University Hospitals of Derby and Burton
NHS Foundation Trust

SPECIALIST MEDICINE BUSINESS UNIT

Cardiology Department Protocol: Employers Procedures for Interventional Cardiology under Fluoroscopic control

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 radiographic / fluoroscopic examinations.

<table>
<tr><td>Reference Number:

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Dr Nauman Ahmed

Job Title: Assistant Clinical Director: Cardiology</td></tr>
<tr><td rowspan="4">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author & Role</td><td>Reason</td></tr>
<tr><td>1.0</td><td>April 2020`</td><td>Mike Barnard Clinical Manager – Compliance</td><td>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.</td></tr>
<tr><td>1.1</td><td>May 2020</td><td>Mike Barnard Clinical Manager – Compliance</td><td>To reflect new Trust policy regarding the communication of Radiation Risks to patients</td></tr>
<tr><td>1.2</td><td>June 2020</td><td>Charlotte Haynes-Walker – Cardiac Catheter Suite Manager</td><td>To make the document cardiology specific</td></tr>
<tr><td colspan="3">Intended Recipients – Essential to Role

Cardiologists, Radiographers and other staff designated as Practitioner or Operator for these examinations.</td><td colspan="2">Intended Recipients – For Awareness / Reference

Other Cardiac Catheter Suite staff and Cardiology staff working within the Cardiac Catheter Suite

All Trust and external staff designated as referrers for these examinations</td></tr>
<tr><td colspan="3">Communication:

The document will be distributed to all Cardiologists, Radiographers and other staff</td><td colspan="2">Training:</td></tr>
</table>

designated as Practitioner or Operator for these examinations. These staff are required to acknowledge that they have received, understood and will comply with the document.	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 Assessment** **Stage 1:** completed **Stage 2:** N/A
Approving Group: Cardiology Radiation Group Meeting	
Authorising Group: Trust Radiation Protection Committee	

Approving SMBU Manager	Richard Doane (SMBU General Manager)	
Approving SMBU Senior Manager	Dr Nauman Ahmed (Assistant Clinical Director: Cardiology)	
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1. Introduction

All Cardiology staff undertaking Interventional Cardiology procedures **must** comply with these procedures.
The Ionising Radiation (Medical Exposures) Regulations 2017 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 a quality assurance programmes are required under IRMER.

2. Purpose

To set out procedures Cardiology 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. There is also a Governance structure specific to cardiology which shows how the various meetings feed into one another. (Appendix 1)

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 the Trust Ionising Radiation Safety Policy. The Governance structure in Appendix 1 shows the roles and responsibilities of the groups specifically related to Cardiology.

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 the role of the referrer to make this formal assessment of the mental capacity of patients. The referrer 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 or as an emergency and the operator has concerns that the patient does not have capacity to give appropriate consent a risk/benefit assessment needs to be carried out. Where such issues cannot be resolved in a timely manner, examinations should be delayed if possible or if necessary carried out in the patients' best interest.

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 at least three independent details to allow the person attending for examination to be confirmed as the person for whom the referral was made. Typically 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 not be performed until this information is provided.

2. It is the responsibility of Radiographer entitled as 'Radiographic Operator' according to the definitions in the Ionising Radiation (Medical Exposure) Regulations to ensure that the patient referred is the person being examined.

3. The Radiographic Operator must confirm the patient's identity in accordance with the Trust Policy for Positive Patient Identification and the Cardiologist Operator confirms it has been done. This requires at least 3 separate points

4. 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 STOP moment within the patient care pathway.

   This check **must** be made in the examination room as part of the STOP moment process, prior to exposure.

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 STOP moment. 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 team 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. This must be fully documented in the patient care pathway.

   - For Day-case Patients and 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 the care pathway, including the name of the person confirming the patient's identity and their relationship / designation. Outpatients within the cardiac catheter suite 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 i.e. 'Written Communication', 'Interpreter' or 'Sign Language' within the care pathway.

   - Patients who are unable to communicate, or have significantly impaired communication, due to conditions such as dementia, head injury or learning difficulties can be identified by a responsible adult who knows or cares for them. This must be fully documented in the patient care pathway, 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. If the Cardiologist 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 Referrer and Practitioner. 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 the patient care pathway.

6. At the STOP moment the cardiologist operator must check that the ID process has been satisfactorily completed before the first radiation exposure to the patient is made.

7. Similar checks must be made by the Cardiologist Operator to ensure that any physical or electronic healthcare records used during the examination process are those belonging to the patient referred for examination eg. Patient notes, previous images, patient data on radiology and physiology equipment.

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. Training will consist of:

        - Core academic / professional qualifications.
            - Cardiologists with CCT or equivalent plus completion of online e-LFH Cardiology IRMER Course will be considered qualified and may be practitioners in any cardiology medical exposures.
        - Specific training on the role of the practitioner and procedures which must be followed at University Hospitals of Derby and Burton.
        - On-going CPD

    - Academic qualifications will be checked on appointment by Medical Staffing and state registration will be checked periodically as part of Trust Human Resources processes. The individual practitioner should undertake relevant CPD. Record of this forms part of the annual

appraisal process. Training records will be kept by Cardiology Catheter Suite Manager.

- The Consultant overseeing the list acts as the practitioner for this list and Justifies all requests for Interventional cardiology procedures under fluoroscopic control as being in the patients best interests; i.e. that the benefits of the procedure outweigh the risks.

- The Cardiology ACD will entitle all practitioners, in writing, and provide a list of their duties.

- A register of Practitioners for Interventional Cardiology procedures under fluoroscopic control is kept by the Cardiac Catheter Suite Manager and is available to staff.

Referrer

2. "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.

For referrals to the cardiac catheter suite the following referrers will be accepted:

- Consultant Cardiologists
- Cardiology Registrars working in cardiology clinic
- Associate Specialists
- Outreach Nurses working in Rapid Access Chest Pain Clinic (RACPC) who have carried out the training required and been signed off to act as a non-medical referrer according to the RACPC pathway with discussion with Consultant.

- 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 recognised in Trust / linked electronic systems are authorised referrers and requests for Interventional cardiology procedures under fluoroscopic control may be accepted subject to Justification. In addition, a register of approved non-medical referrers is kept by the Cardiology Catheter Suite Manager and is available to staff on the shared drive.
- Checks on state registration will be made prior to adding referrers to Trust electronic systems.
- Trust referrers will receive instruction in their role at induction and periodically thereafter.

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. Training will consist of:
  - Core academic / professional qualifications.
    - Qualified Radiographers included on the HCPC register are considered qualified to act as operator.
    - Cardiologists with CCT or equivalent plus online e-LFH course will be considered qualified to act as operator.
  - Specific training on the role of the Operator and procedures which must be followed at University Hospitals of Derby and Burton.
  - Specific training against documented competencies in the safe use of any radiation equipment used as part of their role.
  - On-going CPD.
- Students and trainee Cardiologists are not authorised to act as Operators for medical exposures although may undertake all aspects of the role under direct supervision providing they have complete training on the equipment.

- 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 Cardiac Cather Suite and relevant Business Units. The individual operator should undertake relevant CPD and keep copies of their training records.

- The Lead Radiographer of Cardiology (entitled by the Cardiology ACD) will entitle all appropriate radiographers as operators, in writing, and provide a list of their duties once their cardiac training has been delivered and checked. The training records will be held by the Cardiology Catheter Suite Manager will hold these records.

- The Cardiology ACD will entitle all appropriate Cardiology Medical staff as operators, in writing, and provide a list of their duties.

- A register of operators for Interventional cardiology procedures under fluoroscopic control is kept by the Cardiac Catheter Suite Manager and is available to staff.

- Staff undertaking QC activities [inc medical physics] are Operators

- The MPE is an Operator

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 (SOP in Appendix 2)

Enquiries regarding the pregnancy status of all individuals of childbearing potential must be made prior to Interventional Cardiology procedures.

1. Referrers must consider the possibility of pregnancy when assessing the requirement for examinations involving exposure of the abdomen or pelvis to ionising radiation; as pregnancy is highly relevant to both the Justification and conduct of the examination. In particular:
    a. Referrers are responsible for informing the operator when a patient is a transgender man or gender non-conforming individual who has childbearing potential, as part of the referral.
    b. Referrers are responsible for informing the operator of the pregnancy status of any female or transgender male / gender non-conforming individual patient between 12 and 55 years of age for any examination involving exposing the abdomen or pelvis to ionising radiation when the patient is anaesthetised, sedated or unable to cooperate with standard checking procedures; for example is unconscious or does not have capacity.

2. The operator initiating the exposure is ultimately responsible for ensuring that pregnancy status is / has been checked during the STOP moment/WHO Checklist/care pathway 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.

3. An explanation of the requirement for checking pregnancy status must be given to the patient.

4. Patients should be asked the question *'is there any chance that you could be pregnant?'* This should be done in private; with care and sensitivity, as it may offend or embarrass some individuals.

5. The enquiry and response must be documented within the care pathway.

    - 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 must be documented within the care pathway.

6. When a patient indicates they are not pregnant, or has had a recent negative pregnancy test, the examination may proceed following the normal procedure.

7. When a patient indicates they may be pregnant, or pregnancy cannot be excluded:

    - Non-urgent examinations must be postponed until after the patient's pregnancy status has been established. In most cases this will involve the patient contacting the relevant department to rearrange their examination following a negative pregnancy test or the start of a menstrual period.

- Operators can access support from a Practitioner (Cardiologist) at all times. All referrals for urgent Interventional cardiology procedures under fluoroscopic control on patients who may be pregnant should be discussed with a Practitioner; and this discussion documented in the care pathway.

- When the examination is considered urgent, the examination may proceed with the patients informed consent as follows:

    - Interventional cardiology procedures under fluoroscopic control may proceed if the patient is within 10 days of the start of their last menstrual period.
    - Urgent examinations may proceed, with the patient's informed consent, if this is considered in the patient's best interests/medically necessary by the referrer & practitioner; and this, including the rationale, is documented in the referral/care pathway/patient notes by the practitioner.

8. When a patient indicates they are pregnant.

- Operators can access support from a Practitioner (Cardiologist) at all times. All referrals for urgent Interventional cardiology procedures under fluoroscopic control on patients who are pregnant should be discussed with a Practitioner; and this discussion documented in the patient care pathway.

- Unless mentioned in the referral, discussion with the referrer is necessary to ascertain the risks to the mother/foetus of postponing the examination until after delivery.

- If the examination cannot be postponed, then the possibility of using other imaging modalities that do not use ionising radiation must be discussed with a practitioner.

- If other modalities (U/S, MRI (outside the first trimester)) are not appropriate, then the risk to the foetus, depending upon the stage of pregnancy that has been reached, must be explained to the patient.

    - The risk of not having the examination should also be explained and written informed consent should be obtained.
    - The practitioner must sign the care pathway to state that the pregnancy rule has been considered. The patient, or their representative, will be asked to sign the care pathway to confirm this.

The examination may proceed, with the written informed consent of the patient, if the practitioner considers this Justified

- When a pregnancy, previously unknown to healthcare providers, is identified in a child, a safeguarding concern must be raised. Please see the Trust Policy for Safeguarding.

9. In addition to the above procedures, departments where Interventional cardiology procedures under fluoroscopic control are performed must take measures to raise the awareness of the effects of ionising radiation with individuals capable of childbearing. Within the Cardiac Catheter Suite, 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. Procedure specific information leaflets sent to patients with appointment letters. These include the risks of radiation exposure in pregnancy.

10. Enquiries regarding breast feeding are only required by IRMER for examinations involving the use of radioactive substances. However such enquires should be made for all Interventional cardiology procedures under fluoroscopic control involving the use of contrast agents; or, when relevant, other adjuvant drugs.

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

1. Please refer to the cardiology equipment QA manual for details.

2. The compliance of both equipment and procedure QA within the cardiac catheter suite will be monitored as part of the on-going audit schedule within the cardiac catheter suite. The will feed into the Governance structure (appendix 1).

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

1. The Practitioner justifying any diagnostic radiographic / fluoroscopic 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 as low as reasonably practicable.

2. Examination parameters are programmed into each cath lab for each type of interventional cardiology procedure within each cath lab.

3. Diagnostic reference levels are in place and displayed in each room.

4. If a dose exceeds the DRL by x10 then this will be reported by the Radiographic Operator to the Lead Cardiac Radiographer who will inform

the MPE and the cardiac cathere suite manager.
Also a DATIX form will be completed by the Radiographic Operator.

5. Methods of recording dose from which dose estimates can be calculated if necessary:
    - Dose Area Product (DAP), Air Kerma (AK) and 'screening' time are documented on cardiobase, CRIS and in a paper record available in the cath lab.

These factors must be recorded for all examinations. The may also be recorded by the radiation equipment via DICOM and transferred to PACS and dosewatch.

More detailed calculations of patient dose, e.g., to evaluate organ doses or doses to a fetus where a pregnant patient had been examined must be referred to the MPE.

6. High dose procedure is available in Appendix 3.

h. 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 Interventional cardiology procedures under fluoroscopic control will have a clinical evaluation by an Operator designated to carry out this function.

    - In all cases this will take the form of an Imaging report issued by a Cardiologist or designated member of staff entitled to carry out the procedure performing the procedure.

    - In addition, the Cardiologist may also document aspects of the clinical evaluation; and relevant factors such as aftercare, elsewhere in the patient's healthcare record. E.g. the patients notes.

2. The examination of patients will only be carried out when clinically justified.
    - Examinations requested without reasonable consideration to the radiation risk to the patient, or whether the examination will affect the patient's treatment cannot be justified.

    - A Practitioner cannot Justify a medical exposure if it is known that an evaluation will not take place.

- As part of the audit programme Cardiology will audit that letters are dictated post interventional cardiology procedures.

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. Annually, an audit of patient doses will be undertaken for a wide range of Interventional cardiology procedures under fluoroscopic control**.** Full use will be made of automated systems which collect patient dose information during this process.

   With appropriate input from relevant Medical Physics Experts, these datasets will be used to calculate local DRL's. These will be benchmarked against any national DRL available and local DRL's from other Trusts, where available. These will be reviewed and signed off within the Cardiology Radiation Group Meeting.

2. Annual audit of actual patient doses will be undertaken. This will be replaced by continuous audit of automatically collected data where such systems are available. This data will be used to ensure that actual patient doses are consistently at, or below, the relevant DRL. It will also be used as part of the procedure to optimise doses where local doses exceeds national DRL's.

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

1. All requests to undertake research studies received by the Cardiology Catheter Suite 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 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 Trial Coordinator and the Cardiac Catheter Suite Appointments Team to ensure the examination is performed appropriately.

10. All research studies are discussed with the Cardiology Consultants and acceptance across the team decided. The practitioner for the research exposure is the Consultant who is responsible for the list.

i. Employers procedure for the provision of written instructions and information to patients undergoing treatment or diagnosis with radioactive substances.

This procedure is not relevant to Interventional Cardiology.

j. 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 has decided to take a graduated approach to providing patients with information on the risks associated with the dose associated with exposure to ionising radiation. For lower dose examinations this will be via written information, posters and leaflets available in patient areas such as waiting rooms. For higher dose examinations, the referrer and / or operator 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.

This will be achieved by one or more of the following methods:

1. Referrers 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. Referrers are best placed to discuss alternatives to proposed examinations, including 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.

2. The Operator, usually the Cardiologist conducting the procedure, will check that information on the risks and benefits of an examination, including those from ionising radiation if appropriate, have been made available to the patient, or their representative, as part of the consent process.

3. Posters and leaflets will be displayed in patient areas to provide the information on radiation risks for lower dose examinations and support discussions for higher dose examinations. However staff must discuss the risks and benefits with patients whenever appropriate.
    - Posters are displayed in relevant waiting areas.
    - All interventional procedures are undertaken by prior arrangement.
        - When a procedure is performed as an emergency the referrer must provide information about risks, including

those from ionising radiation if appropriate, as part of the consent process. This should be done as far in advance of the procedure as practicable.

- 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.

4. Where the patient is unsure of the benefit of exposure to radiation they should be advised to undertake further discussion with their referring clinician/practitioner.

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

1. Operators 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 Interventional cardiology under fluoroscopic control are in place and Operators receive training in these to ensure they are aware of all relevant procedures and protocols and will follow these.

3. While the observance of 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 carried out by staff using the appropriate care pathway and STOP moment. 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. Patients are sometimes unable to confirm the required details. Other patients may not be able to cooperate with verbal checks due to language difficulties or healthcare conditions. In such circumstances the examination should proceed as requested.

4. 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
    - The patient dose, divided into intended and unintended/ accidental portions if possible.
    - Confirmation that any diagnostic images obtained from accidental or unintended exposures have been included in the patient's record and sent for reporting.
    - All relevant details required to facilitate investigation of the incident; e.g. the staff and equipment involved etc.

5. 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 the Trust Policy and Procedures for Incident Reporting.

6. 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 Cardiology, SMBU2 and to the wider Trust via the various Governance groups.

7. Compliance will be monitored through the use of audit within the cardiac catheter suite. The results of these will feed into the Cardiology Radiation Group meeting and form part of the Cardiology Governance structure (appendix 1).

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 an accidental exposure, or unintended exposure 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 Cardiac Catheter Suite Manager will:
        - Manage the incident report within DATIX.
        - Send details of the incident report to a Medical Physics Expert (or follow guidance issued by the MPE).
        - Request:
            - A dose report from the MPE

        - Advice regarding the external reporting of the incident.
    - When an incident is considered externally reportable, the Cardiac Catheter Suite Manager 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 Cardiology, the Manager 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. When the Medical Physics Expert considers the patient has received a clinically significant accidental or unintended exposure to ionising radiation the Cather Suite Manager will ensure that the Practitioner and Referrer are informed of the incident. Where the referrer is not the Lead Clinician they will also be informed.

4. Reports of incidents involving additional exposure to ionising radiation, including accidental and unintended exposures are reviewed within the Cardiology Governance structure. Trust oversight of such incidents includes via the Radiation Protection Group, Patient Safety Group and Incident Learning Group.

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

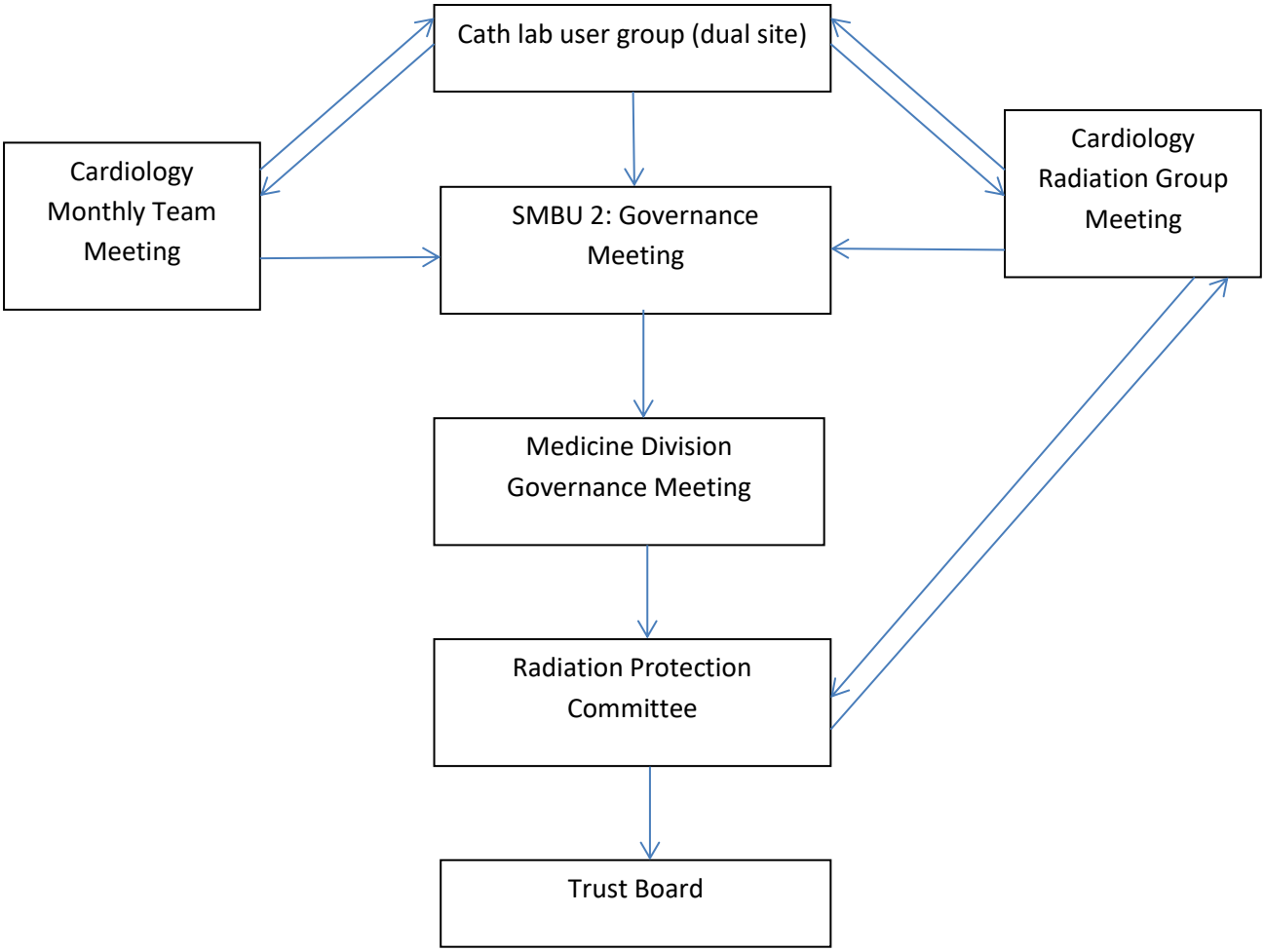
Not applicable to Cardiology

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

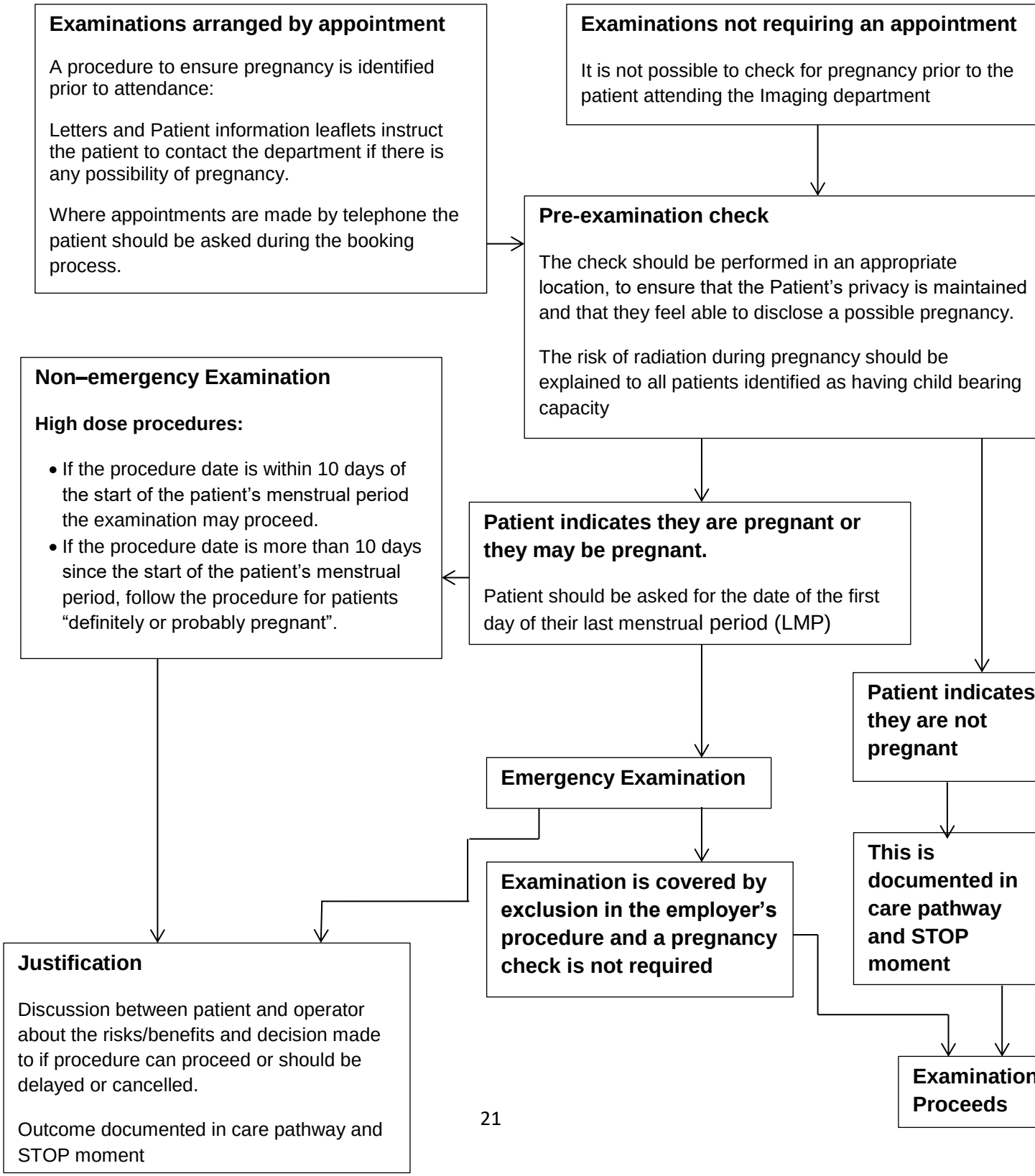
Not applicable to Cardiology

Appendix 1 – Cardiology Governance Structure

Cardiology Governance Structure



Appendix 2 – SOP for pregnancy checks



Examination does not Proceed
Referrer informed

Appendix 3 – SOP for high dose procedures

High Skin Dose Interventional Cardiology / Radiology Protocol

Patient Consented in Normal Fashion Inc Risks of Radiation Usage

Case Completed
DAP > 500 Gycm^2
And / or
Air Kerma > 5 Gy

Yes

1. Complete Handover Documentation for patient notes
2. **Performing clinician** to discuss potential effects of large radiation dose
3. Patient information leaflet given to patient
4. Complete IR1 detailing circumstances, dose received and policy followed

No

No Further Action Required

Radiology Patient

Radiologist to:

- Inform responsible consultant of high skin dose procedure

Responsible Consultant to:

- Follow up patient in their clinic within 30 days
- Inform GP of high skin dose given during procedure

Cardiology Patient

Cardiologist to:

- Follow up patient in their clinic within 30 days
- Inform GP of high skin dose given during procedure

References:

- Institute Atomic Energy Agency – Radiation Protection of Patients http://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/5_Interventional Cardiology/erythema.htm
- British Cardiovascular Intervention Society – Save our Skins http://www.bcis.org.uk/resources/save_our_skins_4.pdf
- Society of Interventional Radiology – Guidelines for Patient Radiation Dose Management http://www.sirweb.org/clinical/cpg/Patient_Radiation_Dose_Management_Stecker.pdf