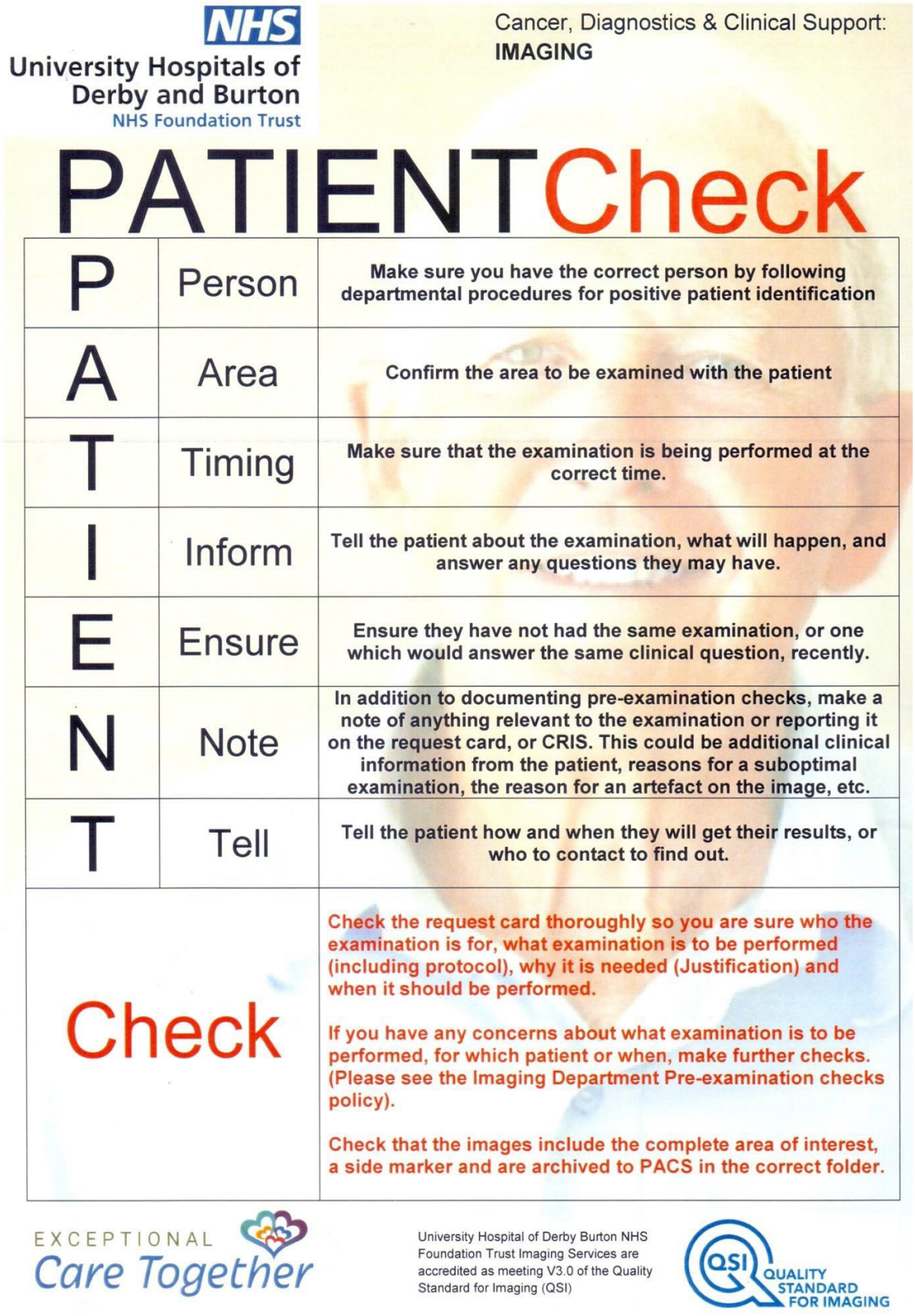
It is acknowledged that these checks are incomplete control measures and will not prevent all errors.

5. Staff must report accidental exposures, unintended exposures and any dose significantly higher than the DRL without obvious cause as an incident, in line with the Trust incident reporting policy. Such reports should include
    - All relevant details required to facilitate investigation of the incident; e.g. the staff and equipment involved etc.

6. When it is identified that the patient has received an accidental exposure, unintended exposure or a dose significantly higher than the DRL without obvious cause, the patient, practitioner and referrer should be informed. Please see Employers Procedure l and the Trust Policy and Procedures for Incident Reporting.

7. Actions or learning identified from the investigation of incidents involving unintended exposures and any dose significantly higher than the DRL without obvious cause will be shared to relevant staff within the Imaging Business Unit and to the wider Trust via the Radiation Protection Group.

Appendix 1 – Patient Check Poster (Operator)



I. 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

1. Where a radiation Incident occurs staff must report the incident on DATIX, in line with the Trust incident reporting policy and ensuring that they have recorded the data required to facilitate investigation.

2. The incident will be reviewed by:
    - The Clinical Manager for the modality concerned, or the Superintendent Radiographer for the department where the incident occurred acting on behalf of the Clinical Manager.
    - The Imaging Compliance Team who will:
        - Manage the incident report within DATIX.
        - Send details of the incident report to a Medical Physics Expert.
        - Request:
            - A dose report from the MPE where relevant
            - Advice regarding the external reporting of the incident.
        - When an incident is considered externally reportable, the Imaging Compliance Team will:
            - Conduct an initial investigation to establish the root cause.
                - If this is within another Business Unit, for example a referral error, then the investigation will be passed to them.
                - If the root cause is within Imaging, the compliance team will:
                    - Ensure that the required report is made promptly and escalated, via the Divisional Governance Team, to the Trust.
                    - Manage the investigation and production of an appropriate report via the Trust process for Higher Level Incidents.
                    - Ensure the Trust 3 stage duty of candour process is followed.
                    - Ensure that the Operator, and other staff involved, complete a reflective statement detailing the nature of the incident and what learning has taken place to reduce the likelihood of future incidents.

3. The MPE must give advice on the dosimetry.

The exposure will be defined as clinically significant if:

- The risk to the patient or fetus of radiation induced cancer is 1 in 1000 or greater. For patients with reduced life expectancy this should be taken into account when calculating the risk.
- The dose is 0.5Gy to the lens of the eye, heart or brain.

- 5Gy to the skin including backscatter e.g. erythema for more than two weeks.
- If the patient suffers physiological harm as a result of being informed of the exposure where it affects the quality of life to a level which requires intervention or treatment.

If the patient has received a clinically significant accidental or unintended exposure to ionising radiation the Imaging Governance Team will ensure that the Referrer, Practitioner and patient or their representative are informed of the incident, as per the Trust Incident Investigation Policy.

Where the referrer is not the Lead Clinician (consultant or GP) they will also be informed by the Imaging Governance Team

4. When the MPE advises that an incident meets the criteria for reporting to the Care Quality Commission as a Breach of IRMER, the Clinical Manager for Compliance, or Superintendent Radiographer for Ionising Radiation Protection will make the report to the CQC on behalf of the Imaging Business Unit, following the timescales as set out by the CQC.

   Details of the investigation will be recorded on Datix, as per the Trust Incident Reporting Policy.

5. Reports of incidents involving additional exposure to ionising radiation, including accidental and unintended exposures, are reviewed at the Imaging Business Unit Patient Experience, Quality, Risk and Safety (PQRS) meeting. Trust oversight of such incidents includes via the Radiation Protection Group. Any issues may then be further escalated by this group as appropriate. The results of the investigation will be shared with relevant staff based on the actions included on the incident action plan.

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

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

2. The request must specify the purpose of the examination so that the Practitioner can identify that this is a non-medical examination.

3. Non-medical exposures will only be carried out following Justification by an IRMER Practitioner who will provide the imaging protocol to be followed.

4. In some cases requests for non-medical exposures may come from referrers outside of the medical and authorised non-medical staff who make medical referrals. For example, requests for medico-legal examinations relating to injury claims may come from solicitors. In this case the radiologist reviewing the letter or request will act as the referrer and should request the examination using the normal referral process. The radiologist should then also justify the exposure.

5. If the Consultant Radiologist 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. Non-medical exposures include:
    - Medico-legal imaging which will be authorised by a Consultant Radiologist.
    - Imaging required for emigration or professional purposes; 'Category 2' Imaging, which will be authorised by a Consultant Radiologist.
    - Imaging conducted for the investigation of suspected physical abuse in children.
        - Initial imaging of injured / symptomatic body areas is considered 'medical' and justified / authorised under the relevant employer's procedures.
        - The imaging of other areas during a 'skeletal survey' is non-medical and is conducted according to the protocol in place for such examinations.
        - Follow-up / delayed imaging conducted as part of a skeletal survey is non-medical and is conducted according to the protocol in place for such examinations.
        - The imaging of siblings is non-medical and is conducted according to the protocol in place for such examinations.

7. Examinations not considered non-medical include:
    - Abdominal examinations of drug mules who may have ingested or inserted packages of drugs into body cavities. Such Imaging will only

be undertaken when there is clinical concern regarding the patient's condition.

- Chest X-rays performed on asymptomatic patients who have been in contact with someone proven to have Tuberculosis.

These examinations are considered to have health benefits to the individual exposed and are justified / authorised as medical exposures.

8. All non-medical imaging procedures must be reported by a Consultant Radiologist. Where coincidental findings are noted that require medical attention, the Consultant Radiologist is responsible for ensuring the finding is appropriately communicated to relevant medical staff.

n. Employer's Procedure to establish appropriate dose constraints and guidance for the exposure of Carers and Comforters.

Carers and Comforters means adult 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 medical exposure. If a person is not knowingly exposed they should be treated as a member of the public and the public dose limit of 1mSv must be applied.

Scope

All carers and comforters exposures.

Procedure

1.0 People accompanying patients undergoing diagnostic radiological examinations are categorised as Carers and Comforters should receive a dose of less than 0.3mSv (Appendix 2) provided:

- For all **general radiographic and dental** x-ray procedures they follow the radiographers' instructions, wear at least 0.25mm lead equivalent PPE, and remain at a distance of 25cm from the centre of scatter.
- For **fluoroscopic** procedures from scattered radiation, provided they follow the radiographers' instructions, wear at least 0.35mm lead equivalent PPE, and remain at a distance of 1m from the centre of scatter.
- For **CT** procedures at 120kV they are likely to receive a dose of less than 0.3mSv from scattered radiation, provided they follow the radiographers' instructions, wear at least 0.35mm lead equivalent PPE and remain at a distance of 50cm from the centre of scatter.

When the conditions are met the dose constraint will be 0.3mSv.

1.1 Should it not be possible for these conditions to be met a medical physics expert should be contacted for a dose assessment.

1.2 If the person accompanying the patient is likely to attend multiple procedures over the course of a year, Medical Physics should be contacted to advise whether it is possible they will receive a cumulative dose of 0.3mSv as a result however procedures must not be delayed.

1.3 The Clinical Director of the Imaging Business Unit justifies all exposures of any Comforters and Carers in accordance with this procedure (as detailed in the department authorisation guidelines) and where the operator decides that their participation in the medical exposure is required. The radiographer will therefore be authorising the exposure to the comforter and carer.

1.4 The Radiographer shall provide the dose and risk information from Medical Physics to the Carer and Comforter. The Carer and Comforter shall have the opportunity to discuss this information with the Radiographer and can receive supplementary advice from Medical Physics if necessary. These discussions will be recorded on the departmental form for this purpose and scanned into CRIS.

1.5 The Radiographer shall provide the Comforters and Carers Record Sheet to the Carer or Comforter who must read, complete and sign the form. The Radiographer should also complete the applicable sections of the form. This should then be scanned into the patients' examination record on CRIS.

Appendix 2: Doses for people accompanying patients undergoing radiological procedures

Doses are calculated based on typical exposure parameters: tube voltages as given in HPA-CRCE-034 *Doses to Patients from Radiographic and Fluoroscopic X-Ray Imaging Procedures in the UK – 2010 Review* – Hart et al, and dose area products (DAPs) as given in *National Diagnostic Reference Levels (NDRLs): 15 November 2018 onwards*. Scatter and shielding transmission factors were calculated using *Radiation shielding for diagnostic radiology* - Sutton et al.

Radiograph	Dose at 0.25m with 0.25mm Pb shielding (mSv)	Dose at 0.5m with 0.25mm Pb shielding (mSv)
Chest AP	<0.001	<0.001
Chest PA	<0.001	<0.001
Abdomen AP	0.010	0.003
L spine AP	0.007	0.002
L spine LAT	0.017	0.004
Pelvis AP	0.009	0.002
T spine AP	0.004	0.001
T spine LAT	0.006	0.002
C spine AP	<0.001	<0.001
C spine LAT	<0.001	<0.001

Fluoroscopic procedure	Dose at 1m with 0.25mm Pb shielding (mSv)	Dose at 1m with 0.35mm Pb shielding (mSv)
Abdomen	0.001	0.001
Barium (or water soluble) enema	0.009	0.005
Barium small bowel enema	0.008	0.005
Barium follow through	0.003	0.002
Barium meal	0.005	0.003

Barium meal and swallow	0.003	0.002
Barium (or water soluble) swallow	0.002	0.001
Barium swallow (video)	0.001	<0.001
Chest	<0.001	<0.001
Coronary angiography	0.006	0.003
Coronary graft angiography	0.008	0.004
Femoral angiography	0.011	0.006
Fistulography	0.002	0.001
Hysterosalpingography	<0.001	<0.001
Intravenous Urography	0.003	0.001
Lumbar spine	0.002	0.001
Micturating Cystourethrography	0.003	0.002
Nephrostography	0.003	0.002
Proctography	0.007	0.004
Sialography	0.001	<0.001
Sinography	0.002	0.001
T-tube cholangiography	0.001	0.001

Dental radiograph	Dose at 0.25m with no shielding (mSv)	Dose at 0.5m with no shielding (mSv)
Dental Panoramic (adult)	0.007	0.002
Dental Panoramic (child)	0.005	0.001

CT procedure	Dose from 120kV scan at 0.5m with 0.25mm Pb shielding (mSv)	Dose from 120kV scan at 0.5m with 0.35mm Pb shielding (mSv)
Head	0.101	0.066
Chest	0.163	0.106
Abdomen	0.244	0.159
Abdomen/pelvis	0.199	0.130
Chest/abdomen/pelvis	0.268	0.174

Appendix 3: IR(ME)R17 Training Requirements

Training Element	Application	Induction	Update Frequency	Delivery Method and Assessment
Referrers training	All UHDB Referrers	Yes	3 yearly	Online presentation
Referrers Information	All Referrers	Yes	Yearly	Letter and instructions
Non-Medical Referrer IRMER Training	Non-Medical Referrers	No	Maximum 5 Yearly	Online Presentation
Practitioner Theory *	All Practitioners	Yes	Once	FRCR / E-Learning / IRMER Course
Practitioners IRMER Procedures	All Practitioners	Yes	3 Yearly	Local training session
Operator Theory *	All Operators	Yes	Once	Radiology Degree / E-Learning / IRMER Course
Operator IRMER Procedures	All Operators	Yes	3 Yearly	Local training session
Operator Equipment / Procedures Training	All Operators	Yes	Once – and following major changes to equipment. Annual assessment of competence	Local training and assessment
Medical Physics Expert (MPE)	All Appointed MPE's	N/A	5 Yearly	Certificate. QPulse for UHDB employees. Held by applicable Medical Physics provider (available on request).
Continued Professional Development (CPD) *	Operators and Practitioners Only	No	Annually	Reviewed annually at appraisal. Record of CPD recorded on QPulse

* For agency staff: As part of the applicable Cooperation of Employers agreement, any staff provided must be appropriately qualified and fully trained to carry out their designated role. All training records are held by the respective agency and should be produced on request.