Trust Policy

University Hospitals Plymouth NHS Trust

Employer's IRMER Procedures for Use of the Mini C - Arm in the Surgery Care Group

Issue Date	Review Date	Version
March 2020	March 2023	2

Purpose

The purpose of these Written Procedures is to ensure the safety of patients undergoing medical exposures utilising 'Mini C-Arms' as part of surgical procedures in compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17).

Who should read this document?

Surgery Care Group Management.

Theatres Service Line Management.

Plastic Surgery & Trauma, Orthopaedic & Rheumatology Surgeons. Service Line Directors and Service Line Managers.

Staff entitled by the Service Lines to be identified as 'Duty Holders'.

Key Messages

These procedures apply to work within the Surgery Care Group, with patients undergoing procedures under the Trauma, Orthopaedic & Rheumatology Surgery or Plastic Surgery. Those staff acting as duty holders may work in the Plastic Surgery Service Line, Trauma, Orthopaedic & Rheumatology Surgery Service Line, and the Theatres Service Line.

Responsibility for medical exposures under these procedures rests with the Service Line responsible for the surgical procedure.

Service Line Clinical Directors must ensure all duty holders are appropriately entitled and trained, and comply with the procedures.

The inappropriate, unsolicited and unsafe use of the Mini C-Arm will be regarded as a disciplinary matter.

Core accountabilities	
Owner	Joanne Hope Clinical Quality Manager for Surgery Care Group Governance Board
Review	Surgery Care Group Governance Board
Ratification	Consultant Upper GI Surgery (Grant Sanders)
Dissemination (Raising Awareness)	Surgery Care Group Governance Board
Compliance	Mandatory Annual Clinical Audit

Links to other policies and procedures

None Applicable

Version History

1	March 2019	Draft

2	March 2020	Reviewed and approved

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

1 Introduction

These procedures apply to work with the Surgery Care Group, with patients under Trauma, Orthopaedic & Rheumatology Surgery or Plastic Surgery. The purpose of these Written Procedures is to ensure the safety of patients undergoing medical exposures utilising 'mini c-arms' as part of surgical procedures in compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17).

2 Purpose

All staff working with Ionising Radiations must do so in accordance with the requirements of The Ionising Radiations Regulation 2017(IRR17). In particular all staff must read the appropriate Local Rules and abide by then at all times. These written procedures must be followed by those with responsibilities under the regulations The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17) as defined in this document.

3 Definitions

Ionising Radiation In this context refers to x-rays

Referrer Registered Medical Practitioner, named non-medical registered healthcare professional (see Appendix 2).

Practitioner For surgical clinical procedures in this document, Surgeons who have completed appropriate training under IRMER may act as the Practitioner.

Operator the Operator carries out practical aspects of the exposure including imaging and any manipulation of the equipment controls and display. Operators may also undertake QA measurements.

- All Operators must be suitably trained and authorised to act in this capacity in accordance with these procedures.
- Suitably trained radiographers may also act as Operators.
- Scientific and technical staff may act as Operators for Quality Assurance programmes for x-ray equipment.

Justification Consideration of the net benefit of a medical exposure taking into account ;

a) The specific objectives of the exposure and the characteristics of the Individual

b) The total diagnostic or therapeutic benefits of the exposure

c) The individual detriment the exposure may cause

d) The efficacy, benefit and risk of alternative techniques having the same objective but involving no or less exposure to ionising radiation

(adapted from IR(ME)R regulation 6)

Authorisation The documented indication that justification has taken place. Indicated by the signature electronic or written of the Practitioner or Operator (if authorisation under agreed justification criteria)

Carer and Comforter Individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure.

Medical Physics Expert An individual or group of individuals having the knowledge, training and experience, to act or give advice on matters relating to medical exposure of patients. Medical Physics Experts (MPE) must hold relevant certification.

Ionising Radiations Regulations 2017 (IRR17) Regulations concerning the safety of staff and members of the public from exposure to ionising radiations

Radiation Protection Supervisor Person appointed under IRR17 with specific responsibilities to supervise the work within the Controlled Area and ensure that the work is carried out in accordance with the Local Rules

Radiation Protection Advisor Appointed by the Trust under IRR17 to give independent expert advice on matters concerning ionising radiations with respect to the safety with respect to members of staff and the public

Controlled Area Designated area where there is a higher risk of exposure. Subject to access control through Local Rules and Systems of Work

Local Rules Required where a Controlled Area exist. Set out rules for the safe working within the Controlled Area

4 Duties

Responsibility for medical exposures under these procedures rests with the Service Line responsible for the surgical procedure. Those staff acting as duty holders may work in the Plastic Surgery Service Line, Trauma, Orthopaedic & Rheumatology Surgery Service Line, and Theatres Service Line. Service Line Clinical Directors must ensure all duty holders are appropriately entitled and trained, and comply with the procedures.

5.0 Use of the Mini C-arm

A risk assessment must be carried out before any new or changed activity involving the use of the mini c-arm. The mini c-arm may only be used by those trained and authorised to do so, and only in accordance with the procedures contained within this document. Equipment is password protected and passwords only issued to entitled Operators

The Operator may directly supervise another member of the theatre team to;

- enable the mini c-arm at commencement of the need to take an exposure
- position the mini c-arm.
- disable the mini c-arm at the end of the procedure

Engineers, radiographers and medical physics staff are authorised to use the equipment for maintenance and Quality Assurance purposes.

5.1 Training Requirements

Surgeons may act as the Practitioner for surgical clinical procedures in this document provided that they undertake appropriate training which satisfies the requirements of IRMER17 schedule 3 of the regulations.

For surgical clinical procedures in this document, the Trust mandatory training programme for referrers is considered adequate training.

Medical Practitioners and other Healthcare Professionals may only act as Operators for use of the Mini C-arm if they have:

1) A certificate from completion of an appropriate course which satisfies the requirements of schedule 3 of the regulations (e.g. the IRMER course provided by the Pulvertaft Hand Centre, e-IRMER (e-lfh.org.uk))

2) Documented practical training in the use of the equipment (Appendix 1)

3) Carried out practical clinical training under the supervision of designated training supervisor (Appendix 2). The designated training supervisor will determine when the individual has carried out sufficient cases to demonstrate competence and understanding of optimisation of image quality. This must be a minimum of 5 cases or until the operator feels competent enough to operate the machine solo.

4) Completed their training log (Appendix 1), obtained approval from the relevant Service Line Clinical Director, (or by delegated authority of the Service Line Clinical Director) and be registered in the relevant mini C-arm Authorised Users Log as an operator.

    - The mini c-arm Authorised Users Log will consist of a list of names of authorised mini c-arm operators, along with their training records and course certificates. A separate log may be maintained within each service line.
    - Operators entitled through entry on any user log may act in this capacity for procedures across the Care Group. Each Operator must only use equipment for which they have been trained.

5) Operators must maintain competencies in the use of the C-arm to remain on the entitled list. This should include a minimum of 12 procedures per year to demonstrate practical competency, and attendance at updates as required. Any Operator who fails to demonstrate adequate competency will be removed from the entitled authorised list. To maintain competency the operator must demonstrate refresher training in IRMER every 3-5 years and must complete on average at least one case a month.

    - If a break of greater than 6 months occurs between cases then the individual will be removed from the list of entitles Operators pending completion of relevant refresher training, which should include training on the equipment and in the written procedures. Considerations should be given to the individual undertaking additional theoretical training – and the use of the Trust training programme for referrers should be considered.

6) Surgeons who have not fulfilled the above criteria, and require a mini c-arm to facilitate their operation, must ensure a trained and entitled Operator is available for the case.

7) Practitioners and Operators must undertake appropriate continuing education and training which should include training related to any new clinical techniques, and the relevant radiation protection requirements.

Service Line Clinical Directors are responsible for maintain training records and ensuring these are available for inspection.

5.2 Referral

Surgical referral for Procedures listed in sections 5.19 & 5.20 of this policy considered the referral criteria to be that the medical exposure is considered implicit to the surgery required. The Referrer must ensure that the patient is uniquely identified on the referral and is responsible for the accuracy of these details.

Referrals for medical exposures under this procedure are completed by the referrer using the iCM electronic referral system.

5.3 Providing Patients with Information on Benefits and Risk of Exposure

Patients must be provided information in risk and benefits of the exposure. This should be carried out by the surgeon as part of the informed consent process.

For clinical procedures within the context of the written procedures, the risk of lifetime cancer following the exposure can be considered as negligible (less than 1 in a million)

The natural lifetime cancer incident is about 1 in 2.

5.4 Justification & Authorisation

IRMER17 requires justification to occur prior to the exposure. Authorisation is documentation of justification occurring. In this case the IRMER operators are 'authorising under protocol' for the procedures listed below. If the referral does not meet the agreed criteria, a Practitioner must individually justify and authorise the exposure.

Authorisation by Operator

The following procedures are justified by the relevant Service Line Director acting as Practitioner, and the Operator may authorise such medical exposures:

<u>For Plastic Surgery :</u>

- Internal fixation of fractures (of the upper and lower extremities*)
- Insertion of K-wires (of the upper and lower extremities*)
- Reduction of fractures, dislocations and subluxations (of the upper and lower extremities*)
- Positioning of screws and implants (of the upper and lower extremities*)
- Location of bone and foreign body fragments (of the upper and lower extremities*)

- Positioning of needles for extremity steroid joint injection (of the upper and lower extremities*)
- External fixator (upper extremities*)

For practical purposes and for the requirement of the Plastic Surgery Service Line this is confined to the hand but on rare occasions may require an examination more proximal in the limb.

For Orthopaedic Surgery:

- Reduction of fractures, dislocations and subluxations*
- External, internal or percutaneous fixation of fractures or joint disruptions*
- Location of bone fragments or foreign bodies*
- Positioning of K-wires, screws and implants*
- Confirmation of the effect of surgery on bones, joints or soft tissues*
- Positioning of needles for joint aspiration or injection*
- Dynamic examinations under anaesthesia for diagnostic purposes*

For practical purposes for the Trauma, Orthopaedic and Rheumatology Service Line this is confined to adult and paediatric hand, wrist, forearm, elbow, foot and ankle. Paediatric knee.

All other procedures must be individually justified by a Practitioner.

Process of **Authorisation** by Operator;

The Operator will authorise the exposure in accordance with the written criteria as detailed above. Authorisation is performed using an electronic process on the Computed Radiology Information System (CRIS).

- On CRIS **prior** to exposure the operator electronically ‘authorises under protocol’ by ticking the ’justify box’ and writing ‘authorised under DOP’ in the ‘events’ section, providing they have the appropriate CRIS training and access .

- In the case of any interruption or disruption to the electronic process it is the expectation that ‘paper contingency plan’ should be instigated and when appropriate amalgamated to the electron patient record.

If the referral does not meet the agreed criteria, a Practitioner must individually justify the exposure.

Process of **Authorisation** by Practitioner;

A Practitioner may in any case justify and authorise any surgical clinical procedures in this document . This must be recorded as detailed below above. The Practitioner must then document justification and authorisation by ;

- Electronic Process - on CRIS prior to exposure the Practitioner electronically ‘authorises’ by ticking the ’justify box’ .

- Additionally for records management - on CRIS
    - attend the patient
    - set location to DTH
    - in auto report, comment ‘op-note’

On the mini c-arm amend the ID with the prefix ‘RK9’

5.5 Patient Verification

It is the responsibility of the operator affecting the exposure to establish the correct identity of the patient undergoing examination or treatment with ionising radiations.

This is performed as part of the pre-procedure WHO checklist (time-out), by checking wrist-band, address, hospital number and DOB against details recorded on the patient care pathway and consent form. This is recorded on the reverse of the data capture form and signed for on the front cover of the peri-operative integrated care pathway in the “surgical safety checklist” section.

The WHO process is the responsibility of the entire theatre team, and the check and recording may be performed by any member of the team. The Operator must always be present during this process and takes the IRMER responsibility for patient ID.

5.6 Irradiation of Women of Child-bearing age (12- 55 years)

For use of the mini-C-arm for procedures in this document the risk to any unborn foetus is considered minimal All exposures under this protocol do not involve direct irradiation of the abdomen of women of child bearing age (12 – 55 years).

There is, therefore, no requirement for the Operator to establish likelihood of pregnancy with regard to the medical exposure.

5.7 Optimisation

The operator has control over each exposure and must make all efforts to reduce the dose to the patient as far as reasonably practicable.

- Keep screening time to a minimum.
- Position the part to be examined properly.
- It is vital that the X-ray tube is as far away from the patient as is possible - ensure a minimum X-ray distance of 30cm
- Use the minimum noise reduction consistent with the intended purpose.
- If in difficult cases, the reassessment screening time (i.e. the maximum screening time allowed for that procedure).
    - An assessment of the procedure should be performed and the following considered:
        - If progress is being made, continue
        - Seek assistance or advice (this is mandatory if a junior surgeon exceeds the maximum recommended screening time).

- Complete procedure with no further screening.
- Abandon procedure if unlikely to achieve desired outcome
- The reassessment screening time is detailed in the respective examination protocol

5.8 Recording of the Procedure and Clinical Evaluation including Assessment of Patient Dose

Following the procedure, it is the operating surgeon's responsibility to make a clinical evaluation of the exposure in the patient's operating notes by:

1) Noting the outcome, in the ICP pages 13 & 17 or notes section of the LA or in the Operating notes.

2) Uploading images to PACS (which includes the record of dose and screening time)

5.9 Diagnostic Reference Levels

Diagnostic Reference Levels (DRL) are dose levels which should not normally be exceeded in normal practice.

- For the purposes of surgical clinical procedures in this document, the Local Diagnostic Reference Level (LDRL) is considered to be the optimum screening time as detailed in the relevant examination protocol.
- The operator is responsible for assessing all exposures against the relevant LDRL and escalating any concerns a series of doses to multiple patients are thought to exceed a relevant LDRL.

Patient Dose and LDRLs will be reviewed through the clinical audit process.

5.10 Non-Medical Imaging Exposures

Exposures for non-medical imaging purposes, such as concealment of drugs, or other legal purposes, are not permitted under these procedures.

5.11 Research Exposures

A research exposure is any medical exposure conducted as part of a clinical trial.

- Specifically a research exposure is exposure required of the trial protocol which occurs following patient consent to participate in the trial.
- Any such research exposures which are performed for surgical clinical procedures utilising the mini c-arm must have appropriate approval through the Trust R&D including local authorisation by an appropriate Medical Physics Expert and Clinical Radiation Expert.
- Any such research exposures which are conducted must clearly be identified as being for research purposes.
- If a surgical patient is participating in a clinical trial, this is identified within the patient's notes. The patient will undergo informed consent for the trial by the surgical team.

- The Operating surgeon must identify to the theatre staff and operator that the patient is within a clinical trial (and therefore any medical exposure is a research exposure).

5.12 Procedures for Quality Assurance of Standard Operating Procedures

These written procedures will be reviewed at least every 3 years or if there are any relevant changes to legislation and any paper copies then updated.

Approval of written procedures will be through relevant Trust delegated authority as detailed on the title page

Staff acting as duty holders will be informed of any changes and appropriate training provided.

All work under the procedures is subject to assurance compliance monitoring by the Radiation Safety Committee.

5.13 Clinical Audit

'Clinical audit' under the regulations means 'a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated, and the application of new standards if necessary;'

- As part of clinical audit undertaken within the clinical service, this must include consideration of the use and outcome of medical exposures.
- Additionally
    - audits of compliance with written procedures must be conducted at least annually. This to include audit of patient dose and review of DRL
    - Audits of recording of clinical evaluation of the exposure must be conducted at least annually
    - Audits of Operator competency must be conducted annually

Results of these audits must be presented to the Radiation Safety Committee. The work will be subject to audit and review by the Radiation Safety Committee under the Trust Radiation Safety Assurance Programme. Overall responsibility for Clinical Audit lies with the Service Line Clinical Director, who must attend the Radiation Safety Committee to present the outcome of audits and completion of action plans.

5.14 Management of X-Ray Equipment

X-Ray equipment must be subject to an appropriate Quality Assurance Programme. Mini c-arm equipment used for medical exposures under these procedures must be;

- **subject to appropriate maintenance in accordance with the manufacturer's specifications**
- **tested prior to first use**
- **performance tested at regular intervals**
- **performance tested following any maintenance or repair which is capable of affecting the performance**

- The responsibility for ensuring an appropriate Quality Assurance Programme in in place and is effective is with the Service Line Clinical Director for Theatres.

- The provision of performance testing is supported by Medical Imaging (level A tests) and Clinical & Radiation Physics (level B tests).
- Clinical staff must ensure cooperation with equipment engineers and staff from Medical Imaging and Clinical & Radiation Physics to ensure equipment is made available for maintenance and routine testing.
    - Equipment that shows signs of a fault, must be withdrawn from service until it has been examined and passed as fit for clinical use. Operators must record equipment errors and faults and seek the assistance of an engineer as required through Medical Imaging.
    - On return of equipment from the engineer clinical staff must heed the information contained in the handover form.
    - Advice and assistance can be sought from the appointed Medical Physics Expert.

5.15 Expert Advice

Medical Physics Experts (MPE) are appointed by the Trust and employed through Clinical & Radiation Physics. The MPE must be consulted regarding;

- optimisation of imaging procedures
- dosimetry and quality assurance matters
- measurements for the evaluation of dose
- equipment used for medical exposure
- The MPE should also contribute to Selection of new equipment
- The investigation and analysis of incidents potentially involving accidental or unintended exposures
- The training of duty holders
- The provision of advice on compliance.

5.16 Procedure For Patients Receiving an Accidental or Unintended Dose

If an incident occurs during a medical exposure using the mini c-arm, the Trust incident procedure should be followed. The surgeon or relevant member of staff must explain and apologise to the patient (if present). The Senior Matron for Theatres and MPE must be informed. The MPE will determine whether an accidental or unintended exposure has occurred as part of the initial incident investigation. The MPE will liaise with the chair of the Radiation Safety Committee regarding notification of any such incident to CQC. To minimise the risk of such incidents all exposures using the mini c-arm must be carried out in accordance with this protocol and all staff must have received adequate training. If an Operator feels they have not had sufficient training or lacks sufficient experience to carry out a procedure they must seek assistance and inform the relevant Service Line Clinical Director who will ensure that they receive further training before being allowed to act as an Operator again.

5.17 Procedure For Carers and Comforters

IRMER17 requires the benefit versus the risk of the exposure to the comforter or carer is justified and explained to them prior to exposure where practicable. In the circumstances

governed by this policy this is unlikely to arise, but should a carer or comforter be present during the exposure this needs to considered in the justification and the risks of the exposure explained to them. The risk of increased life time cancer to a carer or comforter from the exposures governed by this policy are considered 'negligible' (Less than 1 in a million) by Public Health England in HPA –CRCE- 028 (p55). It is highly unlikely a Carer or Comforter will be involved in any aspect under these written procedures. Should however this be judged to be necessary the Surgeon must discuss any associated risks with them and consider their exposure as part of justification

Dose constraints are specified for Carers and Comforters;

- 0.3 mSv on each occasion
- 5 mSv per annum.

Dose constraints are highly unlikely to be approached from any involvement of a Carer or Comforter in this work; if present a comment in the events comments of CRIS detailing name, relationship to patient, exposure is justified and they are aware of the risk/benefit.

5.18 Reducing the Probability and Magnitude of Accidental or Unintended exposures

This procedure is intended to minimise the probability and magnitude of accidental or unintended doses to individuals so far as reasonably practicable.

- Procurement of equipment: The Service Line Manager is responsible for ensuring that the appropriate specification is produced prior to the purchase of equipment and ensuring the advice of the appointed MPE is sought.

- Exposure technique: The Practitioner is responsible for ensuring that other appropriate imaging techniques are considered in preference to those using ionising radiation.

- Equipment: The MPE is responsible for the design of the Quality Assurance (QA) programme, including acceptance testing, calibration and routine Quality Control (QC). The MPE is responsible for those aspects of equipment QA that must be undertaken by Medical Physics staff . The Principal Radiographer (Medical Imaging) is responsible for those aspects of equipment QA that must be undertaken by Radiography staff .

- Justification: The key radiation protection principle is justification. Each exposure requires individual justification, i.e. benefit/risk analysis, prior to it being conducted.

- Optimised Exposure:The operator making the exposure is responsible for ensuring that the dose to the patient is optimised and as low as reasonably practicable for the purpose of the exposure (i.e. providing diagnostic image quality).

- Training: Only appropriately trained operators must be allowed to make exposures. Those in training may do so under supervision. The Service Line Clinical Director has overall responsibility for training.

- Avoidance of Inadvertent Exposure : The mini c-arm should be armed immediately prior to screening and disarmed after the procedure . It should also be disarmed during the surgical procedure where it is likely no further screening is imminently required .

- Incident Learning: The Service Line Manager is responsible for ensuring that learning from incidents is appropriately disseminated and integrated into working practices.

5.19 Examination Protocols for the of the use of the Mini C-arm in Plastic Surgery

Prior to exposure, the operator must ensure that the patient's details and those of the planned procedure are correctly entered into the mini C arm, and that the dose meter is set to zero

Plastic Surgery Protocol A: Internal fixation of fractures Hand & Wrist	
Name of Surgical procedure	Internal fixation of fractures Hand & Wrist
Justification for use of ionising radiation	intra-operative radiological examination of the anatomical reduction of the fracture and the integrity of the fixation
Points at which use of radiation used	– During fracture manipulation – Following insertion of K-wire – Following plate or screw fixation – Prior to skin closure
Purpose of Screening	To determine the correct fracture alignment, anatomical reduction of fracture and rigidity of fixation To negate the need for an immediate post operative radiograph To facilitate the surgical procedure
Optimum screening time	< 60 seconds
Reassessment screening time (time at which: – Procedure should be abandoned – Surgeon should seek assistance – Procedure should be completed with no further screening	2 minutes
Assessment of outcome	– Surgeons operation note

Plastic Surgery Protocol B: Insertion of K-wires Hand & Wrist	
Name of Surgical procedure	Insertion of K-wires Hand & Wrist
Justification for use of ionising radiation	intra-operative radiological examination of the anatomical reduction of the fracture and the integrity of the fixation
Points at which use of radiation used	– During fracture manipulation – Following insertion of K-wire – Prior to skin closure
Purpose of Screening	To determine the correct fracture alignment, anatomical reduction of fracture and rigidity of fixation. To negate the need for an immediate post operative radiograph To facilitate the surgical procedure
Optimum screening time	< 60 seconds
Reassessment screening time time at which: – Procedure should be abandoned – Surgeon should seek assistance – Procedure should be completed with no further screening	2 minutes
Assessment of outcome	– Surgeons operation note

Plastic Surgery Protocol C: Reduction of fractures, dislocations and subluxations Hand & Wrist - MUA's	
Name of Surgical procedure	Reduction of fractures, dislocations and subluxations Hand & Wrist - MUA's
Justification for use of ionising radiation	intra-operative radiological examination of the anatomical configuration of the fracture and stability of fracture reduction after manipulation
Points at which use of radiation used	– Prior to fracture manipulation – At intervals during the manipulation – Upon completion of the manipulation
Purpose of Screening	To determine the effectiveness of the manipulation in reducing the fracture
Optimum screening time	< 60 seconds
Reassessment screening time (time at which: – Procedure should be abandoned – Surgeon should seek assistance – Procedure should be completed with no further screening	2 minutes
Assessment of outcome	– Surgeons operation note

Plastic Surgery Protocol D: Positioning of screws and implants Hand & Wrist (i.e. Swansons, Avanta joint replacement)	
Name of Surgical procedure	Positioning of screws and implants Hand & Wrist (i.e. Swansons, Avanta joint replacement)
Justification for use of ionising radiation	intra-operative radiological examination the integrity of the fixation device or implant
Points at which use of radiation used	– Following insertion of screw or implant – Prior to skin closure
Purpose of Screening	To determine the correct position of the screw or implant
Optimum screening time	< 60 seconds
Reassessment screening time (time at which: – Procedure should be abandoned – Surgeon should seek assistance – Procedure should be completed with no further screening	2 minutes
Assessment of outcome	– Surgeons operation note

Plastic Surgery Protocol E: Location of bone and foreign body fragments Hand, Wrist, forearm, elbow, foot & lower limb	
Name of Surgical procedure	Location of bone and foreign body fragments Hand, Wrist, forearm, elbow, foot & lower limb
Justification for use of ionising radiation	intra-operative radiological examination to locate location of fragment
Points at which use of radiation used	– Prior to surgical exploration – At certain intervals during the surgery – Prior to skin closure
Purpose of Screening	To optimize efficient removal/relocation of fragment, thereby reducing operative time and minimizing soft tissue dissection
Optimum screening time	< 60 seconds
Reassessment screening time time at which: – Procedure should be abandoned – Surgeon should seek assistance – Procedure should be completed with no further screening	2 minutes
Assessment of outcome	– Surgeons operation note

Plastic Surgery Protocol F: Steroid Injections of Joint Spaces (upper and lower extremities)	
Name of Surgical procedure	Steroid Injections of Joint Spaces (upper and lower extremities)
Justification for use of ionising radiation	Pre and intra-procedural radiological examination to locate specific joint space
Points at which use of radiation used	– Prior to invasive procedure – At certain intervals during the surgery
Purpose of Screening	To optimize efficient view of joint, thereby reducing procedural time
Optimum screening time	<60 seconds
Reassessment screening time time at which: – Procedure should be abandoned – Surgeon should seek assistance – Procedure should be completed with no further screening	2 minutes
Assessment of outcome	– Surgeons operation note – Images are saved to PACS

5.20 Examination Protocols for the of the use of the Mini C-arm in Trauma, Orthopaedic and Rheumatology Surgery

Orthopaedic Surgery Protocol A : Reduction of fractures, dislocations and subluxations	
Justification for use of ionising radiation	Intra-operative radiological examination of the configuration of the fracture and the quality and stability of fracture or joint reduction achieved
Points at which radiation employed	Prior to fracture manipulation At intervals during manipulation After manipulation Following application of an external splint
Purpose of Screening	To determine the effectiveness of the manipulation To obviate the need for post-operative radiographs To reduce the need for repeat anaesthesia and manipulation
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeon's operation note Images are saved to PACS

Orthopaedic Surgery Protocol B : External, internal or percutaneous fixation of fractures or joint disruptions	
Justification for use of ionising radiation	Intra-operative radiological examination of the anatomical reduction of the fracture or joint and the integrity of the fixation
Points at which radiation employed	Following fracture manipulation Prior to insertion of implants Following insertion of implants
Purpose of Screening	To confirm the reduction of the fracture or joint To confirm the position or integrity of implants To obviate the need for a post operative radiograph To reduce the need for revision surgery
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeon's operation note Images are saved to PACS

Orthopaedic Surgery Protocol C : Localisation of bone fragments and foreign bodies	
Justification for use of ionising radiation	Intra-operative radiological examination to locate foreign body or bone fragment
Points at which radiation employed	Prior to surgical exploration At intervals during the surgery Following surgical intervention to the bone fragment or foreign body
Purpose of Screening	To optimize efficient localization and / or removal of a fragment, thereby reducing operative time, minimising soft tissue dissection and increasing the chances of a successful outcome
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeon's operation note Images are saved to PACS

Orthopaedic Surgery Protocol D : Positioning of K-wires, screws and other implants	
Justification for use of ionising radiation	Intra-operative radiological examination of the position and integrity of the fixation device or implant
Points at which radiation employed	Prior to hardware insertion Following hardware insertion
Purpose of Screening	To confirm the correct position and effect of the wire, screw or implant To obviate the need for a post operative radiograph To reduce the need for revision surgery
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeons operation note Print of images secured to operation note

Orthopaedic Surgery Protocol E : Ligament reconstruction, joint debridement	
Justification for use of ionising radiation	Intra-operative radiological confirmation of the effect of surgery on bones, joints or soft tissues
Points at which radiation employed	Following the surgical intervention
Purpose of Screening	To confirm the desired surgical effect has been achieved (eg. that a joint has been adequately debrided of osteophytes, that a ligament reconstruction has satisfactorily reduced a joint, etc) To obviate the need for post operative radiographs To reduce the need for revision surgery
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeon's operation note Images are saved to PACS

Orthopaedic Surgery Protocol F : Joint aspiration or injection	
Justification for use of ionising radiation	Intra-operative radiological confirmation that the needle is positioned in the joint space
Points at which radiation employed	Before inserting the needle into the joint After inserting the needle into the joint
Purpose of Screening	To avoid unintentional extra-articular injections
Optimum screening time	< 30 seconds
Reassessment screening time	2 minutes
Assessment of outcome	Surgeon's operation note Images are saved to PACS

Orthopaedic Surgery Protocol G : Dynamic fluoroscopic screening under anaesthesia for diagnostic purposes	
Type of Surgical procedure	
Justification for use of ionising radiation	To acquire information from dynamic screening not available on static films. To allow screening of a joint, without the limiting effect of pain
Points at which radiation employed	During manipulation and movement of the joint
Purpose of Screening	To acquire information to assist diagnosis, and help plan treatment
Optimum screening time	< 120 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeon's operation note Images are saved to PACS

6 Overall Responsibility for the Document

Surgery Care Group Clinical Quality Manager with support from the appointed Medical Physics Expert and Radiation Protection Team.

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Surgery Care Group Governance Board and ratified by the Surgery Care Group Director.

Non-significant amendments to this document may be made, under delegated authority from the Surgery Care Group Director, by the nominated owner. These must be ratified by the Surgery Care Group Director.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

Annual audit schedule specific to procedures undertaken using the Mini C Arm with an expectation that a sample of 50 procedures will be considered satisfactory. Any identified areas of concern should be managed through the Service Line Governance Forums and escalated to the Surgery Care Group if required. These audits should be presented to the Radiation Safety Committee Assurance programme as requested.

10 References and Associated Documentation

The Ionising Radiation (Medical Exposure) Regulations **(**2017)
http://www.legislation.gov.uk/uksi/2017/1322/contents/made

Guidance on the Ionising Radiation (Medical Exposure) Regulations 2017 for employers and health professionals who carry out medical radiological procedures.
https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance

Significant accidental or unintended exposures
https://www.cqc.org.uk/guidance-providers/ionising-radiation/definition-significant-accidental-or-unintended-exposures

The Ionising Radiations Regulations 2017
http://www.legislation.gov.uk/uksi/2017/1075/contents/made

Training Log of for Use of the Mini C-arm II during extremity surgery — Appendix 1

Name			
	Date		Signatures
Completion of an approved theoretical course on the use of Mini c-arm II			Name of Course
Copy of Pass Certificate held by Service Line Clinical Director *(or delegated authority)*			
Receipt of local rules : declaration to abide by :			
Receipt of written procedures for IRMER : declaration to abide by :			
Supervised training sessions (Supervising radiographer)	*1*	Some form of tracking	
	2		
	3		
	4		
	5		
Completion of Training			
Authorisation by Service Line Clinical Director for Plastic Surgery) (or delegated authority) to act as Operator for mini c-arms in accordance with these procedures (unsupervised)			

Designated Training Supervisors | Appendix 2

Dy Scott-Melhuish, Sister, Plastic Theatres
SN Kim Desborough
SN Debbie Mackin, Freedom Unit
Sue Fullilove, Consultant Surgeon, Orthopaedics
Charles Gozzard, Consultant Surgeon, Orthopaedics

Entitled Non Medical Referrers:

Anita Harper – Senior Physiotherapist. – Orthopaedic procedures

Dissemination Plan and Review Checklist | Appendix 3

Dissemination Plan	
Document Title	**Employer's IRMER Procedures for Use of the Mini C - Arm in the Surgery Care Group**
Date Finalised	March 2020
Previous Documents	
Action to retrieve old copies	Service Lines to ensure paper copies on the mini c-arms and in folders are replaced. Document now to be stored on trust 'G' drive and not on Service Line drives to ensure version control oversight and accessibility.

Dissemination Plan

Recipient(s)	When	How	Responsibility
Trauma, Orthopaedics and Rheumatology Service Line. Plastic Surgery Service Line. Main Theatres Service Line. Radiation Physics.	March 2020	Vital Signs	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance &	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes

Effectiveness	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Equalities and Human Rights Impact Assessment | Appendix 4

Core Information	
Date	March 2020
Title	Employer's IRMER Procedures for Use of the Mini C - Arm in the Surgery Care Group
What are the aims, objectives & projected outcomes?	The purpose of these Written Procedures is to ensure the safety of patients undergoing medical exposures utilising 'Mini C-Arms' as part of surgical procedures in compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17).
Scope of the assessment	
Collecting data	
Race	No Forseeable Impact Noted
Religion	No Forseeable Impact Noted
Disability	To be risk assessed locally
Sex	No Forseeable Impact Noted
Gender Identity	No Forseeable Impact Noted
Sexual Orientation	No Forseeable Impact Noted
Age	No Forseeable Impact Noted
Socio-Economic	No Forseeable Impact Noted
Human Rights	No Forseeable Impact Noted
What are the overall trends/patterns in the above data?	None noted
Specific issues and data gaps that may need to be addressed through consultation or further research	None noted
Involving and consulting stakeholders	
Internal involvement and consultation	Consulted
External involvement and consultation	Not required
Impact Assessment	
Overall assessment and analysis of the evidence	No significant impact
Action Plan	

Action	Owner	Risks	Completion Date	Progress update

Not required				