East Sussex Healthcare
NHS Trust

FOI REF: 25/291

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1st August 2025

FREEDOM OF INFORMATION ACT

I am responding to your request for information under the Freedom of Information Act. The answers to your specific questions are as follows:

Please may I request the following:

1. Overarching Policy for Radiology (if available)

Clarification was sought with regard to which policies you would require and confirmation was received as follows:

Specifically, an overarching radiology policy and a clinical interventional radiology policy.

We can confirm that there are no overarching policies for Radiology currently in place.

2. Any other policies related to radiology

Please see the attached policies which can be considered as related to Radiology.

3. Interventional Radiology Policy (if available)

Further clarification was sought asking you to specify your definition of 'clinical interventional radiology policy' and confirmation was received as follows:

This is in relation any policies or procedures you hold relating to interventional radiology.

Interventional radiology works to all relevant Trust Policies with an extensive suite of LOCSips for specific procedures. There is no one overarching Policy which covers all Interventional Radiology procedures.

Please note that it is the Trust's FOI policy to only provide the names of staff that are grade 8a or above, therefore staff that are below that grade have been redacted from the attached policies.

Cont…/

Please note that we have also redacted the names of staff that no longer work within the Trust, signatures, personal email addresses, and names of individuals that do not work for the Trust, within the policies. We are therefore applying Sections 40(2) and 44.

I can confirm that we hold this information, but it is exempt under section 40(2) of the Freedom of Information Act 2000 – Personal Information of third parties. This is because disclosure of this information would breach the principles of the Data Protection Act.

This is an absolute exemption and there is, therefore, no requirement to consider the public interest.

We are unable to provide the contact details of staff as we consider this information to be exempt from release in accordance with section 44 of the Freedom of Information Act (Prohibition on disclosure) and would refer to the Privacy and Electronic Communications EC Directive Regulations 2003 which provide specific rules on electronic communication services, including marketing (by phone, fax, email or text) and keeping communications services secure. We will not provide any information that could result in the transmission of unsolicited communications which may place an unacceptable risk to our email network and could also have a detrimental impact on patient care and treatment.

The contact number for the Trust are accessible on the Trust website http://www.esht.nhs.uk.

This is an absolute exemption and there is, therefore, no requirement to consider the public interest.

If I can be of any further assistance, please do not hesitate to contact me.

Should you be dissatisfied with the Trust's response to your request, you have the right to request an internal review. Please write to the Freedom of Information Department (esh-tr.foi@nhs.net), quoting the above reference, within 40 working days. The Trust is not obliged to accept an internal review after this date.

Should you still be dissatisfied with your FOI request, you have the right of complaint to the Information Commissioner at the following address:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 0303 123 1113

Yours sincerely

Freedom of Information Department
esh-tr.foi@nhs.net

East Sussex Healthcare NHS Trust

IR(ME)R 2017 Employers Procedures Manual

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Version:	V13
Ratified by:	Radiation Protection Committee
Date ratified:	26 September 2023
Name of author and title:	Dr Justin Harris, Clinical Lead, ESHT [redacted] Medical Physics Expert, UHSussex [redacted], Clinical Scientist, UHSussex
Date originally written:	January 2001
Date current version was completed	26 September 2023
Name of responsible committee/individual:	Chairman, Radiation Protection Committee
Date issued:	14 December 2023
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Target audience:	All Radiological Staff and all Staff involved in Radiological Procedures
Compliance with CQC Fundamental Standard	Safe Care and Treatment Premises and Equipment Good Governance
Compliance with any other external requirements (e.g. Information Governance)	Ionising Radiation (Medical Exposure) Regulations 2017
Associated Documents:	Medical Devices Training Policy and Procedure Management of Medical Devices Policy Procedures for the Communication of Critical, Urgent and Unsuspected Radiological Findings Radiation Safety Policy

Did you print this yourself?

Please be advised the Trust discourages retention of hard copies of the procedural document and can only guarantee that the procedural document on the Trust website is the most up to date version.

Version Control Table

Version & Issue Numbers	Date	Author(s)	Reason for Change	Description of Changes Made
V 6.0 2010255	May 2010	[redacted] Lead Radiographer EDGH [redacted], MPE	Amendments to IR(ME)R Regulations 2000, 2011 Annual Review	Update of 2011 Regulation Update of current working in Department and new processes
V 7.0 2014193	September 2014	[redacted], RPA	New organisation Annual review overdue	Changes to format of document. Section 15 incidents update to reflect new local reporting system, all reference to East Sussex Hospitals NHS Trust changed to East Sussex Healthcare NHS Trust Updated information on Research (section 7)
V 8.0	October 2017	Dr Justin Harris, Clinical Lead [redacted], MPE [redacted], Clinical Scientist, UHSussex	Review overdue and CQC request	Changes to format and pregnancy guidelines
V 9.0	February 2019	Dr Justin Harris, Clinical Lead [redacted], MPE [redacted], Clinical Scientist, UHSussex	Review & Update	Updated references. Added section on C&Cs. Merged with NM EPs.
V 10.0	December 2020	Dr Justin Harris, Clinical Lead [redacted], MPE Kate Poulter, Advanced Practitioner Radiology	Update	Removal of patient X-ray shielding advice for EP-09a General X-ray pages 43 – 45 in line with national guidance (British Institute of Radiology). NMR application form updated with current job titles and contact numbers.
V 11.0	August 2021	[redacted], MPE	Update	Updated to incorporate the latest CQC guidance (24/08/2020) on reporting Significant Accidental and Unintended Exposures (SAUE) . References to BSUH changed to UHSussex. Generic BSUH MPE e-mail address changed to **uhsussex.mpe@nhs.net** Research application form title added.
V12.0	July 2022	Neil Barlow David Sallomi	Update	Referral criteria for SMSKPE refers added on page 25. Appendix 8 added. NMR application form - queries contact changed on Page 85.
V13.0	September 2023	Heidi Barnett	Update	EP-09 Pregnancy and Breastfeeding Protocol. Updated to reflect latest guidance.

		Chris Salt 		EP-09b Foetal Dose Classification for the Practitioner updated. EP-13 Incident reporting procedure. Updated tables to the latest SAUE guidance. Appendix 8 – reference to Nuclear Medicine referrals added. Non medical referrer application form updated. New EIA form added to replace the Equality and Human Rights Statement

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
[redacted]	Head of Radiological science (Radiation Protection Advisor to ESHT and Medical Physics Expert)	February 2014
Dr Neil Barlow	Clinical Radiology Consultant	February 2014
Dr Justin Harris [redacted]	Clinical Lead, Radiology RPA & MPE, UHSussex Clinical Scientist UHSussex	October 2017
Dr Justin Harris [redacted] Chris Salt	Clinical Lead, Radiology RPA & MPE, UHSussex MPE, UHSussex Clinical Scientist UHSussex Nuc Med Manager	February 2019
Dr Justin Harris [redacted] Kate Poulter	Clinical Lead, Radiology RPA & MPE, UHSussex Advanced Practitioner Radiology	December 2020 (October 2020 Radiation Protection Committee meeting)
Dr Neil Barlow Dr David Sallomi Dr David Hughes Matthew Carr	ESHT IRMER Practitioner Consultant Radiologist Radiology Clinical Lead SMSKPE Clinical Director	February 2023 (July 2022 & February 2023 Radiation Protection Committee Meeting)
Heidi Barnett Neil Barlow Helen Perry [redacted] Chris Salt [redacted]	Clinical Scientist (UHSussex). ESHT IRMER Practitioner. Radiology Divisional Administrator. Deputy Head of Nuclear Medicine Physics. ESHT Nuclear Medicine Modality Manager. Nuclear Medicine- Molecular Radiotherapy Lead Physicist.	July 2023 & Radiation protection Meeting in September 2023

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

Purpose

This Document describes the framework that enables and governs all diagnostic imaging and therapeutic medical exposures of patients within East Sussex Healthcare NHS Trust (ESHT). It contains the administrative and practical arrangements for these exposures, including for those persons requesting an exposure as well as departments performing these exposures. All are expected to follow the arrangements detailed here.

This applies to all Imaging Departments administered by the Trust at:

- The Eastbourne District General Hospital, Eastbourne
- The Conquest Hospital, St. Leonards
- Bexhill Hospital, Bexhill
- Dental units operated by The Emergency Dental Service

This Manual is originally based on the IR(ME)R documents operated by Brighton & Sussex University Hospitals NHS Trust (Now University Hospitals Sussex NHS Foundation Trust (UHSussex)). This is largely a result of the pan-Trust working of medical physics and radiation protection staff at both UHSussex and ESHT. This also aligns with principle 5 of the NHS England Constitution, which obliges the NHS to work across organisational boundaries for the good of patients and communities.

Trust Policy

This manual has been produced in conjunction with the Trust's Radiation safety policy entitled 'The policy for the Safe Use of Ionising and Non-ionising Radiations' and is available via the Trust Extranet.

This includes a commitment to comply with all legislation relevant to the use of ionising radiation (therefore including the Ionising Radiation (Medical Exposure) Regulations, 2017).

The Policy requires that all medical exposures are appropriately justified. The Trust also accepts the need to optimise such exposures and maintain this framework to enable this.

The East Sussex Healthcare NHS Trust agrees to comply with all statutory legislation and accompanying guidance pertaining to the use of ionising radiation for medical exposures. All exposures of patients to ionising radiation must be justified - that is, the benefits to the individual and society must outweigh the risks involved from the exposure. In addition, all diagnostic and therapeutic processes must be optimised to ensure that the desired result is obtained at the minimum practicable dose to the patient. All therapeutic exposures are individually planned to ensure that doses of non-target tissues are as low as reasonably practicable consistent with the intended radiotherapeutic purpose of the exposure. The Trust will ensure that the standards of radiation safety required by law are maintained in accordance with best professional practice.

The Trust will ensure that individual staff are appropriately trained for the tasks they are required to perform. The Trust will also enable continuing training for such staff.

The Trust's Chief Executive has responsibility for compliance with the Regulations, and the production of this document will enable the Trust to fulfil its responsibilities. Practical implementation is through a series of Employer's Procedures relevant to each Speciality, which must be distributed to all relevant staff within the Trust and individuals outside the Trust who have a role in a medical exposure.

The East Sussex Healthcare NHS Trust agrees to provide adequate and appropriate Medical Physics Experts to all areas where ionising radiation is used.

Legislation

The specific legislation addressed in this manual is the Ionising Radiations (Medical Exposure) Regulations, 2017, abbreviated to IR(ME)R. The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 came into force immediately after the Ionising Radiations (Medical Exposure) Regulations, 2017.

The Ionising Radiations Regulations, 2017 (IRR17) which deals with the safety of employees still applies. See the Imaging Department Local Rules.

This introduction sections deals generally with the requirements of IR(ME)R and also specifically with Regulations 10, 11, 12(1), 12(3), 12(8), Schedule 2(1)(i) and Schedule 3.

Scope

The term medical exposure is defined in IR(ME)R as covering the exposure of an individual to ionising radiation in the following categories:-

- the exposure of patients as part of their own medical diagnosis or treatment;
- the exposure of individuals as part of health screening programmes;
- the exposure of patients or volunteers participating in medical or biomedical, diagnostic or therapeutic, research programmes;
- the exposure of carers and comforters;
- the exposure of asymptomatic individuals;
- the exposure of individuals undergoing non-medical imaging using medical radiological equipment.

Overview of an Imaging Medical Exposure

All imaging exposures (with the exception of a recognised National Health screening programme) arise from the consultation of an individual and a referrer. If the referrer believes an exposure is required, they will, wherever practicable, discuss with the individual to be exposed or their representative, the benefits and risks associated with the radiation dose from the exposure. They will then, in accordance with criteria laid down by the Employer and if authorised to do so, make a request to the Imaging Department where a Practitioner will examine the request. The Practitioner will assess the circumstances and weigh the benefit from the exposure with the risks involved, both from the x-ray procedure and from alternative techniques.

If the Practitioner decides there is a net benefit, a trained Operator using appropriate equipment and techniques carries out the exposure. The exposure should generally be carried out with a dose to the patient within the Unit Diagnostic Reference Level (UDRL) identified for most procedures. The outcome of the exposure must be recorded together with data to permit a patient dose to be measured. If the UDRL is exceeded, a note is made of the reason for audit purposes.

The procedure is audited at appropriate intervals in accordance with national guidelines, and the doses administered to the patients are reviewed to ensure Local and Unit DRLs are still relevant. In particular, if a DRL is consistently exceeded an investigation will be carried out to establish the circumstances and appropriate remedial action.

The definitions of Local and Unit DRLs are given in the ESHT DRL Strategy document.

Accountabilities, Responsibilities & Roles

The Employer is responsible for the implementation of IR(ME)R. The Employer is the Trust, therefore ultimate duty for compliance sits with the Chief Executive Officer.

i. Radiation Protection Committee (RPC)

The Radiation Protection Committee is chaired by the Radiology Lead Consultant. The IR(ME)R Subgroup (individual RPSs) of the RPC will consider and act upon those issues relevant to this legislation. This and other specialist subgroups of the Committee may be empowered to undertake specific tasks on behalf of the Committee and the Employer, though the responsibility for all actions remains with the Employer under this legislation.

ii. Head of Radiology

The Radiology Lead Consultant is the IR(ME)R Practitioner responsible for defining Practitioner Guidelines, IR(ME)R 2017 and subsequent amendments policies, procedures and the implementation thereof.

iii. Radiation Protection Advisor Role

The role of the Radiation Protection Adviser (RPA) is defined within Schedule 4 of the Ionising Radiation Regulations 2017 and is separate to the role of the Medical Physics Expert defined within IR(ME)R 2017. However, the RPA is a key member of the Radiation Protection Committee which oversees the compliance with IR(ME)R 2017. The Advisor is appointed by the Chair of the Radiation Protection Committee, on behalf of the CEO, as the representative of the Radiation Employer.

iv. Medical Physics Expert

A Medical Physics Expert (MPE) is defined as “an individual or a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State’

.

The MPE is required to have been adequately trained (as defined in the Regulations) for their involvement in medical exposures under the Regulations. Within ESHT all Medical Physics Experts are required to hold HCPC registration as Clinical Scientists and be on the current national register of MPEs or be HCPC Registered Clinical Scientists working under the supervision of a registered MPE.

The MPE is expected to undertake tasks such as giving advice on patient dosimetry, optimisation of exposure and the development and use of new and/or complex techniques, as well as other matters related to radiation protection concerning medical exposures.

The MPE should not be confused with the RPA as identified under the IRR17. The functions are different although, in practice, it is possible that the same person may undertake aspects of both roles. ESHT will have access to the HCPC registered staff within Radiological Science at Brighton who have the required knowledge and experience to fulfil the role of an MPE covering Diagnostic Radiology and Nuclear Medicine.

v. Referrer

Referrals can only be accepted from registered medical or dental practitioners, or other approved registered health care professionals. In general terms this covers medically qualified personnel within the Trust and in designated GP Practices. Other named referrers may be identified in the Employer's Procedures (*EP-02 Roles*).

Referrers are required to refer patients in accordance with ***Referral Criteria*** produced by the Trust. Detailed criteria are available in a separate document while *EP-03 Referral Criteria* presents some general criteria. An identifiable Referrer must legibly and fully complete all referral forms. Sufficient medical data must be supplied that enables the Practitioner to justify the exposure.

If possible, it is also appropriate for the Referrer to establish the likelihood of pregnancy. Referrals may be refused by Practitioners or Operators acting under Practitioner's Guidelines if there is insufficient medical data provided on the Referral.

vi. Practitioner

The Practitioner is required to justify a medical exposure, taking into account the benefits to the patient and society and balancing them against the risk inherent in the medical exposure.

The Practitioner must ensure that the exposure type (e.g. plain radiography/CT) is selected to ensure that doses arising from the exposure are kept As Low As Reasonably Practicable (ALARP) consistent with the intended purpose. Alternative procedures not using ionising radiation must also be considered, as well as the risks inherent in those procedures.

All Practitioners must be adequately trained which, in addition to sufficient medical knowledge, includes both theoretical and practical knowledge as detailed in Schedule 3 of IR(ME)R. A practising Radiologist with an FRCR qualification will be taken as adequately trained. Other staff will need to demonstrate their training to the Trust which will include attendance at a training course which fulfils the requirements of IR(ME)R Schedule 3.

As a group, only Consultant Radiologists are designated as Practitioners. Other staff members may be so designated as listed in *EP-02 Roles*.

All Practitioners are expected to maintain their knowledge through continuing training. They must maintain a training record available for inspection by the relevant enforcing authority and ensure the training record is kept up to date.

When justifying a medical exposure, Practitioners must take into account special circumstances as described in Regulations 11(1), 11(2), 11(3) and 11(4). The Practitioner must pay particular attention in relation to medical exposures of children, medical exposures as part of a health screening programme, high dose procedures and pregnant and breastfeeding individuals. When an exposure has been justified, the Practitioner shall authorise the exposure on the Computed Radiology Information System (CRIS.)

In most circumstances a Practitioner will not be available to directly justify and then authorise every exposure. In such circumstances Practitioner's Guidelines are used; these Guidelines are incorporated in the Examination Protocols listed in the Imaging Protocol Manual. The Operator will then authorise the exposure on CRIS, provided it complies with the Practitioner's Guidelines. As with Practitioners, when justifying a medical exposure, Operators must take into account special circumstances as described in Regulations 11(1), 11(2), 11(3) and 11(4).

vii. Operator

The Operator is responsible for a variety of tasks that cover the practical aspects of an exposure, as well as tasks of a more general nature that might affect the dose a patient receives. This might include, for example, patient identification, equipment quality assurance, maintenance of a CR system and reporting an x-ray, as well as the obvious function of initiating an exposure.

All Operators must be adequately trained for the tasks they are expected to carry out. If this involves irradiating a patient, it includes both theoretical and practical knowledge of radiation as detailed in Schedule 3 of IR(ME)R. They may also be under training and supervised by a trained Operator. Operators are identified in *EP-02 Roles*.

All Operators must undertake continuing training, and details must be supplied to the relevant modality lead so that their training record can be made available for inspection by the relevant enforcing authority.

A practising State Registered Radiographer will be accepted as fully trained, as will a Radiologist qualified to FRCR level for certain procedures. Other staff may be identified as Operators according to the tasks involved and appropriate training in accordance with Schedule 3 of IR(ME)R.

An Operator undertaking an exposure is ultimately responsible for confirming the identification of a patient even if initial identification is carried out by another (see *EP-08 Patient Identification Procedure*), and for determining the likelihood of pregnancy in a patient of childbearing age (see *EP-09 Pregnancy and Breastfeeding Protocol*).

The Operator is also responsible for optimising the exposure to ensure adequate diagnostic information is obtained for the intended purpose of the exposure with the least possible radiation dose to the patient. Equipment and protocols must be chosen accordingly, taking into account QA and dosimetry data, and the DRL for the procedure.

For Operators not directly employed by the Trust (e.g. Agency staff), the requirement for adequate training (and continuing training) must be included in the contract with the Operator's employer. The training records of such staff must be made available to ESHT immediately on request (IR(ME)R17 Regulation 17(6)).

2. IR(ME)R Management and Employer's Procedures

Introduction

This section contains the individual Employer's Procedures, as required under IR(ME)R 2017. Where procedures have significant variation between X-ray imaging and nuclear medicine, sub-sections have been created to clearly differentiate between the two.

Structure

The document structure for the compliance with IR(ME)R is as follows:

- The Trust Radiation Safety Policy details the Trusts commitment to all legislation applying to ionising radiation.
- This document forms the top level, overarching explanation of how the Trust's IR(ME)R documentation fulfils the requirements of the Regulations. It looks at each of the Trust's Employer's Procedures and indicates how this is dealt with Trust wide.

Employers procedures

IR(ME)R Schedule 2 describes a set of Employer's Procedures that are required by the Regulations. These are regarded as a minimum set – there may be others that it is appropriate to include. In addition, there are a number of requirements placed on the Employer within the Regulations.

The table below lists each Employer's Procedure or other requirement, indicates which part of the Regulations it satisfies and gives relevant information on compliance with the Procedure.

The individual Employer's Procedures are presented in sections EP-01 to EP-22, with various appendices.

Employer's Procedure	Schedule 2	Regulation
EP-01 Licensing		5(1)(a), 11(1)(a)
EP-02 Roles	1(b)	4(4), 5, 6(5), 9(1), 9(2)(c), 11(1,2,3) and 11(4)
EP-03 Referral Criteria		6(5)(a)
EP-04 Patient Information - Risks and Benefits	1(i)	12
EP-05 Nuclear Medicine - Patient Instructions	1(h)	12(5), 12(6), 12(7)
EP-06 Justification and Authorisation of Exposures		**5(1)(b), 10(2), 10(3) and 11**
EP-07 Optimisation		12
EP-08 Patient Identification Procedure	1(a)	
EP-09 Pregnancy and Breastfeeding Protocol	1(c)	
EP-10 Carers and Comforters	1(n)	6(5)(d)(ii) and 12(5)
EP-11 Evaluation of Images/Studies	1(j)	12(9)
EP-12 Accidental or Unintended Exposures – Reducing Risk	1(k)	8
EP-13 Reporting of Incidents involving Exposure to Ionising Radiation	1(l)	8
EP-14 Assessment of Patient Dose and Estimation of Population Doses	1(e), 1(l)	12(9), 13,
EP-15 Use of Diagnostic Reference Levels	1(f)	6(5)(c), 6(7), 13
EP-16 Quality Assurance Programme - Equipment (Inc. Inventory)	1(d)	14(2), 14(3) and 15
EP-17 Quality Assurance Programme - Employers Procedures	1(d)	6(5)(b)
EP-18 Clinical Audit		7
EP-19 Medico-Legal and Health Screening Exposures	2(1)(m) and 3 (Table 1)	11(3)(a), 11(3)(c)(ii), 12(8)(b)
EP-20 Research Involving Ionising Radiation	1(g)	

EP-01 Licensing

Purpose

This Employer's Procedure satisfies the requirements of IR(ME)R 2017 Regulations 5(1)(a) and 11(1)(a).

The Regulations require the Trust to hold a valid licence for each site at which radioactive substances are to be administered. Practitioners must hold a valid licence.

Readership

- Medical Physics Experts
- Practitioners
- Nuclear Medicine Manager

Licensing

Schedule 1 details the application and change process for IR(ME)R Licenses. The Trust must hold a valid licence for each site at which radioactive substances are to be administered. Practitioners must hold a valid licence to enable them to justify exposures.

These Employer's Procedures ensure that the information required by the Licensing Authority to licence a person – listed in Schedule 1 (2), with guidance in sections 2 and 3 of the ARSAC notes for guidance – is present in the Nuclear Medicine Quality Management System.

Location

Physical licences are stored in the Nuclear Medicine department. Electronic copies are stored on the Radiology database. Electronic and hard copies are also held by the Radiological Science section of UHSussex Medical Physics.

Responsibilities

The Department Manager holds overall responsibility for ensuring that each site is licensed as appropriate. Advice may be sought from the Trusts MPEs.

Practitioners are responsible for obtaining their own licence, as appropriate.

Practitioners are also responsible for ensuring that both the Trust and practitioner are licenced to undertake exposures they justify, in line with Regulation 11(1)(a).

EP-02 Roles

Purpose

This Section satisfies the requirements of Schedule 2(1)(b), Regulations 4(4), 5, 6(5), 9(1), 9(2)(c), 11(1, 2 and 3) and 11(4). It identifies Practitioners, Operators, Referrers and Medical Physics Experts and their training requirements.

Readership

- Practitioners, Operators and all potential Referrers
- Clinical Directorate Managers and Directors
- The Director of Personnel and the Chief Executive Officer
- Medical Physics Experts (MPEs)

Description

IR(ME)R requires that Practitioners, Operators, Referrers and Medical Physics Experts be identified in the Employer's Procedures. This section identifies staff fulfilling these roles, and describes the qualifications and training required by those staff. It also identifies the arrangements for maintaining training records for those staff.

It is the responsibility of each IR(ME)R Practitioner and Operator to ensure their training details, and details of continuing training are available for inspection at any time.

The Trust uses Practitioner's Guidelines to allow operators and other fully trained staff to authorise exposures.

The following tables contain the details of these IR(ME)R roles:

- Table 1 – Referrers (All Modalities)
- Table 2 – Practitioners (General Radiology)
- Table 3 – Practitioners (Nuclear Medicine)
- Table 4 – Operators (General Radiology)
- Table 5 – Operators (Nuclear Medicine)

Note: There are separate requirements for IR(ME)R Practitioners and Operators taking responsibility for Nuclear Medicine examinations.

Referrers

Non-medically trained staff may refer patients for x-ray imaging only when following protocols as agreed by the Radiation Protection Committee of East Sussex Healthcare NHS Trust. Individual staff members who wish to act as referrers under these protocols must be able to prove that they have been adequately trained for the task. Radiographers acting under Practitioners' guidelines and agreed protocols will be considered to have been adequately trained for this task.

For all other staff groups, The Radiation Protection Committee of East Sussex Healthcare NHS Trust IR(ME)R will consider the question of adequate training and decide whether the evidence provided about the level of training the individual has received is adequate and acceptable to the Trust.

Non-medically qualified professionals who wish to apply to become (new) referrers must complete the Trust's application form and submit this with evidence of training and agreed protocols/schemes of work for the speciality in which they wish to practice.

Application for Entitlement to Act as Referrer

The Ionising Radiations (Medical Exposure) Regulations, 2017 require that all patients x-rayed at East Sussex Healthcare NHS Trust are referred by a registered medical practitioner, dental practitioner or other health care professional that have been granted entitlement by the Trust. Application is made to the Radiation Protection Committee via a form – this may be found in Appendix 1.

Service Engineers

Service engineers are not Trust appointed 'operators' but will perform operator tasks as specified by their employer. The Department must carry out its own QA measurements before the equipment is used clinically after a Service Visit whether Corrective or Preventative.

Authorisation

Operators who physically perform the patient exposure are also trained to authorise an exposure in accordance with EP-06 - Justification and Authorisation of Exposures. Provided they follow the Practitioner's Guidelines explicitly, the clinical responsibility for the exposure remains with the Practitioner.

If the Operator does not comply with the Guidelines then they take responsibility in law for their actions. Note, under these circumstances it is not possible for the Operator to take on the role of Practitioner.

Medical Physics Experts

A Medical Physics Expert (MPE) must be closely involved in every non-standard therapeutic nuclear medicine practice. They must be involved in all other nuclear medicine practices, ,high dose computed tomography and high dose interventional radiology . They must be available for consultation on optimisation in all other radiological practices. They must give advice on dosimetry and quality assurance.

They must contribute towards training, advice on legislative compliance, radiation protection (in liaison with the Radiation Protection Adviser and Radioactive Waste Adviser), optimisation, all stages of the equipment lifecycle including quality assurance and incident analysis. An MPE must be a Clinical Scientist registered with the Health and Care Professionals Council (HCPC), hold Corporate Membership of IPEM (MIPEM) and be on the RPA2000 MPE Register.

Referrers		
Definition A Referrer is defined as a registered health care professional who is entitled in accordance with these Employers Procedures to refer an individual for a medical exposure to an IR(ME)R Practitioner. Referrals must be carried out in accordance with the Referral Criteria laid down by East Sussex Healthcare NHS Trust (Section 2 of this document).		
Referrer	**Location of Determining List**	**Special Comments**
All medically qualified staff within East Sussex Healthcare NHS Trust	Medical Staffing	For certain specialised procedures, referrals can be made ***only*** as specified in the referral guidelines. The responsibility lies with the Trust to ensure all medical staff are appropriately qualified. On-Call CT – follow on-call procedure
Any Registered GP on the East Sussex Healthcare NHS Trust Radiology Information System	RIS ESHT and Community	Can refer for examinations as determined by the Employer's Referral Guidelines (Royal College of Radiologists' Referral Guidelines) The Principle GP at each Practice is responsible for ensuring the practice GPs (including locums) are appropriately qualified and IR(ME)R trained.
Any Registered GP in England	GMC Register and Confirmation of Practice Address (RIS)	Can refer for examinations as determined by the Employer's Referral Guidelines (Royal College of Radiologists' Referral Guidelines) The Principle GP at each Practice is responsible for ensuring the practice GPs (including locums) are appropriately qualified and IR(ME)R trained.
Dentists	Radiology Department - RIS	Dental x-rays only (OPG, CephStat, Intra Oral) Practices must be responsible for ensuring all staff are appropriately trained and able to refer.
Other non-medically qualified healthcare professionals	Radiology Department	As per referral criteria, Practitioners' guidelines, agreed protocols or as defined in the body of this documentation. To be agreed by the RPG – Podiatrists, Stroke Nurses, A&E ENPs, A&E Nurses, Physiotherapists

Table 1 - ESHT Referrers

IR(ME)R Practitioners – General Radiology			
Definition A Practitioner is defined as a registered health care professional who is entitled to take responsibility for a medical exposure. They are responsible for the justification of a medical exposure, and they must comply with the Employer's Procedures.			
Practitioner	**Minimum Qualification**	**Training**	**Special Comments**
Radiologist Radiology SpR	FRCR 2nd year and upwards	Included in FRCR Part 1	Covers all general, non- specialist examinations, cross-sectional imaging and some dental radiology. Interventional examinations will be justified on an individual basis by an Interventional Radiologist. Paediatric examinations will routinely be justified by the Radiologists specialising in paediatric imaging, but in their absence, may be justified by the other Radiologists. Mammography requests will be justified by Radiologists specialising in breast imaging.
Consultant Cardiologist	MRCP	Specialist Training within their own speciality	Examinations limited to Cardiology x-ray procedures. All Other procedures e.g. renal angiography, are covered by Radiological Practitioner guidelines
Dentists	Minimum BSc Dental surgery	Included within BSc training	Dental Radiology only. Acting according to National Guidelines

Table 2 - ESHT IR(ME)R Practitioners – General Radiology

IR(ME)R Practitioners – Nuclear Medicine	
Task	**Training Requirement**
Diagnostic examinations involving the administration of radioactive medicinal products	CCT Nuclear Medicine ***OR*** CCT/CESR(±CP) Level 1 Competency in Radionuclide Radiology FRCR **AND** ARSAC certificate including the relevant serial number, for the site performing the examination ***OR*** IR(ME)R licence including the relevant procedure code
Therapeutic examinations involving the administration of radioactive medicinal products	CCT Nuclear Medicine ***OR*** CCT/CESR(±CP) Level 2 Competency in Radionuclide Radiology FRCR **AND** ARSAC certificate including the relevant serial number, for the site performing the examination ***OR*** IR(ME)R licence including the relevant procedure code

Table 3 - ESHT IR(ME)R Practitioners – Nuclear Medicine

Operators				
Definition An operator is a person entitled to carry out any practical aspect of an exposure. They must act in accordance with the Employer's Procedures and any Guidelines laid down by Practitioners. It is the responsibility of each operator to ensure their training details, and details of continuing training, are available for inspection at any time and are kept up to date				
Task	**Operator**	**Qualification**	**Training**	**Special Comments**
Authorisation of Exposures	Radiographers Radiologists Cardiologists Radiology Registrars	State Registration FRCR MRCP + speciality training HPCP Registration	In line with Authorisation Procedure and personal competence level	All exposures must be authorised according to Practitioner's Guidelines
	A&C staff book appointments following vetting procedure carried out by clinical members of staff	Radiology A&C staff trained in the making of appointments depending on the urgency and vetting instructions.	Awareness of Authorisation Procedure and own level of competence	On an individual basis by the appropriate practitioner Request forms must have the initials of the authorising operator noted on the front of the form.
	Clinical Modality Managers	State Registration		For FB in orbits only under agreed protocol
Patient Identification	The person actually irradiating the patient		Patient identification procedures (section 3) IRMER Training	
Radiography (General)	Radiographers	State Registration	Degree qualified or DCR	General radiography

	Student Radiographer Assistant Practitioner under training Assistant Practitioners			Must be under direct supervision of Radiographer or Radiologist
Radiography (Dental)	Dentists	BSc Dental Surgery	Within BSc Course	Dental Radiography ONLY
	Dental assistants		As per guidance notes for dental practitioners	
Radiography (CT)	Radiographers	State Registration	Additional training in CT scanning	Post Grad Course, or must be assessed as competent to practice in the speciality in line with competency sign off
Fluoroscopy and associated Radiography	Radiologists	FRCR	To Part 1 FRCR at least	
	Radiographers and student Radiographers	State Registered or under training	Training in special procedures as necessary	Post Grad Course, or Competency Standards achieved. Students must be supervised
	Nurses Assistant Practitioners under training		Locally provided training and assessment of competencies by Clinical Lead	Assisting Radiologists, Radiographers and Cardiologists under direct supervision. Competency Standards achieved Nursing staff are considered operators as some of their actions may affect the dose E.g. scrub nurses assisting in Interventional procedures.

	Radiology Registrars	MRCP +speciality training	Registrars undergoing speciality training	Registrars under training must be adequately supervised. Radiographers may judge whether the Registrar is being supervised, and if not, should immediately voice their concerns to the Head of Service
	Cardiologists	IRMER Trained & Cardiologist Training	Consultant Level	Cardiologists perform a variety of procedures in the Cardiac Angiography Suites
	Surgeons & Assistant	IRMER Training & Equipment Training & Approval from RPC	Training in special procedures as necessary Specialist roles with JD reflecting Practice	MINI C-ARM use in Theatres only Examinations are extremity only
Radiographer Quality Assurance Programme & Tests	Radiographers	State Registered	Within BSc degree or departmental training programme and competency assessment	Radiographer QA only
	Student Radiographers and Assistant Practitioners +/- under training			Students and Assistant Practitioners under training must be under direct supervision by a Radiographer/Physicist
Medical Physics Quality Assurance Programme & Tests	Medical Physicists	IPEM Training scheme or equivalent	In house training in appropriate tests	Medical Physics Tests only - no patients. As per contract with Brighton and Sussex University Hospitals NHS Trust
	Medical Technical Officers	Training scheme or equivalent	In house training in appropriate tests	

Reporting General X-Ray Examinations	Radiologists	FRCR	GMC & FRCR	Report all radiographs
	Advanced Practitioner Radiographers	State Registration	Post Graduate Qualification in Speciality area of reporting	**Subject to audit and re-validation**
	SLA with QVH NHS Trust - Radiologists	FRCR	GMC & FRCR	
Reporting CT Examinations	Radiologists	FRCR	GMC & FRCR	
	Advanced Practitioners Radiographers	State Registration	Post Graduate Qualification in Speciality area of reporting	**Subject to audit and re-validation**
	Medica – Outsourcing Radiologists	FRCR	GMC & FRCR	
Clinical Evaluation	Non-Medicine Specialty e.g. Orthopaedics	Medical qualification	As per clinical speciality	**Subject to Audit & Must be clearly documented in the patient's notes**
	Dentists	Dental qualification		
	DEXA Referrals		GP Reviews Report	

Table 4 - ESHT Operators - General Radiology

Operators – Nuclear Medicine				
Task	**Operator**	**Training Status**	**Additional Training**	**Comments**
Authorisation of exposures	ARSAC Consultants	As for IR(ME)R Practitioners taking responsibility for Nuclear Medicine examinations	Awareness of authorisation procedure and local competency based training	In accordance with Nuclear Medicine practitioners guidelines.
Dispensing radioactive medicinal products	Nuclear Medicine Radiographers or Technologists	State Registration	IRMER update training (ESR) every 3 years. Local competency based training	In accordance with NM SOP's
Administration of radioactive medicinal products				
CT component of hybrid NM examinations				
Patient identification				
Quality control of Gamma cameras	Nuclear Medicine Radiographers, Technologists or Physicists			
Quality control of dose calibrators				
NM Imaging	Nuclear Medicine Radiographers or Technologists	State Registration		
Reporting of Nuclear Medicine Examinations	ARSAC Consultants Or Reporting NM Radiographers	FRCR or MSc level NM Reporting		
Training on new equipment	Applications specialist	Manufacturer training		Broadly supervised by NM staff

Table 5 - ESHT Operators – Nuclear Medicine

EP-03 Referral Criteria

Purpose

This Section satisfies the requirements of Regulation 6(5)(a). It lists the referral criteria appropriate for different radiological procedures.

Readership

The referral criteria are available to any of the referrers to East Sussex Healthcare NHS Trust, and to all Operators authorising exposures under Practitioner's Guidelines.

Description

The Regulations require, the Employer, i.e. East Sussex Healthcare NHS Trust, to establish criteria for Referrers. This details the minimum information required by the Practitioner to justify the exposure considering the benefits to the patient and the risks involved in the procedure.

iRefer is the essential radiological investigation guidelines tool, from The Royal College of Radiologists (RCR). This can be accessed by registered users at;

https://www.rcr.ac.uk/clinical-radiology/being-consultant/rcr-referral-guidelines/about-irefer

Referrers should also be aware of the document RP118 of the European Commission, available at: http://ec.europa.eu/energy/sites/ener/files/documents/118.zip

General Criteria

i. Medical Exposure WILL NOT occur until a valid Referral has been completed, unless in an Emergency as per point v, below.
ii. Referrals MUST come from an approved Referrer as per *EP-02 Roles*.
iii. Paper requests - The Referrer MUST be clearly identifiable, with a signature and printed name in the designated referral form. For Internal Hospital referrals, bleep numbers or contact number of the referrer should also be given on the referral form.
iv. Electronic requests are created using a password protected / smart card protected login to access the referral IT Systems. This means only authorised referrers can create these requests. The requests come with details of the requesting referrer but there is not the functionality to add electronic signatures. These requests are acceptable to process as the approval process provides assurance that application approval and IRMER training has been completed for each of these referrers prior to IT system set up. This also includes all appropriate competency training. These requests also provide an audit trail of who created the request, and the contact details should the radiology team want to contact the referrer to discuss the request. Requests are typically made by appropriately qualified referrers who work in the ESHT catchment area. See Appendix 8 for organisations requesting outside of the Trust.
v. Any referral not complying with these criteria will be returned to the Practice or referrer to be corrected. A record of referral forms being returned will be kept on the RIS system for monitoring purposes. Referrers with a frequent record of poor referrals may have their referral rights removed, at the discretion of the Chair of the Radiations Safety Committee.

vi. In an emergency, if a referral form has not been completed by the referrer requesting fluoroscopic control of a procedure (e.g. in theatre or pacing suite) and;

i. The requesting Clinician is unable to complete the request form at that time because they are scrubbed
ii. **and** the patient is already anaesthetised or sedated for that procedure

Then the attending Radiographer MAY complete and sign a request form on behalf of the referrer. The Radiographer MUST indicate on the request form that the requesting Clinician was unable to sign the form at that time. This should occur ONLY in those cases where the patient's treatment / condition would be compromised by the examination being delayed. The Radiographer must exercise professional judgement in these cases. The responsibility for the referral however, remains with the requesting clinician. Near Miss Incidents will be reported on datixweb at such time by the radiographer for monitoring purposes.

vii. Patient data MUST be CLEAR & LEGIBLE and include Patient's:

- Full Name
- Full Residential Address
- NHS number (if available)
- Date of Birth
- Gender
- Date of LMP if female between the ages of 12 and 60*
- Is patient breastfeeding or pregnant?
- Is transport required?

viii. Relevant medical information must be supplied including:-
- Relevant clinical details
- Suggested examination including a clear statement of anatomical site and laterality if relevant
- Other relevant information e.g. allergy to x-ray contrast media, disabilities, language difficulties, any pre-existing medical conditions requiring special consideration.
- Date and place of last x-ray

ix. Cancellation. If it is discovered that an examination that has been requested is no longer necessary, the Referrer must ensure that the appropriate Radiology Department is notified immediately to prevent an unnecessary exposure.

x. Clinical Evaluation. Should a report on an image not be required it is essential that a clinical evaluation be made on that image in the patient's notes. The Referrer should do this or the team on whose behalf the referral is made.

xi. Research. Research projects that involve the use of radiation should be discussed with a Radiologist for further advice. See *EP-20 Research Involving Ionising Radiation*.

Non-Medical Referrers

Certain other non-medical healthcare professionals may also refer for specific examinations. Separate documentation is maintained to describe the Employer's policy and strategy for enabling specific groups of qualified Advanced Healthcare Practitioners to refer to the Trust.

EP-04 Patient Information - Risks and Benefits

Purpose

This Section satisfies the requirements of Schedule 2 1(i).

Readership

- Referrers
- Practitioners
- Operators

Description

Schedule 2 1(i). states that the Employer must have written procedures for "*providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure".*

This broad requirement may be met in a variety of ways, depending on the examination/procedure to be undertaken. The guidance to IR(ME)R provided by the Department of Health & Social Care states that the *"amount of information and the methods of conveying information should be commensurate with the associated risk."* This section details the methods and level of complexity of such information, broken down by modality.

General X-Ray

- Information posters in the waiting areas.
    - Written in conjunction with MPEs
    - Qualitative information presented in a succinct manner – for example, equating the dose from a typical chest X-ray to the number of days of normal background radiation, trans-Atlantic flights, bananas etc.
    - Relevant to the clinical context – i.e. low-dose.
    - Highlights that the patient may approach a radiographer to discuss if they wish to – junior radiographers may approach an RPS if unable to sufficiently answer the patient's questions.

Nuclear Medicine, Non-Emergency CT Scans & Dental Radiography

- Imaging studies;
    - A short contextual paragraph is provided in each appointment letter sent to the patient;
        - Based on the ARSAC activity for each study (NM) or ESHT typical effective doses (CT & Dental).
            - Doses estimates for CT and descriptors thereof cannot be too specific; given the population body habitus distribution and the variation in exact imaging protocol used, a range of doses/descriptors may be used. For example, "*This CT scan may deliver a dose of between 5-10 years' worth of background radiation*"

        - Radiation dose is equated to natural exposure sources, such as the general background radiation field, trans-Atlantic flights etc.
        - Highlights the Justification process and in particular, how the potential benefits (in terms of diagnosis and treatment) outweigh the theoretical risks.
        - Notes that the radiation induced secondary cancer risk drops-off with patient age.
        - Highlights that the aim is to deliver an optimised dose, which is a dose that is ALARP.
        - Highlights the risks of **not** having the study.
    - For example, an appointment letter for an NM bone scan might read;
        - "***Please note****: You will receive a small dose of radiation during this scan. This dose is approximately equivalent to the dose we all receive from a couple of years' worth of natural background radiation. The healthcare professional authorising this scan believes any risk associated with this extra dose is very small, especially set against the risk of not having this scan and potentially missing a diagnosis or negatively affecting any treatment plans. If you have any questions, please feel free to discuss them with your referring doctor or at your appointment.*"
    - A leaflet describing the general risks and benefits is available within the department to all patients.
- NM Therapy patients;
    - I-131 treatments for thyrotoxicosis are given by ESHT.
    - Risks and benefits are discussed in-person with each patient by the endocrinologist ARSAC licence holder.
    - A set of written instructions (see *EP-05 Nuclear Medicine - Patient Instructions*) is given to the patient – this also describes the risks and benefits.
    - The patient has a further opportunity to discuss such matters at the administration appointment, prior to administration of the treatment capsule.
- MPEs are available via phone or in-person during normal working hours to answer any patient questions.

Interventional Radiology

- For elective procedures, a short contextual paragraph is provided in the appointment letter in a similar fashion to those described above.
- Additional statements regarding the potential for deterministic effects, such as skin burns, are included. The potential for such effects must also be discussed with the patient if practicable, by a suitable healthcare professional (i.e. radiologist, senior radiographer).

Emergency Examinations

- In emergency situations, for example A&E trauma cases or emergency cardiac catheter lab work, precedence must be given to the immediate medical needs of the patient.
    - Normal justification and authorisation applies (see *EP-06 Justification and Authorisation of Exposures*).
    - Risks and benefits associated with any exposures should be discussed with the patient at a suitable convenient time, for example in recovery.

EP-05 Nuclear Medicine - Patient Instructions

Purpose

This Nuclear Medicine Employer's Procedure satisfies the requirements of IR(ME)R 2017 Regulations 12(5), 12(6), 12(7) and schedule 2(h).

The Regulations require that appropriate guidance is established for the exposure of carers and comforters and that written instruction and information is provided, where appropriate, to patients undergoing treatment or diagnosis with radioactive materials. Such information must be given to a suitable other person where the patient lacks capacity.

Information for Carers and Comforters

The employer will provide standard information and instructions, in the form of patient leaflets, for the carers or comforters of patients undergoing the following;

- Diagnostic administration of ^{99m}Tc
- Diagnostic administration of non-^{99m}Tc radionuclides
- Administration of radioiodine
- Administration of Radium

Such written information should be accompanied by a verbal walk-through of the instructions by the operator, if possible, prior to administration of the radioactivity.

Advice on the content of the written information and instructions must be sought from the MPE(s) and take into account any published guidance from appropriate professional bodies or government departments/agencies.

Advice to Radioactive Patients

Where appropriate, patients administered with radioactive medicinal products must be given written information on the risks of ionising radiation and any appropriate practical advice for reducing those risks as far as reasonably practicable.

This is appropriate when the exposure to the patient may exceed the level at which measurable harm may be done; therapeutic administrations may satisfy this criterion. It is also appropriate when the exposure to persons in contact with the patient may exceed 3/10ths of the limit specified in paragraph 7 of Schedule 3 of the Ionising Radiations Regulations 2017; breastfeeding patients may satisfy this criterion.

In the case of paediatric patients, the person with parental responsibility should be given this information and advice. Where the patient lacks the capacity to consent to the procedure, the person judged to be most appropriate by the practitioner should be given this information and advice.

In all other cases where a patient is administered with a radioactive medicinal product, appropriate practical advice for reducing the risks arising from exposure to ionising radiation as far as reasonably practicable should be given verbally

Location

Written information and advice to patients is located in the Letters section.

EP-06 Justification and Authorisation of Exposures

Purpose

This Section satisfies the requirements of IR(ME)R 2017 Regulations 5(1)(b), 10(2), 10(3) and 11. The Regulations require the Trust to establish the strategy for justification of medical exposures.

Readership

- Administrative Staff
- Operators
- Practitioners
- Medical Physics Experts

Introduction

All medical exposures must be justified taking into account the objectives of the exposure for the individual concerned. This involves balancing the potential benefit of the exposure to the patient and their family (or society) against the radiation doses and hence the associated individual detriment that exposure may cause. The exposure must have a sufficient net benefit over that of suitable alternative techniques for the medical exposure to be justified and this also applies to any exposure of an asymptomatic individual.

All diagnostic procedures carry some personal risk to the patient. Irradiation during pregnancy may be a risk to the foetus, so it is important that only exposures that are necessary are undertaken. Alternative methods of obtaining the required diagnostic information with less risk to the patient or foetus should be considered, e.g. by the use of non-ionising radiation.

Clearly, the practitioner must be well versed in matters that pertain to the relative risks and benefits arising from the procedure as well as possible alternative procedures with their associated risks and benefits.

As well as justifying the exposure to the patient, Regulations 11(1)(b) stipulates that when there is to be an exposure to a carer or comforter, the practitioner must also justify this exposure with regard to the type of net benefits set out in 11(2) and 11(3)(b). It is acknowledged that in the case of carers and comforters, these benefits are likely to be psychological. This should be done on an individual basis and is fulfilled with a set of Practitioner's Guidelines covering exposures to carers and comforters, which a member of staff can then use to authorise individual exposures.

EP-06a General Operators Responsibilities

In order to authorise and/or perform an x-ray procedure, an Operator needs to be aware of the following:

- The referral criteria; to ensure adequate information has been supplied
- The Practitioner's Guidelines, to enable them to authorise the exposure
- The examination protocols AND standard operating procedures (i.e. typical exposures)
- Previous x-ray/NM study history
- The Unit Diagnostic Reference Levels (UDRLs) for the examination
- Whether the equipment QA is current
- Whether the equipment is operating normally

If there is any uncertainty as to whether the exposure can be authorised under Practitioners' Guidelines, the Radiographer/Technician concerned must not proceed until they are certain that the exposure is justified, and can be authorised.

Ultimately it is the responsibility of the Operator to be satisfied that the exposure has been authorised either directly by the IR(ME)R Practitioner or by the Operator using the Practitioner's Guidelines.

In both cases, the Practitioner takes the responsibility for the justification of the exposure – if an Operator performs the task in accordance with the Practitioner's Guidelines, the Operator MUST follow those guidelines or in the event of litigation, they will be held personally responsible for their actions.

Justification and Authorisation Procedure

Before any referral is processed, reference should, whenever possible, be made to the RIS or to other appropriate records (e.g. patient's notes for Cardiology) to check the patient's previous imaging history to avoid unnecessary exposures. If records cannot be checked, a verbal enquiry of the patient should be made at the very least.

a) Exposures Authorised by an IR(ME)R Practitioner

In this case an Operator will be requested to take an x-ray after a Practitioner has directly and personally justified the exposure. The request (referral) will carry the signature of the Practitioner, which authorises the Operator to proceed with the exposure.

Within Cardiology, the referral will be according to set protocols determined by the Consultant Cardiologists, acting as IR(ME)R Practitioners, and will be written within the patient's notes.

The Operator is required to ensure the Practitioner is recognised by East Sussex Healthcare NHS Trust. They must adhere to the requirement to ensure the patient is not pregnant, and to check the correct identification of the patient.

The Radiographic staff should use their professional skill and judgement to ensure the exposure is optimised i.e. that an appropriate image of acceptable diagnostic quality is obtained at the minimum dose.

Equipment must be selected with optimisation in mind (see *EP-07 Optimisation*).
The operator must be convinced that the equipment has been subject to an up to date QA check and is working within acceptable performance limits

b) Exposures Authorised by the Operator (under Practitioner's Guidelines)

Operators may carry out an exposure if the procedure has been justified by a Practitioner as described in the Imaging Protocol Manual – the Practitioner's Guidelines. The Operator then authorises the examination directly on CRIS.
The process is as follows:-

- Confirm the request has complied with the referral criteria. If not, the request must be returned to the Referrer to be completed correctly.
- If the request has come from someone you do not recognise as an approved Referrer, confirm this by reference to the CRIS system. If the request appears to be urgent discuss with an IR(ME)R Practitioner who may act as a Referrer in this instance. All other requests should be returned to the referrer explaining it can only be accepted by an approved referrer. Ensure the relevant Clinical Modality Manager is aware of the situation.
- Check that the request complies with the Practitioner's Guidelines. If not, refer the examination to a Practitioner who may still authorise the exposure, or they will return the request to the Referrer with an appropriate explanation.
- The Operator must ensure that the request complies with the Referral Criteria and the Practitioner's Guidelines. The Operator may then proceed to x-ray the patient in accordance with the Imaging Protocol Manual. It is best practice that the operator indicates on CRIS that the procedure has been both authorised under Practitioner Guidelines and undertaken by the operator. However it is implicit that Operators will always work in accordance with Practitioner Guidelines and where the CRIS Practitioner field is not completed then the Operator takes full professional responsibility for having imaged the patient with due regard to the Guidelines.
- If any radiographer is unclear as to whether they should authorise an exposure they should refer the matter to a more senior colleague who, in light of their experience, may authorise the exposure and will complete the CRIS entry. The Operators will also be required to confirm completion of the procedure on CRIS.

In the event of a dispute, advise the Referrer to contact an IR(ME)R Practitioner.

If the room QA is not current, the examination is urgent and can only be carried out in that room, a Practitioner must be consulted before the exposure takes place. Alternatively, the QA could be carried out first.

After Authorisation

Once an examination has been authorised by either of the above methods, the Operator must perform the examination in accordance with best professional practice.

If further views to those identified in the Guidelines are necessary, these must be individually justified and authorised by an IR(ME)R Practitioner.

Post Examination

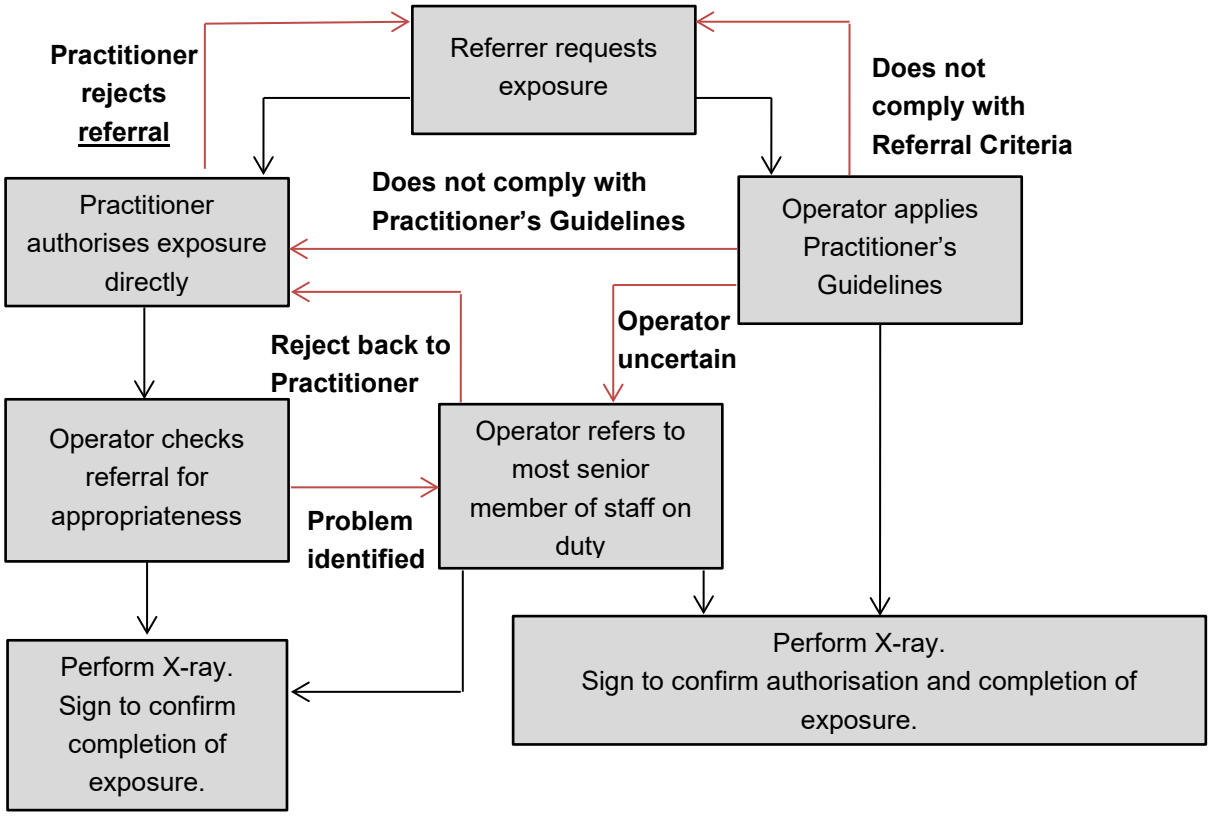
After the exposure has been completed, all relevant information must be recorded on the RIS, on the patient request form, in the imaging logbook, or in the patient's notes, including information relevant to the calculation of a patient dose (see *EP-14 Estimation of Patient Dose and Population Doses*).

If the dose to the patient exceeds the UDRL for that examination, then the actions described in *EP-15 Use of Diagnostic Reference Levels* must be followed

Standard Operating Protocols and DRLS must be available to all Radiographers and assistants within the rooms. These should be signed and dated by the Modality Manager in charge of that area. Any changes to the Standard Operating Protocols can be authorised only by the Radiology Services Manager.

For manufacturers pre-programmed settings, a record of those settings must be kept in the room and any changes to them must be indicated and notified to the Modality Manager for that area, and the Radiology Services Manager. Under no circumstances are they to be changed or written on by anyone other than the person authorising them.

A flowchart outlining the alternative ways of justifying an exposure is given below:



EP-06b Nuclear Medicine

Practitioners in Nuclear Medicine

The practitioner is defined as an appropriately trained person holding an ARSAC certificate or IRMER licence, including the serial number or procedure code for the relevant examination. The practitioner is solely responsible for carrying out justification of nuclear medicine procedures.
An appropriately trained person with a delegation letter from an ARSAC certificate or IRMER licence holder may authorise nuclear medicine procedures. In this way the person is acting as an operator.

Justification and authorisation are NOT performed by any staff without a relevant delegation letter from an ARSAC certificate or IRMER licence holder.

For the practitioner to justify the exposure, or the operator to authorise the exposure acting under the Practitioner's Guidelines, these steps must be followed:

- Check that the referral has come from an approved referrer, e.g. a doctor. See referral guidelines for exams a GP can request.
- Ensure that the requested examination is listed in the clinical indications of the relevant examination protocol.
- Ensure that adequate information has been supplied to justify this exposure.
- Check previous history to ensure that exam needs to be performed.

If the examination is not justifiable then the referrer must be contacted for further information, or the referral rejected.

Authorisation in Nuclear Medicine

Authorisation is a separate process demonstrating that Justification has been carried out. In order to authorise a Nuclear Medicine procedure, the following information must be available:

- The referral clinical details to ensure adequate information have been supplied
- The clinical indication and examination protocols
- The Practitioner's Guidelines
- The estimated effective dose to the patient
- Previous imaging history

If the examination is justified, then authorisation can be demonstrated by one of the following two methods:

- Physically sign the request (referral letter or request form) and write the intended study protocol, including CT where applicable. Return the request to the booking team so it can be scanned onto CRIS.
- Enter these details on CRIS using the e-vetting module.

Operator in Nuclear Medicine

When the patient attends for their examination ensure that the request has been authorised, either by signature and written study protocol on the request, or the same information has been entered on the CRIS e-vetting system.

Write your initials in the box on the Patient Record Sheet that the request has been appropriately vetted.

If you have any questions regarding the validity of the request or authorisation, then contact a senior colleague for advice. If further clarification is required, then discuss with an appropriate practitioner.

EP-07 Optimisation

Purpose

This Employer's Procedure satisfies the requirements of IR(ME)R 2017 Regulation 12.

Readership

- Operators
- Practitioners
- Medical Physics Experts
- Modality Managers

Optimisation

Practitioners ensure that radiation doses are kept ALARP by individually justifying medical exposures. Once an exposure has been justified and authorised, it is the Operator's responsibility to optimise the exposure - that is to ensure the dose is as low as reasonably practicable consistent with the intended purpose. Operators must exercise their best professional judgement in the tasks they carry out to minimise the patient dose whilst producing x-ray images of acceptable diagnostic quality.

Possible examples are:

- Good Radiographic technique which includes checking any previous imaging which might help in the choice of technique and factors that should be used.
- If Room 'A' results in lower fluoroscopy doses and acceptable image quality compared to Room 'B', then preference should be given to Room 'A'. This could mean scheduling higher risk patients and higher dose procedures in Room 'A'.
- Use the most appropriate equipment for the examination.
- For digital imaging, it is essential that the minimum factors necessary be used for these exposures. Giving deliberate additional radiation in the knowledge that post processing can produce an acceptable image is both unprofessional and in breach of the Regulations, and could result in a personal prosecution by the Department of health.
- Operators must exercise their best professional judgement in the tasks they carry out to minimise the patient dose whilst producing x-ray images of acceptable diagnostic quality. Students and other staff under training must be adequately supervised by competent staff.
- Recognising personal limitations and asking for help from those more experienced if necessary.
- Regular CPD for all staff including Imaging technique updates where appropriate

The Regulations require that special consideration be given to:-

- The need to keep doses as low as reasonably practicable (ALARP) in medico-legal exposures
- The exposure of children
- Exposures as part of a health screening programme
- Exposures involving high doses to the patient (e.g. CT, Cardiac, Angiography, Barium enema)
- Possibly pregnant patients
- Exposures of paediatric patients - The operator must make use of scaling charts for activities used for paediatric studies.

Nuclear Medicine

Operators ensure that radiation doses are kept ALARP by following standard operating procedures for diagnostic and therapeutic examinations and only authorising exposures under the practitioner's guidelines.

For all diagnostic nuclear medicine radiopharmaceutical administrations local DRL's are set following the current ARSAC notes for guidance. Local DRL's for the CT component of nuclear medicine hybrid imaging have been established by the Radiological Science department and are reviewed every 3 years.

Current DRL's can be found in the Nuclear Medicine Standard Operating Procedure Manual.

Staff must pay special attention to the following:

- The results of quality control and assurance tests which may affect radiation dose.
- The requirement to assess and record the expected and delivered radiation dose.
- The requirement to adhere to Local Diagnostic Reference Levels (LDRLs) where appropriate

The Employer must take advice from suitably qualified and appointed Medical Physics Experts (MPEs) in nuclear medicine. The role of MPE(s) includes optimisation of acquisition and processing protocols, to ensure the minimum dose is delivered that is consistent with the desired image quality and diagnostic potential. Particular care should be taken to ensure that doses from the CT element of hybrid studies are kept ALARP.

Radionuclide Therapies

The practitioner will prescribe an activity that is suitable for the presenting condition. The practitioner will also act on the latest published guidance from all relevant professional bodies.

Clinical audit should also be used to assess the efficacy of currently prescribed activities. The practitioner and MPE(s) will keep abreast of the latest publish scientific research on therapy dosimetry.

EP-08 Patient Identification Procedure

This procedure must be read in conjunction with the trust's Policy and Guidelines for Identification of Patients

Purpose

This Section satisfies the requirements of Schedule 2 1(a) and describes the steps necessary to identify patients correctly for an examination involving the use of ionising radiation. In addition to this, data quality on the Radiology Information System (RIS) must be of the highest standard for information extracted from the system, in the form of reports or data transfer, to have any credibility. All staff have a responsibility to ensure that the standard of data entry is as high as possible. Correct and precise identification of the patient must be a priority within departments.

Readership

- Referrers
- Practitioners
- Operators

Rationale

Incorrect identification of patients remains one of the major causes of inappropriate irradiation of patients nationwide. This Procedure is aimed at minimising these incidents.

Process to Follow

First Identity Check point

Imaging reception staff, radiographers, departmental assistants, or nursing staff receiving patients directly will first check that all the fields in the Referral Criteria are completed correctly on the request form or that the patient has presented for the examination as per an agreed protocol. If this is not the case, the form should be returned to the referrer for more details or contacted for clarification in order not to delay patient's management.

Where the patient is present then contacting the referrer to obtain sufficient information successfully over the telephone will validate the demographic part of the request.

The following questions should be asked of the patient on arrival to Reception:-

- What is your full name? How do you spell that? Are you known by any other name?
- Can you confirm your address and postcode?
- Have you ever lived anywhere else previously? (if answer to above is different from our records on RIS)
- What is your date of birth?
- Do you have a telephone number?
- Who is your GP?

- Have you ever had an x-ray or scan before? (Note the answer and check the RIS for imaging history)
- If so, when and what?

The patient will then be registered on HIS/RIS or checked in and the appropriate labels completed, and the patient directed to the appropriate waiting area.

Second Identity Checkpoint
The patient will be called from the waiting area using their FULL NAME AND TITLE

Third Identity Checkpoint
The clinical member of staff carrying out the examination will introduce themselves then identify the patient by asking (not telling) for:

- Full name
- Date of birth
- Address
- What area of the body they are expecting to have x-rayed or examined
- Whether they have had an x-ray or scan recently

At this point if there are any discrepancies between the patient and what has been written on the request form the radiographer MUST NOT proceed with the examination until the discrepancies have been investigated.

Within the x-ray department, the patient's imaging history must also be checked on the RIS IMMEDIATELY before the examination proceeds.

For patients of childbearing potential, the LMP must be checked in accordance with the protocol in *EP-09 Pregnancy and Breastfeeding Protocol*.

Additional Checks for In-patients

For in-patients the radiographer should also check not only verbally with the patient, but also the patient's wristband. If there is any doubt as to the patient's identification, or if the patient is not wearing a wristband, then the appropriate ward or department should be contacted prior to carrying out the examination, and a member of the ward staff should identify the patient in person and add a wristband. If necessary, the patient should be taken back to the ward and the examination deferred until full identification of the patient is possible.

In Theatres, Fluoroscopy Room, Angiography and in the Cardiac Cath-Lab

The radiographer MUST check the identification of the patient with the appropriate theatre staff and also the patient's wristband. If the patient has not yet been anaesthetised, the Operator should check with the patient themselves.

For patients of childbearing potential under anaesthetic

The LMP check should have been carried out before the patient was anaesthetised, and the operator should check that this has taken place and has been recorded in the patient's notes. This should be checked routinely prior to operation by the ward staff, and the information may be held in the nursing notes. If it is not possible for the Radiographer to be 100% certain that this check was carried out prior to the patient being anaesthetised, the Medical Practitioner undertaking the operation MUST sign the request form to take responsibility for the exposure to the patient. An electronic clinical incident form (Datixweb) should be completed in this latter situation.

For portable x-rays carried out on the wards or in A/E

The Radiographer MUST check the patient's identification with the patient as well as the patient's wristband. If the patient is unconscious, the radiographer should check with the attending staff and the wristband. If the patient cannot be identified e.g. accident victims who have no ID on them and who are unconscious, the examination should go ahead if the patient's condition is considered life-threatening. Patient Identification details can, in these circumstances, be added to the patient's imaging history, at a later date.

For nuclear medicine (radioactive) administrations on the wards

For injections carried out on the wards, the operator should again check verbally with the patient, *and* on the patient's wristband. If the in-patient is not wearing an ID bracelet, the ward staff must be asked to attach an ID bracelet before proceeding with the examination. If the patient is unconscious, the operator should check with the ward staff and the ID bracelet.

For Identification of patients with sensory and or comprehension deficits

Please refer to Trust procedure.

For patients who are deaf, the correct details must be checked by written instructions or if that is not possible by asking the patient to peruse the request form and confirm their identity details, or

For patients who are unable to comprehend, the radiographer may have to simplify their questions, or, if the patient has an escort check details with them.

If the problem is one of language, a Trust translator must be located via the hospital switchboard. The use of a translator must be indicated on the request form, and if possible, their identity and relationship to the patient indicated also.

The responsibility of full identification as per this procedure rests with the member of staff actually irradiating the patient

IF FOR ANY REASON THE DETAILS ON THE REFERRAL FORM CANNOT BE VERIFIED THE EXAMINATION MUST NOT BE CARRIED OUT AND MUST BE REFERRED TO THE MOST SENIOR RADIOGRAPHER ON DUTY

EP-09 Pregnancy and Breastfeeding Protocol

Rationale

This Section satisfies the requirements of Schedule 2 1(c).

EP-09a General Radiology

Introduction

This section describes the protocol for x-raying patients of child-bearing capacity.

Pregnant or Breastfeeding patients and X-ray contrast media

No special precaution or cessation of breast-feeding is required however if contrast is administered to a pregnant patient, new-born thyroid function testing is recommended (Standards for intravascular contrast agent administration to adult patients, 3rd Edition, Royal College of Radiologists, 2015)

Procedure for X-Raying a Patient with Childbearing Potential

If a patient is known to be, or maybe, pregnant, the person justifying the exposure should, whenever possible, explain the risks and benefits of the exposure to the patient.

The use of patient contact shielding, such as gonad shields and lead aprons, is no longer required as per guidance from The British Institute of Radiology (BIR) (Guidance on using shielding on patients for diagnostic radiology applications, March 2020). Literature is available from the BIR website for both staff and patients. https://www.bir.org.uk/patientshielding.

1. **Extremity/appendicular skeleton (including skull, shoulders, cervical and thoracic spine, and chest but excluding the hips.**

   X-ray examination can be carried out.

2. Abdomen/pelvic areas

This procedure applies to all patients of childbearing potential undergoing any X-ray examination between the lowest rib and mid-femur.

- High dose examinations that encompass the uterus on patients aged between 12-60 years who are of childbearing capacity may only be done if the patient is within 10 days of the start of their last menstrual period (often referred to as the “10 day rule”).

- Low dose examinations that encompass, or may irradiate, the uterus (e.g. Abdomen/Pelvis/Lumbar spine examinations, Video swallow and CT chest) on patients aged between 12-60 years who are of childbearing capacity may only be done if the patient is within 28 days of the start of their last menstrual period (often referred to as the “28 day rule”)

- Definitions and examples of high and low dose examinations can be found below.

- Where there is an unintended foetal exposure **AND** the resultant foetal dose is **10mGy** or more, the incident should be externally reportable to CQC (Reference: IR(ME)R EP-015 Incident Reporting).

Please note: HSGs can be performed between days 10-14 if the IR(ME)R practitioner concerned authorises this.

Definitions

High foetal dose	Any CT examination between lowest rib and mid-femur Interventional examinations directly targeting organs between lowest rib and mid-femur. Three or more planned planar views between lowest rib and mid-femur (lumbar/sacral spine, pelvis etc) Examples: Barium enema Intravenous Urogram Angiography or vascular intervention of the abdomen and pelvis
Low foetal dose	Any examination between lowest rib and mid-femur, not defined above. Examples: Lumbar spine, pelvis, and/or abdomen fluoroscopy in theatre Fluoroscopy guided hip/spine injections Videofluoroscopy swallow only (not barium swallow) CT chest

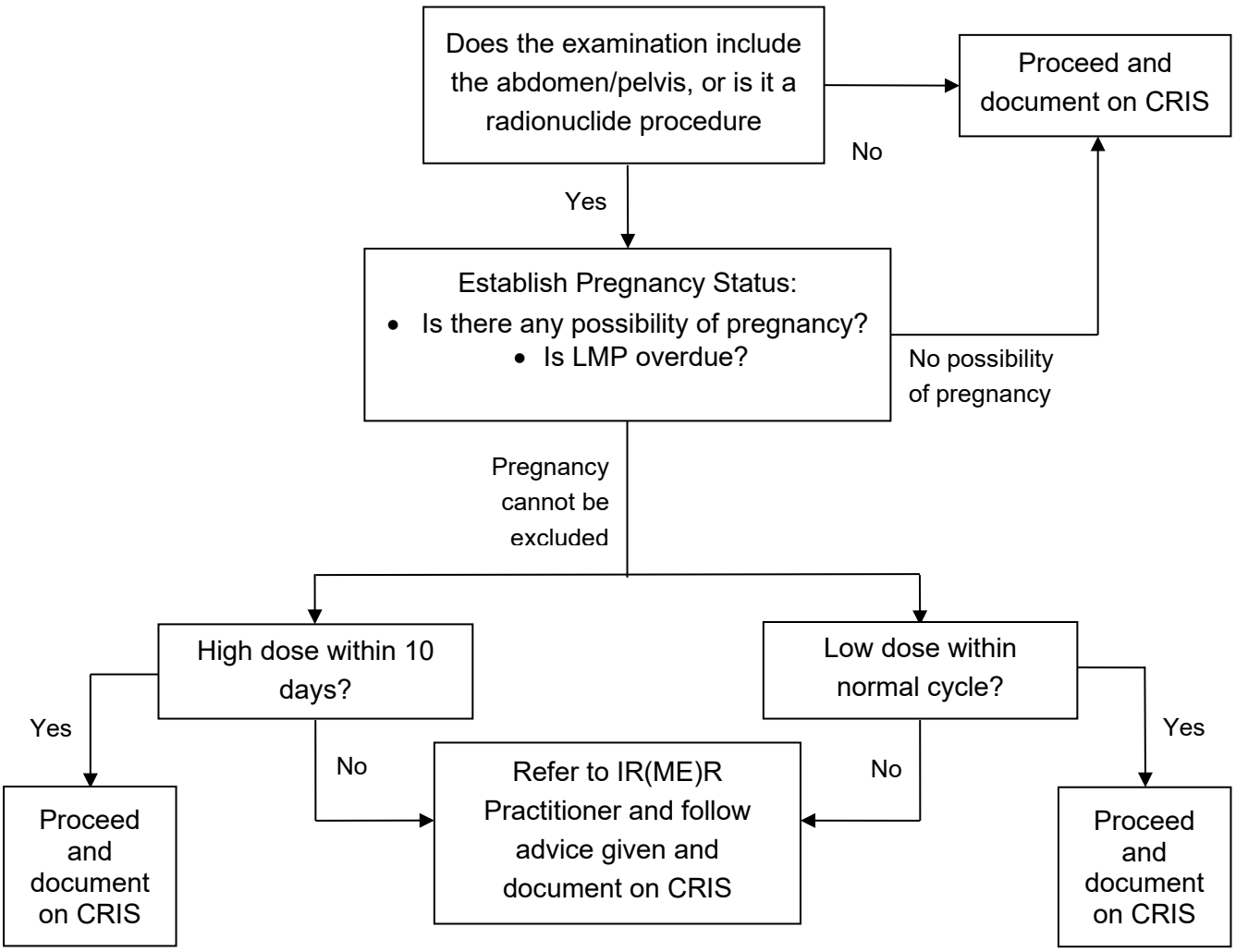
Where relevant, it is the Radiographer's responsibility to confirm that an individual of childbearing potential in theatre who requires imaging, is not pregnant (The result of the pre-op pregnancy test is available in the patient's pre-op checklist document).

CLINICAL EMERGENCY

For patients referred from A&E, by the on-call team for in-patients or in theatre, the 10/28 day rule can be over ruled in cases of clinical emergency. The box for over ruling the 10/28 day rule must be signed by the referrer.

Note: If the exposure seems inappropriate for exemption from the 10/28-day rule, the radiographer should query this with an IR(ME)R Practitioner.

FLOWCHART FOR APPLYING 28/10 DAY RULE (PATIENTS OF CHILD BEARING POTENTIAL AGED 12 TO 60 YEARS OLD)



Responsibilities of the Operator taking the x-ray

- The patient should sign to confirm they are not pregnant (including minors).
- A parent or carer should be asked to sign on behalf of the patient if they lack capacity (under the Mental Capacity Act).
- If a minor, i.e. a patient under 16 years old, is found to be pregnant, the referrer should be notified, or failing that, the Trust's Safeguarding Children & Young People team should be contacted for advice on extension 62363. Any actions taken should be recorded in the CRIS event comments.
- Please also refer to the Trust's Consent Policy, available on the Trust's intranet site.
- All signed documentation must be scanned onto CRIS. Patients of childbearing potential between the ages of 55 and 60 particularly fertility treatment question for those between 55 and 60 should be asked about their pregnancy status. The Regulations do not state an age range - just the potential for them to be pregnant.

Procedure for patients outside the 10/28 day rule

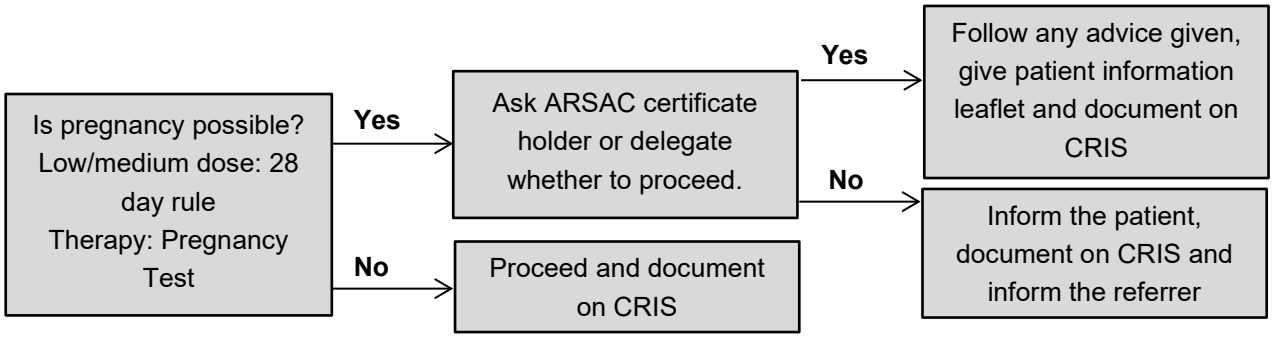
- Imaging of patients outside the 10/28 day rule will only proceed if the need for diagnostic information outweighs the clinical risk of ionising radiation to a potential foetus.
- This will be a clinical decision made by a suitable IRMER practitioner.
- The decision to proceed will be documented on CRIS

Procedure for unconscious/anaesthetised patients when LMP is unknown

- Imaging will only proceed if the need for diagnostic information outweighs the clinical risk of ionising radiation to a potential foetus.
- This will be a clinical decision, made by either a suitable IRMER practitioner.
- The decision to proceed will be documented on CRIS

EP-09b Nuclear Medicine

Flowchart for the Operator



Safeguarding

- A parent should be asked to sign if the minor lacks capacity (under the Mental Capacity Act.)
- If a minor i.e. <16 yrs is found to be pregnant, the referrer should be notified, or failing that, the Trust's Safeguarding Children & Young People team should be contacted for advice. Actions should be recorded in CRIS comments.

Please see Trust Consent Policy on Trust Intranet site.

Foetal Dose Classification for the Practitioner

Examinations are classified in table 1 below based on foetal radiation dose as low (minor risk), medium (intermediate risk) and high (moderate risk) dose; risks taken from table A10.1 of the Medical and Dental Guidance Notes.

If pregnancy is certain, ARSAC Notes for Guidance 2019 (NFG) section 7.9 recommends a 1 mGy dose constraint for the foetus. Low foetal dose examinations are therefore permitted. Medium foetal dose examinations may be permitted if the administered activity can be reduced while achieving a diagnostic outcome. High foetal dose and therapeutic examinations on pregnant patients are not permitted.

No High dose diagnostic examinations are undertaken within the Trust.
All therapeutic examinations are classified as high foetal dose. As such a pregnancy test must be undertaken on all patients with child bearing potential. A urine pregnancy will be undertaken on the day of the treatment. Treatment will only be administered following a result that is negative for pregnancy.

Examination	Foetal Dose (mGy)	Classification
WB Bone	3.7	Medium
Bone SPECT	5	Medium
DATSCAN	2.6	Low
Brain Perfusion	5.0	Medium

Myocardial Perfusion Rest (800MBq)	6.2	Medium
Myocardial Perfusion Stress (800MBq)	5.6	Medium
Renal Cortex (DMSA)	0.4	Low
HIDA	1.7	Medium
Cardiac Amyloid (DPD)	4.4	Medium
Gastric Empty	0.2	Low
GI Bleed	1.6	Medium
Lung Ventilation	0.5	Low
Lung Perfusion	0.2	Low
Lymphoscintigraphy	0.0005	Low
Meckels	3.0	Medium
MIBG	4	Medium
MUGA	3.1	Medium
Parathyroid	7.0	Medium
Renogram (MAG3)	1.2	Medium
Salivary Gland	0.6	Low
Sentinel Lymph (Breast) Same day surgery	0.001	Low
Sentinel Lymph (Breast) Next day surgery	0.003	Low
Somatostatin (Tektrotyd)	3.0	Medium
Thyroid Uptake (Tc04)	0.6	Low
I131 Therapy (500MBq)	35 to 135 *	High

*** SNMMI Practice Guideline for Therapy of Thyroid Disease with I-131 3.0**

Table 1 - Foetal Radiation Dose Classification

Advice to Pregnant Patients

Administration of RMPs to pregnant patients will result in a foetal radiation dose. IR(ME)R regulation 12(6) requires that the patient is provided with written information on the risks associated with exposure to ionising radiation, and instructions for reducing the exposure to persons in contact with the patient as far as reasonably practicable.
Appropriate information and advice is written for examinations likely to be performed on pregnant patients and should be provided before administration of RMPs.

Advice to Breastfeeding Patients (Diagnostic Procedures)

Administration of RMPs may result in radioactive contamination of breast milk. All patients who are breastfeeding, chestfeeding, wet-nursing or donating breast milk to milk banks must be given written information on the risks associated with ingestion of radioactive breast milk, and instructions for reducing the exposure to any child fed. In line with the ARSAC NFG, the information and advice will contain:

- A recommendation to store a feed in a refrigerator or freezer prior to the examination date.
- A recommendation to breastfeed shortly before administration of RMPs.

- Instructions to express as completely as possible and safely discard breast milk 3-4 hours after administration of RMPs, regardless of the interruption time below.
- Instructions to interrupt breastfeeding, wet-nursing or donating breast milk to milk banks for a period described by table 7.2 of the ARSAC NFG 2019, and in table 2 below.
- Information and reassurance on the risk to any child fed, assuming interruption advice is followed.

Advice to Breastfeeding Patients (Therapeutic Procedures)

Patients undergoing I-131 Iodine therapies need to cease breast/chest feeding 8 weeks prior to treatment, as lactation needs to have stopped before treatment (this is because of the dose to breast tissue if the patient is still producing milk, in addition to the already mentioned contamination of milk). They shouldn't resume breast/chest feeding until a subsequent pregnancy.

Radiopharmaceutical	Examination	Activity (MBq)	Interruption Time (hrs)
99mTc Colloid	Liver/Spleen	80	0
99mTc DMSA	Renal Cortex	80	0
99mTc DPD	Cardiac Amyloid	700	4
99mTc HMPAO	Brain Perfusion	500	0
99mTc IDA	HIDA	150	0
99mTc MAA	Lung Perfusion	80	12
99mTc MAG3	Renogram	100	0
99mTc MIBI	MPI/Parathyroid	900	3
99mTc Myoview	MPI	800	12
99mTc Pertechnetate	Thyroid/Salivary/Meckels	80	30
99mTc Phosphates	Bone	600/800	0
99mTc RBC	MUGA/GI Bleed	800	20
99mTc Tektrotyd	SSR	740	24
67Ga Citrate	Infection	Any	Stop
75Se SeHcat	Bile Pool	0.37	4
111In Octreotide	SSR	220	60
123I MIBG	MIBG	400	25
123I Ioflupane (DAT)	DAT	185	72
131 Iodine	Any	Any	Stop

Table 2. Breastfeeding Interruption Times (ARSAC NFG 2019 T7.2 or SPC)

The Nuclear Medicine Employer's Procedures are located on the Radiology database. Written information and advice to patients is located on the radiology database

Responsibilities

Practitioners and Operators are responsible for making enquiries of patients of childbearing capacity between the ages of 12-60 to establish whether the patient is or may be pregnant or breastfeeding. Practitioners and Operators are responsible for optimising radiation doses.

Nuclear Medicine Physicists are responsible for formalising the information and advice given where appropriate to patients, regarding the risks of ionising radiation and their mitigation. Operators are responsible for giving appropriate written information and advice to patients. The Medical Physics Expert holds overall responsibility for the content of this information and advice.

EP-10 Carers and Comforters

Purpose

This Section satisfies the requirements of Regulations 6(5)(d)(ii) and 12(5) and Schedule 2(1)(n). It identifies processes required for carers and comforters.

Readership

- Practitioners
- Operators

Description

Carers and comforters are defined as 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.

For Carers and Comforters in radiology, the dose constraint is set as 1mSv per year.

Procedure

Mechanical devices must be used to support the patient or imaging plate wherever possible. The Lead IRMER Practitioner has justified the exposure of carers and comforters to scattered radiation within general imaging where this is required to produce diagnostic quality images.

Before any person agrees to support a patient or imaging plate during an exposure as a Carer and Comforter the Operator must fully explain the risks involved regarding the radiation they may receive.

Any person supporting a patient or imaging plate must wear protective clothing, and stand as far from the useful beam as possible.

The dose to the Carer and Comforter must be as low as reasonably practicable. To ensure this the following procedures must be followed:

- The person holding the patient is an informed adult member of the public.
- A lead apron is worn, and wherever possible lead lined gloves.
- A fully adjustable light beam diaphragm is used such that the person holding is not in the main beam.
- The total number of images is kept to a minimum.

Records should be kept noting the date, person's name and relationship to the patient, pregnancy status check if appropriate, and guidance given on the History / Comments field of the Events Details page of CRIS (See Appendix 4).

If the above rules are followed, it is most unlikely a significant dose will be received.

If any of the above conditions are not satisfied, then the person may wear a personal dosemeter under a lead apron as this will give an estimate of effective dose.

A dose constraint of 1 mSv Effective Dose is recommended though the dose likely to be received by the Carer and Comforter for a simple radiographic procedure is estimated as being only a small fraction of this.

The same Carer and Comforter should not perform the task on a regular basis. If a person is repeatedly found to be holding patients, a dose assessment may be necessary.

In addition to the above a personal dosemeter may be issued to the Carer and Comforter for reassurance purposes if felt necessary by the radiographer.

Carers and comforters of nuclear medicine patients will be given individual advice appropriate to their situation. A dose constraint of 5mSv a year will apply. See also EP-05 Nuclear Medicine – Patient Instructions.

EP-11 Evaluation of Images/Studies

Purpose

This Section satisfies the requirements of Regulation 12(9) and Schedule 2(1)(j). NHSLA Standards for diagnostic testing and screening are linked to this section.

Readership

All staff required to report on or provide a clinical evaluation on X-Ray imaging.

Rationale

The failure to access, acknowledge and act upon the results of diagnostic tests may result in an inappropriate delay and lack of timely treatment resulting in harm to patients. Organisations should have in place clear clinical risk management systems that identify guidance to reduce this risk. These should include the ability to record timely and accurate data; ensure that staff are trained in the use of software systems that support diagnostic functions; enable communication channels that are consistent across the organisation; provide known pathways that assist in the tracking of patients; and advise patients on how their test results will be communicated to them.

Analysis of claims on the NHSLA database shows that a failure or delay in interpreting or acting on test results is one of the most common factors in relation to claims. NHSLA 2013

Introduction

It is a requirement of the Regulations that ALL radiographic and nuclear medicine examinations have a clinical evaluation recorded.

Procedure

A report is a radiological report and can only be made by a Radiologist, specially trained Radiographer, Consultant Cardiologist, Nuclear Medicine Consultant or Consultant Urologist.

Radiologists and specially trained Radiographers carry out reporting within the Imaging Departments and the report is made available through the Radiology Information System or PACS system

Cardiologists report Cardiology x-ray imaging directly into the patient’s medical notes.

Urologists report Micturating Cystometry x-ray examinations directly into the patient’s notes.

A clinical evaluation takes the form of a written evaluation in the patient’s notes, and may be made by any medical practitioner (or other healthcare professional acting under employers' guidelines) who will influence the patient's medical management.

Other members of staff outside the Imaging Departments only evaluate images/procedures.

Any subsequent change in patient's management based on this evaluation is the responsibility of the person carrying out the evaluation.

For recognised Nurse or Allied Health Professional (AHP) referrers, who interpret an image for the purposes of immediate patient management, the initial responsibility for this lies with this nurse concerned. Responsibility for the overall patient management in these circumstances lies with the Supervising Clinician, responsible for the protocol under which the Nurse/AHP referrer is operating.

Radiographer Evaluation

When an image is taken and in the opinion of the Radiographer - although not qualified to interpret the image - immediate action is perceived as appropriate, the image should be shown to a Radiologist/Reporting Radiographer. If there are no Reporting Staff available – e.g. out of hours - the Radiographer will discuss with the referrer or with the A&E teams for a clinical decision.

This decision and actions MUST be recorded on RIS and communicated to the referrer. The Trust's 'Red Dot' procedure, which draws a Referrer's attention to a possible abnormality, will be followed where appropriate and will be represented on PACS images.

Within the Imaging Departments

An examination report is typed onto the CRIS system and sent to the Referrer either as a paper record, or electronically and it is available on the PACS system. Ultimate responsibility for the accuracy of the report lies with the originator not the person typing the report as all reports are validated by the dictating member of the reporting staff.

For examinations undertaken in the Cardiology Imaging departments, reports are entered into the patient's notes using pre-defined report formats.

Urologists undertaking Micturating Cystometry x-ray examinations within the Radiology department enter the report directly into the patient's notes.

Nuclear Medicine

- A clinical evaluation in Nuclear Medicine is a radiological report, generally made by a Nuclear Medicine Radiologist or Nuclear Medicine reporting Radiographer. It takes the form of a written and subsequently verified report stored on the radiology information system (CRIS). The report will also include details of Radiopharmaceutical including dose in MBq and where applicable CT dose in mGycm. Dose details are also recorded on the CRIS system and the Patient administration "daybook".
- Once verified a report may only be amended by creation of an addendum. The modified report must be brought to the attention of the referrer.
- Under normal circumstances no unverified report shall be sent out. Where a report is urgently required referring clinicians may request a copy of an unverified report however this should only be made available with the permission of the original reporting clinician or 'duty Consultant' and under the proviso that this has not been authorised and will be clearly indicated as unverified.

- The clinical evaluation is available on the PACS system with the images – it is the referring team's responsibility to access these and take appropriate actions regarding the patient's management.
- Referrers requiring an urgent report can email can contact the Nuclear Medicine department directly.
- Email notification of reports highlighted "critical, urgent or unsuspected radiological findings" will be sent to referrers (in addition to the report being available on PACS).

Outside the Imaging Department

Unreported x-ray images are available for viewing on PACS but if no report is required a clinical evaluation must be performed and recorded in the patient's notes. They may be subject to review, interpretation, and evaluation by other individuals in departments other than Radiology.

This is subject to audit by the Radiology Department who will report the results of such an audit to the Trust's Radiation Protection Committee.

Examples of such departments are:-

- Orthopaedic Department
- ERCP
- Cath lab
- Orthodontic/MaxFAx Department
- Theatres

If fluoroscopy is used as an evaluation tool as opposed to diagnosis e.g., in theatre during a hip pinning procedure, or during a temporary pacemaker insertion, then the use of x-rays must be recorded in the patient's notes by the Clinician undertaking the procedure, or by the competent Radiographer who attends the procedure. In these cases, fluoroscopy is being used to monitor the progress of a procedure and a specific evaluation may be difficult. However, the fact that the patient has been irradiated for the purposes of monitoring the procedure MUST still be recorded in the patient's notes. The Radiographer attending the procedure must ensure this takes place, as well as recording full details of the exposure to the patient.

Indicative Reporting Times are illustrated in the table below but these may vary throughout the year:

Examination Status	Reporting Time in Working Days
Emergency	1
Urgency	2
Routine	5
Private/Research & Other	10

Patients are instructed to contact their primary referrer for information about results

EP-12 Accidental or Unintended Exposures – Reducing Risk

Purpose

This Section satisfies the requirements of Regulation 8 and Schedule 2(1)(k). This states that the written procedures for medical exposures shall include procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

Readership

- Operators
- Practitioners
- Medical Physics Experts
- Clinical modality Leads

Measures

The following measures are in place that will reduce the probability and magnitude of accidental and unintended exposures to patients.

Training and qualification requirements

- All Operators and Practitioners are appropriately trained and familiar with the contents of this manual, and must abide by it. These staff will sign in Appendix 7 to show they have read this documentation and agree to abide by it.
- All Radiographers hold a qualification in Diagnostic Radiography and are registered with the Health Professions Council. Radiographers working in specialised areas will follow a local training programme and be signed off as competent by staff in charge of that area.
- Assistant Practitioners in Radiography hold a foundation degree (FdSc) or DipHE in Diagnostic Radiography. They only work in areas for which they have satisfactorily completed the appropriate module.
- Assistant Practitioners and Student Radiographers always work under the supervision of trained Radiographers.
- Technologists must hold a minimum of a qualification in Nuclear Medicine Technology and will follow a local training programme.
- Practitioners authorising administration of a radioactive substance must hold an ARSAC certificate or have written delegation under an ARSAC certificate.

Standard Operating Procedures

- **All Modalities**
    - All staff must follow the patient identification procedure (*EP-08 Patient Identification Procedure*).
    - All staff must ensure the request complies with Referral Criteria (*EP-03 Referral Criteria*).
    - Regular preventative maintenance of equipment is conducted in accordance with the Trust's Radiation Safety Policy.

  - All Operators must ensure room and equipment are correctly selected and prepared for the procedure to be undertaken (relevant Imaging Protocol Manual).
  - All Operators must ensure that appropriate checks are made on the Computerised Radiology Information System (CRIS) for relevant patient history.
  - All Operators must ensure patient is correctly prepared and understand their role in the examination, (relevant Imaging Protocol Manual).
  - Regular staff meetings for exchange of new information.

- **X-Ray Specific Measures**
  - Depending on the equipment, sensible selection of automatic exposure control (AEC) backup times.
  - Pre-programmed charts must not be changed or defaced. The Clinical Modality Managers for an area are the only staff permitted to update the pre-programmed charts and suggestions must be directed to either of these staff.

- **Nuclear Medicine Specific Measures**
  - Operators must check that the practitioner is able to authorise administration of a radioactive substance (either holds an ARSAC certificate or has written delegation under an ARSAC certificate).
  - Staff administering a radioactive substance to a patient must check that the following details are in accordance with the specified exam:
    - Radiopharmaceutical
    - Activity (MBq)
    - Volume (if applicable)
    - Staff administering a radioactive substance to a patient must check that the following details are in accordance with the specified exam:
      - Radiopharmaceutical
      - Activity (MBq)
      - Volume (if applicable)

Equipment QC and preventative maintenance

- Appropriate selection and commissioning of new equipment.
- Regular preventative maintenance of equipment is conducted in accordance with the Trust's Radiation Safety Policy.
- Active and effective equipment QA and reject analysis programme, in accordance with the Trust's Radiation Safety Policy and Equipment QA Programme Manual.
- The equipment must permit assessment of the dose of ionising radiation that a person may be exposed to, by way of the ordinary operation of that equipment.
- An equipment fault log is kept.
- Completion of the Handover Form by engineers after carrying out work on equipment to identify if their work would affect patient dose/image quality.
- Completion of Medical Physics handover form after carrying out physics tests.

Clinical Audit

Clinical Audit is conducted within all departments.

Risk Assessment - Nuclear Medicine

It is the duty of the employer to ensure that all radionuclide therapies are assessed for risk of accidental or unintended exposures. These risk assessments shall be written / reviewed at the following occasions:

- New radionuclide therapy
- Major change in procedure for a radionuclide therapy
- Three years after last review

The risk assessments shall include assessment of the following incidents:

- Incorrect patient
- Incorrect administered activity
- Incorrect radionuclide
- Incorrect patient preparation
- Radionuclide administration to pregnant patient

The risk assessments shall be approved by the MPE for Nuclear Medicine.

The Chair of the Radiation Safety Committee, with support from the Medical Physics Expert for Nuclear Medicine, is responsible for ensuring that identified actions are carried out.

Incidents – all modalities

In the event of an incident (whether externally reportable or not) or a near miss, it is essential for the circumstances to be investigated by the IR(ME)R Team, Radiation Protection Supervisor or Clinical Modality Managers.

Recommendations from such an investigation should indicate actions to be followed to prevent a recurrence. It is important these recommendations are followed, and it is the responsibility of the Imaging Services Manager and Clinical Modality Managers to ensure this happens.

It is the duty of the Employer to establish a system for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to radiological risk posed by the practice.

In the event of an incident (whether externally reportable or not) or a near miss, an investigation is carried out by the modality manager. The investigation must include recommendations for remedial action to minimise the chance of a similar failure in the future. The modality manager is responsible for ensuring that identified actions are carried out.

Full details of actions to be taken following an incident are given in *EP-13 Reporting of Incidents involving Exposure to Ionising Radiation.*

EP-13 Reporting of Incidents involving Exposure to Ionising Radiation

Purpose

This Employer's Procedure satisfies the requirements of IR(ME)R 2017 Regulation 8 and Schedule 2(1)(l).

The Regulations require an investigation and report in the event of an **accidental or unintended** exposure given to an individual (See Appendix 5). Staff exposures should also be considered.

An **unintended exposure** is defined as any exposure to ionising radiation which is significantly different from the exposure intended for a given purpose. This can arise from any cause including equipment malfunction or Operator error.

An **accidental exposure** is defined as an exposure of an individual as a result of an accident or where no exposure was intended.

Note: This section specifically deals with clinical incident reporting under IR(ME)R to the Regulatory Authorities. Other incidents may also be reportable under the Department's internal arrangements and that procedure must also be followed.

Readership

- Operators
- Practitioners
- Medical Physics Experts
- Modality Managers
- Service Managers

Initial Actions after Any Suspected Accidental or Unintended Exposure

Person	Action(s)
Operator	• As soon as possible notify a senior member of staff, preferably your line manager • Complete an exposure data form (Appendix 5) and give to the Clinical Modality Manager who in turn will send to the MPE. • Add the incident on the DATIX reporting system

Modality Manager	• When notified of a suspected accidental or unintended exposure by a member of staff inform the following people: • Radiology Services Manager • Contact the MPE (or authorised clinical scientist in Radiological Science) to determine if the exposure is externally reportable • Initiate a preliminary investigation to determine what has happened
Medical Physics Expert (MPE) or authorised clinical scientist	• Assess the dose received
MPE, Clinical Modality Manager and Radiology Services Manager	• Review the details of the incident including the dose received and jointly decide if the incident needs to be reported

Table 1 – Initial Actions

When Is Notification Required?

The Care Quality Commission (CQC) must be notified as soon as possible if the exposure is "significantly greater than generally considered to be proportionate in the circumstances" (use guidelines from the CQC, given in Tables 2 and 3), including the preliminary report if available. For staff exposures, the Health and Safety Executive (HSE) may need to be notified. The RPA will be able to advise on this.

To determine whether the incident is reportable to the CQC the guidance published by the CQC must be used. This involves either calculating the total dose or a multiplying factor using the unintended and intended effective doses. The total dose or calculated multiplying factor is then compared to the guideline doses or multiplying factors listed in Tables 2 and 3 below (taken from CQC guidance). If the calculated value exceeds the guideline value for the particular type of diagnostic examination or therapy, it should be reported to the appropriate regulatory body:

CQC notification codes, categories and criteria

Table 2: Accidental exposure

Notification code	Exposure category	Criteria for notification
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) (c) Note: In England, Wales and Northern Ireland, a child is someone who has not yet reached their 18th birthday. In Scotland, this is someone who has not yet reached their 16th birthday.
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose

Table 3: Unintended exposure

Notification code	Exposure category	Criteria for notification
2.1	Intended dose less than 0.3mSv	3mSv or above (adult) 1mSv or above (child)
2.2	Intended dose between 0.3mSv and 2.5mSv	10 or more times than intended
2.3	Intended dose between 2.5mSv and 10mSv	25mSv or above
2.4	Intended dose more than 10mSv	2.5 or more times than intended.
3	Interventional/cardiology	Where there has been a procedural failure resulting in observable deterministic effects. Procedures that do not have a procedural error but result in unintended or unpredicted observable deterministic effects.
5	Foetal All modalities	Where there is an unintended foetal exposure **AND** the resultant foetal dose is **10mGy** or more.

Table 3: Complementary notification codes

For these codes, you need to add the relevant suffix code 1 to 9. As well as notification codes 1 to 10. For example:

- M1 (accidental exposure of more than one individual within the same incident or theme)

Notification code	Exposure category	Criteria for notification
M	More than one individual exposed within the same incident or theme. (plus relevant suffix code 1 to 9)	All cases regardless of dose.

- M2.1 (unintended exposure of more than one individual within the same incident or theme)

Notification code	Exposure category
E	Equipment fault exposure (plus relevant suffix code 1 to 9)
V	Voluntary notification (plus relevant suffix code 1 to 9)
C	Clinically significant event (plus relevant suffix code 1 to 9)

6	Breast feeding infant Nuclear medicine only	Where there has been a failure in procedure **AND** the resultant infant effective dose is 1 mSv or more

IR(ME)R 17: Guidance on significant accidental and unintended exposures © Care Quality Commission 2020

Follow-up Actions for the Modality Manager - Any Incident

These actions may be carried out with assistance from senior radiographer(s) / technologist(s), and MPE(s) as necessary.

Carry out a detailed investigation, record this on DATIX and ensure any appropriate action identified is carried out.

The detailed investigation must include:

- Identification of what has happened
- Root cause analysis of the failure
- Remedial action to minimise the chance of a similar failure
- Estimation of the dose involved

Complete a written report of the investigation, attach on DATIX and send to the Radiology Service Manager.

Follow-up Actions for the Radiology Service Manager – Reportable Incident

- Inform the following parties at the time of the incident:
    - Imaging Principal Lead Modality Radiologist
    - Imaging Clinical Lead Radiologist (Radiation Safety Chair)
- Inform the Care Quality Commission as soon as possible (must be within 2 weeks of identifying an incident) using their on-line reporting system. Include the details provided in the preliminary report by the Modality Manager
- Send a copy of the notification to the parties listed above and:
    - Chief Executive
    - Medical Director – Quality and Safety
    - Radiology General Manager
    - Head of Clinical Investigations
    - Medical Physics Expert
    - RPA
- Send copy of final report to CQC within a month of notifying them of the incident.
- Ensure that referrer, IR(ME)R Practitioner and patient or their representative (if there is one) are informed of the occurrence and outcome of the investigation.

Follow-up Actions for the Modality Manager - Non-Reportable Incident

- Report findings to:
    - Radiology Services Manager
    - Principal Lead Modality Radiologist
    - Imaging Clinical Lead Radiologist (Radiation Safety Chair)

EP-14 Estimation of Patient Dose and Population Doses

Purpose

This Section satisfies the requirements of Regulation 12(9), 13, Schedule 2(1)(e) and 1(l).

The purpose is to provide adequate information to assess the dose a patient has received, and to be able to estimate population doses. The Regulations require the employer to make a prior determination of the parameters and method by which patient radiation dose is measured.

The dose calculations are performed by Radiological Science, Medical Physics Department, UHSussex.

Readership

Operators exposing patients to ionising radiation, Medical Physicists

Introduction

The Regulations require that it be possible to retrospectively assess the dose to a patient. In order to do this the following information must be recorded, and it is the responsibility of the operator undertaking the examination to ensure this is done.

Data Collection

Radiography

If standard protocols, pre-programmed into the x-ray machine are used then only the data listed below is required to be recorded for the individual patient.

For all non-extremity exposures:

- Room/mobile code
- Post-exposure mAs
- Projection
- DAP reading
- DAP units

For all extremity exposures:

- Room/mobile code
- Projection

If programmed exposures are modified, or non-standard coverage is used, then this should also be recorded, together with the details of the amendments made.

If non-standard exposures are used then the data listed below is required to be recorded for the individual patient.

For all exposures (extremity or non-extremity):-

- Room/mobile code
- kV
- Post-exposure mAs/mAs set
- Projection
- DAP reading
- DAP unit

Nuclear Medicine

Information sufficient to calculate the radiation dose received by the patient must be recorded on the radiology information system (CRIS) and the administration “daybook”. This can be either entered electronically, or by scanning on paperwork.

The following information must be recorded for each administration of radioactivity:
Radiopharmaceutical

- Activity in units of Mega Becquerels (MBq)
- Date and time of measurement of activity
- Date and time of administration
- Residual activity (MBq), if appropriate
- Administered activity (MBq) if a residual activity was measured.
- The following information must be recorded for each CT exposure:
    - Dose-Length Product (DLP) in units of milligray.centimetres (mGy.cm)

Estimation of Effective Doses

Nuclear Medicine
Nuclear Medicine Physicists use the ARSAC Notes for Guidance to estimate the effective dose received by the patient.

The activity of radiopharmaceutical administered is required. The effective dose received from the ARSAC recommended DRL activity of the relevant radiopharmaceutical is scaled by the administered activity. Caution should be exercised in conditions where abnormal retention is exhibited.

Contribution to the patient effective dose from the CT element of hybrid imaging studies is calculated by Physicists from the Radiological Science section of the Medical Physics Department using the ImPACT CT dosimetry spreadsheet (which makes use of Monte Carlo datasets). Information required to calculate this effective dose may be obtained from the SPECT/CT system and from relevant DICOM image headers. Please see the Radiological Science Work Instruction for full details.

X-Ray

Effective doses for X-ray, CT and interventional procedures are estimated by Radiological Science, UHSussex. Use is made of widely available software packages to calculate the effective dose to an anthropomorphic phantom, using acquisition parameters supplied by the radiographers.

Population Dose Estimates

Patient dosimetry audits are carried out as detailed in *EP-15* Use of Diagnostic Reference Levels. These audits give typical DLP, DAP, screening times and administered activities for common examinations and procedures in all departments, for both adult and paediatric patients (with paediatric data split by age).

From this data and typical exposure factors used, *typical* Effective Doses can be estimated by Radiological Science, Medical Physics Department, UHSussex.

The Imaging Department's CRIS collects data of all exposures given, which can be split by age and gender, as well as by date, type of examination and room.

The above processes allow UHSussex MPEs to provide dose estimates of the ESHT exposed population when requested by the Secretary of State, as per IR(ME)R regulation 13.

EP-15 Use of Diagnostic Reference Levels

Purpose

This Section satisfies the requirements of Regulations 6(5)(c), 6(7), 13 and Schedule 2(1)(f).

Readership

- Operators
- Modality Managers
- Medical Physics Experts
- Practitioners
- Referrers

Introduction

The Regulations specify that medical exposures must be assigned Local Diagnostic Reference Levels (Local DRLs), which are defined as mean dose levels for typical examinations for groups of standard size patients across the Trust.

In radiography, Unit Diagnostic Reference Levels (Unit DRLs) are used by this Trust as a tool for Clinical Audit and for optimisation of exposures. For all common procedures on each x-ray unit, a Unit DRL will be established that will act as a level that one would hope not to exceed during fluoroscopy/radiography of standard size patients on this particular x-ray unit.

More details of the use of DRLs is given in the Trust's IR(ME)R DRL Strategy document.

A DRL is set in terms of quantities that are easily measurable by an Operator. If a Dose Area Product (DAP) meter is fitted, this value is used. For fluoroscopy a screening time might also be appropriate. For CT, Dose Length Product (DLP) is used. In nuclear medicine, administered activity is used.

Local DRLs (LDRLs)

Local DRLs for an examination are established whenever sufficient dose information has been collected for all x-ray units performing that examination throughout the Trust.

If Local DRLs are greater than published National DRLs, the employer is required to carry out an appropriate review with a view to taking corrective action if appropriate.

Two important notes regarding LDRLs;

1. With the individual patient, the Local DRL is the dose that is used by the Referrer and Practitioner in assessing the risk to the patient,
2. Establishing Local DRLs for administered activity which exceed the ARSAC recommended DRLs may only be permitted if ARSAC accept an amendment to the Employer licence providing adequate scientific and Imaging & clinical justification.

The Local DRL for an examination is the mean of all unit means across the Trust.

Unit DRLs

The unit DRL is set at the 90th percentile of patient dose data collected from an individual x-ray unit or CT scanner at the time of setting the Unit DRL. This means that at the time of setting, only 10% of patients received doses higher than the Unit DRL.

Unit DRLs provide an overall audit tool to see if the individual procedure has been optimised, that is, carried out with the lowest dose whilst producing acceptable diagnostic images.

UDRLs are listed in x-ray and CT scanner rooms and on mobiles as appropriate.
Should it be evident from the recorded exposure factors that a Unit DRL has been exceeded, then the Operator must try and identify a reason for this. This must be recorded within CRIS so it can be queried within Clinical Audit.

If Unit DRLs are consistently exceeded, the employer is required to carry out an appropriate review with a view to taking corrective action if appropriate. This is where recording dose information, particularly DAP figures, on CRIS is vital as it allows queries on the data to be run, and easy identification of instances where the Unit DRL has been exceeded.

‘Consistently Exceeding’ UDRLs

The Regulations do not define ‘consistently exceeding’. For the purposes of this Manual, ‘consistently exceeding’ will be taken as if more than 20% of the recorded values are greater than the Unit DRL, as this demonstrates an increase from the time of setting the Unit DRL.

During the audit process, the dose information will be reviewed, and if greater than 20% of values exceed the Unit DRL, then the Trust’s Imaging Patient Dosimetry Group will instigate an investigation. This investigation will seek to ascertain the cause and recommend remedial action. Possible action could be to recommend additional training for Operators, additional training for other, non-radiographic staff or a revision of a Unit DRL if it is too restrictive.

If the Unit DRL appears too high, it might also be appropriate to reduce it in order to optimise exposures as much as possible.

In order that Unit DRLs are an effective tool it is important to record them accurately. Furthermore, if a Unit DRL is exceeded for individual patients, it is useful to review why this happened at the time and make an appropriate note to assist audit at a later date.

‘Consistently Exceeding’ LDRLs

For Local DRLs ‘consistently exceeding’ will be taken as per the Institute of Physics and Engineering in Medicine Report 88. Details of this can be found in the Trust’s IR(ME)R DRL Strategy document.

During the setting and auditing of Local DRLs, if Local DRLs are greater than National DRLs, then the Trust’s Patient Dosimetry Group will instigate an investigation. This investigation will seek to ascertain the cause and recommend remedial action. Possible action could be to recommend changes in procedure, or additional training for Operators.

Advice during fluoroscopic screening procedures

During fluoroscopic screening procedures, the Operator should, where possible, advise surgeons or other relevant staff of the progress of the examination with regard to the Unit DRL – e.g. when 50%, 75%, 100% etc of the DRL has been reached.

The Unit DRL must not be regarded as a limit – it may be exceeded provided it is clinically required.

Also during the procedure, the operator should advise the Radiologist or Surgeon if a Potential Skin Damage (PSD) caution or reporting level is reached. See Standard Operating Procedure (SOP) for 'Potential Skin Damage', saved in the IR(ME)R folder on the Imaging Shared Drive.

Patient dosimetry audits

Audit schedules will be produced annually by the Patient Dosimetry Group, and ratified by the IR(ME)R Management Group. The Clinical Audit & Risk group will be updated quarterly on progress. Audits will be prioritised in order of importance. The Audit Plan produced for each year will include a 3-year rolling programme of reviewing all DRLs and more detailed audits/investigations identified as necessary. Reports of audits performed will be sent to relevant staff, and summarised to the IR(ME)R Management Group.

Review of DRLs

Local and Unit DRLs will be reviewed every 3 years by the Patient Dosimetry Group. New charts will be produced, and circulated by the MPE, with any amendments identified from audits. Hence all charts displayed should be no more than approximately 3 years old, and should be signed by the MPE.

EP-16 Quality Assurance Programme - Equipment (Inc. Inventory)

Purpose

This Employer's Procedure satisfies the requirements of IR(ME)R 2017 Regulations 14(2), 14(3) and 15, and Schedule 2 1(d).

This section must be read in with reference to the Trust's Management of Medical Devices Policy, Medical Devices Training Policy, The Decontamination of Equipment and Medical Devices and Manual for the Management of Medical Devices.

Equipment Inventory

The Regulations define equipment as any equipment which delivers ionising radiation to a person undergoing exposure or equipment which directly controls or influences the extent of such exposure.

A full (electronic) inventory of all x-ray and nuclear medicine imaging equipment is held in each of the departments. It is the responsibility of the Modality Leads in each area to ensure the inventory is compiled, checked and updated on a regular basis. The data quality of the inventory will be audited annually by the MPE or their delegate, with any gaps found highlighted at the next Radiation Safety Committee meeting.

The inventory lists all current individual items of equipment and shall include:

- Type of equipment
- Manufacturer name
- Model number
- Serial number or other unique identifier
- Year of manufacture
- Year of installation
- Routine servicing arrangements
- Modification details
- Critical Examination date
- Commission date
- Date of Disposal
- Means of Disposal
- RPA informed of Disposal

Equipment Quality Assurance Programme

A full technical quality assurance programme for all x-ray and nuclear medicine equipment is in place in East Sussex Healthcare NHS Trust. It is the responsibility of the Modality Leads to ensure that the rolling QA programme within their areas of responsibility is maintained and reported upon.

Full details of the equipment quality assurance programme may be found in the ***ESHT Equipment QA Programme and Manual*** document. In broad terms, the equipment QA programme specifies that equipment must be:

1. Procured to meet tendered technical specifications for equipment and installation design, informed by all relevant stakeholder requirements
2. In a suitable installation which has been safety tested, including a critical examination if appropriate
3. Acceptance tested against the tender and manufacturer specifications by a body independent of the installer
4. Brought into commission and verified by a body independent of the installer, including the establishment of baseline and acceptable performance levels for future monitoring
5. Optimised based on the results of ongoing surveillance of stakeholder requirements or best practice
6. Routinely monitored for performance degradation leading to remedial work, or failure against acceptable performance levels leading to it being taken out of use until corrected.
7. Tested following maintenance procedures, upgrades or modifications capable of affecting IR(ME)R regulated performance by a body independent of the manufacturer or maintainer
8. Monitored for safety and reliability, the results of which shape its projected lifetime and may lead to a reduction in the scope of its use
9. Assessed against regulatory compliance and the capabilities of new technology in order to identify when its further use cannot be justified
10. Decommissioned and disposed of in line with relevant legislation

EP-17 Quality Assurance Programme - Employers Procedures & SOPs

Purpose

This Section satisfies the requirements of Regulation 6(5)(b) and Schedule 2(1)(d). This ensures that procedures are regularly reviewed so that they are effective and appropriate and any necessary amendments are made.

Readership

- Practitioners
- Operators
- Administrative Staff
- MPEs
- Modality Managers

Description

IR(ME)R requires that the Employer's Procedures are subject to quality assurance. The Trust has produced an overarching procedure document, the 'Trust Management Procedures for Medical Exposures'. This describes how the Trust has addressed IR(ME)R from a Trust wide perspective and addresses each Employer's Procedure, as required in Schedule 2 and within the Regulations themselves. This document allows for Speciality Documents for each user Department – this document is the Speciality Document for the Imaging Department.

Quality Management

The Radiology Quality Management System enables the department to comply with the Regulations by ensuring that all policies and procedures for standard radiological practice are:

- Written by an individual responsible for the accuracy of the document and future review, in line with Regulations 6(1) and 6(4)
- Authorised by a different individual taking responsibility on behalf of the Trust, in line with the DHSC Guidance to the IR(ME)R 2017 (June 2018)
- Version and page numbered, in line with the DHSC Guidance to the IR(ME)R 2017 (June 2018)
- Brought to the attention of and read by all relevant stakeholders when issued or revised, in line with Regulation 6(2)
- Reviewed at an appropriate frequency, in line with Regulation 6(5)(b)
- Subject to reasonable change requests from all relevant stakeholders
- Audited at an appropriate frequency, in line with Schedule 2 (1)(d)

Responsibilities

Each section of the IR(ME)R document must be reviewed periodically. Ultimate responsibility for this review and organising any subsequent revision rests with the Imaging Services Manager however this task is delegated to the relevant Clinical Modality Manager.

Each review of the EPs compares departmental practice with the written Employer's Procedure and Regulations, as well as checking that current practice results in the intended task being performed.

Each section of this manual has a history/review sheet. The person making the review/update must fill in appropriate brief details on the history sheet. Any updates must be allocated a new issue number and issue date.

- Small amendments can be made as required and recorded on the History/Amendment Sheet
- Major amendments must be the subject of a re-issue of the procedure

Any suggested modifications will be passed to the IR(ME)R Team who will review them and, if necessary, ensure the Manual is updated and that electronic copies are also updated.
Old copies are retained for knowledge preservation and legal purposes.

It is the responsibility of the IR(ME)R Team to ensure staff are made aware of any changes in the manual relevant to their work. With every new issue of the manual an amendments summary is produced and staff are requested to sign to indicate they have read this.

The IR(ME)R Team also ensures new staff are aware of the Manual and its contents through the Imaging Departmental Induction Programme (including IR(ME)R Practitioners).

EP-18 Clinical Audit

Purpose

This Section satisfies the requirements of Regulation 7. The Trust must ensure resources are available to carry out appropriate clinical audits.

Readership

All staff associated with the irradiation of the patient, Clinical Governance Facilitators and Clinical Audit Leads and co-ordinators.

Clinical Audit Group

The Imaging Department's Clinical Audit Group (CAG) satisfies the requirements of regulation 7 and is in place to co-ordinate and support all clinical audit activities and patient safety work.

This multidisciplinary group consists of representatives as follows:

- Lead Consultant for Clinical Audit
- Management Lead for Audit

Representatives from the following groups:

- Radiographers and Technologists
- Radiologists and Nuclear Medicine Clinicians
- Other invited parties as appropriate (eg. Medical Physics)

CAG will maintain the departmental Audit Log and will review this at each meeting. Audits may include nationally commissioned audits, audits for nationally produced guidance, targets and projects as well as locally identified projects. The group will also support progress of audit. Regular audit presentations will be made to the Department.

CAG may look at IR(ME)R related issues, such as:

- Patient dosimetry and DRL audits (through the Patient Dosimetry Group)
- Evidence of adherence to the Quality Management System
- Evidence of a clinical evaluation
- Referral and Practitioner's Guidelines
- Topics selected from the RCR Audit Manual Patient Dosimetry Audits should be kept
- Evidence of compliance with this Manual
- Have QA procedures been carried out on this Manual
- Evidence of a report/clinical evaluation
- Referral Criteria and/or Practitioner's Guidelines
- Patient Pathways
- Topics selected from the RCR Audit Manual
- Topics suggested by staff which are relevant to these policies and procedures

EP-19 Non-Medical Exposures

Purpose

This Section satisfies the requirements of Regulations 11(3)(a), 11(3)(c)(ii), 12(8)(b) and Schedule 2(1)(m) and 3 (Table 1).

Readership

- Referrers
- Practitioners

Introduction

Non-medical exposures are defined as any deliberate exposure where the primary intention is not to bring a health benefit to the individual exposed. In general, non-medical exposures are not performed by the Employer.

Procedure

Exposure to ionising radiation may only be justified for non-medical reasons if the benefits to society outweigh the detriment to the individual exposed.

Such exposures must be ***individually*** justified by a Practitioner. An Operator may not authorise a non-medical exposure as no practitioner's guidelines exists for this type of exposure.

This must be carried out with due regard for the fact there may be no direct clinical benefit to the patient

It should also be noted that the booklet 'Making the best use of a Department of Clinical Radiology - Guidelines for Doctors' RCR, 2007 states that:-

"*No investigation should be requested unless it can be clinically justified, and its result, normal or abnormal, is likely to influence management of the patient.*"

However, under certain circumstances exposures can be justified for non-clinical reasons such as:

Immigration/emigration

Non accidental injury (NAI) – See ESHT protocol 'Skeletal surveys for the investigation of suspected physical abuse in children'. All medico-legal exposures will need to be individually assessed by a practitioner.

EP-20 Research Involving Ionising Radiation

Purpose

This Section satisfies the requirements Regulations 11(1)(d), 11(6), 12(4) and Schedule 2(1)(g).

Readership

These criteria must be available to:

- all persons who might wish to embark on a research project involving ionising radiation procedures with the East Sussex Healthcare NHS Trust
- Chief Investigators / Principal Investigators, Practitioners, Research Nurses

Introduction

All medical research project applications within the Trust must be submitted through the IRAS (Integrated Research Application System) and agreed by an appointed Research Ethics Committee. Application to a REC is handled by NRES (National Research Ethics Service) and/or HRA (Health Research Authority).

Different arrangements exist according to whether the Trust is the main co-ordinating centre or a participating site to a project co-ordinated elsewhere. This procedure is based on the application form 'IRAS Version 2.5' and the associated NRES Guidance (Version 2, September 2008). http://www.IRAS.npsa.nhs.uk/applications/guidance/#ionisingrad

Medical research projects include instances where:

- **There is no medical benefit to the volunteer/patient**
- **There is some medical benefit to the volunteer/patient.**

Trials may involve exposures that would be given as part of normal standard of care, or may involve additional exposures.

A dose constraint must be identified if there is no medical benefit to the volunteer. A target dose must be identified if the patient is expected to benefit from the exposure.

There is considerable advice and assistance on completing the IRAS form – some of this is on the form itself, some in the form of Guidance Notes: all accessible via the IRAS website: https://www.myresearchproject.org.uk/

Note: Trials involving therapeutic uses of ionising radiations are not undertaken at this time.

Clinical Radiation Expert. (CRE)

For research trials where ESHT is the sole or main centre, a CRE must be appointed for the trial for the initial application to the REC. Essentially the role of the CRE is to provide justification for the trial as a whole regarding exposures to radiation (for a more detailed explanation of the role, please see the Guidance mentioned above).

- Where ESHT is the main or sole centre, the CRE will be identified by the Modality Manager, and will be an IR(ME)R Practitioner for the Trust, relevant to the imaging modality.
- For trials where the exposure to radiation is not carried out under the control of the Imaging Department (e.g. Cardiology), the relevant research team should discuss the appointment of the CRE with the IR(ME)R Team.
- Please note: the CRE and the Chief Investigator (CI) should not be the same individual.

Application of IR(ME)R

It is important to be clear when exposures come under the remit of IR(ME)R.

IR(ME)R must be complied with for ‘research exposures’. These are defined as ‘any exposure required by the research protocol following initial consent from the participant’. It includes all exposures carried out on the participant as determined by the protocol including those which would otherwise be part of routine clinical care for patients treated outside the research setting.

If exposures are required prior to recruitment to the trial in order to assess whether the participant is suitable for the trial then this would be included in the trial protocol and would be regarded as a research exposure and would require ethical approval.

However if the selection criteria refer to exposures received outside the study and the study protocol does not include these exposures then they will be regarded as normal clinical exposures and would not require ethical approval.

If there is any doubt as to whether research exposures form part of the study this should be discussed with the MPE at an early stage.

Application Process for Research Projects Involving Ionising Radiation For Diagnostic Purposes

There are two categories of project that need to be considered:-

> **First Category:** where ESHT is the sole or main co-ordinating centre and provides the Chief Investigator (CI) for the trial

Here there are two distinct phases required –

- the IRAS application for ethical approval and when ethical approval has been granted,
- the local arrangements for IR(ME)R compliance.

Second Category: where the Trust is a participating site to a trial organised elsewhere. The Trust will then provide the Principal Investigator (PI). If it is a single-site project, the CI will also be the PI.

Here it is only the local arrangements that need to be considered.

1. Sole or Main Co-ordinating Centre

As the sole or main co-ordinating centre, we will initiate the trial and the CI will complete the IRAS Application Form. REC approval will be through a Multi-Centre Research Ethics Committee (MREC) appointed by NRES or HRA.

The first point of contact for the CI is the Modality Manager.

The process is as follows:

1. The Clinical Radiation Expert (CRE) and Medical Physics Expert (MPE) are identified by the Modality Manager. These persons are responsible for the justification and risk evaluation for all the participants in the whole trial. The CI must consult the CRE and MPE at the stage of producing the research study protocol.

More than one CRE/MPE may need to be identified if multiple modalities are involved. In this case an individual CRE/MPE will be identified as the lead and they will be responsible for completion of the relevant section of the IRAS form. Contributing CRE/MPEs will be identified on the form.

2. It is important at this stage to identify what are regarded as exposures for the normal management of the patient, and which are additional exposures required for the trial. This information must be supplied to the CRE/MPE.

3. The MPE will need to make an assessment of the total research protocol dose for the trial and attempt to ensure this is set such that other participating centres can work within this dose. It is important that the CI and CRE consider imaging requirements such that variations between research sites are considered, and these variations are included in doses assessed. The total research protocol dose (for all imaging modalities) will be the ethically approved dose.

4. It is unlikely that information from external participating sites will be available, and in any case other sites may be recruited later. These sites will assess their imaging against the ethically approved dose - if it transpires that they are not able to operate within this dose they will either be excluded from taking part in the trial or the CI will have to apply to the original MREC for a substantial variation on the ethical approval.

Completion of the IRAS Application Form

Assistance should be sought from the MPE on the completion of the Ionising Radiation Sections of the IRAS application form (Part B, Section 3).

Note: the form asks at an early stage if any ionising radiation is involved in the project (even if it is deemed to be part of normal care for the patient). It is important to answer this 'Yes' as it results in the correct generation of forms later in the process.

Please note that there are other sections of the form that need to be completed in relation to ionising radiation – in particular A19

When it has been established what imaging procedures are required the MPE will calculate doses and establish a target dose/dose constraint taking into account possible variations in standard clinical practice and doses between centres. The CRE will provide the justification for the exposures. Appropriate text will be provided to complete the relevant sections of Part B, Section 3, and the patient information sheet.

Nuclear Medicine Specifics

Under IR(ME)R research involving the administration of radioactive substances must be approved by an expert committee, which is the Administration of Radioactive Substances Advisory Committee (ARSAC).

If ESHT are the main or only centre then the study sponsor must submit a preliminary research assessment (PRA) form to ARSAC. This is generated by the IRAS system. The form must be emailed to ARSAC along with a copy of the patient information sheet (PIS) at the same time as submitting the Research Ethics Committee (REC) form to the REC.

Under IR(ME)R any research trial involving the administration of radioactive substances also requires the employer and practitioner to hold a license that includes the procedures within the research protocol. If the procedure is not included on either a Practitioner of Employer license then an application for a new license or amendment to an existing license will be required. Please note that it may take up to 2 months for the license to be approved. If you are not sure whether a license already exists then contact the nuclear medicine department for advice.

The co-ordinating MPE will provide a Word document with appropriate text to be pasted into Part B Section 3 of the IRAS application form.

Site Specific (Information) Form (Part C)

A Site Specific form needs to be completed for each participating site, including the main centre, in order for the relevant imaging modality to assess capacity to perform the required trial examinations.

Locally, this must be authorised by either the IR(ME)R Team or the IR(ME)R Practitioner by submitting a Feasibility Form.

Radiation related information is populated in this form depending on answers of previous questions (in particular A19).

This is fairly self-explanatory – however please note the following:

- If necessary, an ARSAC application form is generated by using the button in section 22.
- Authorisations required in section 23 are managerial, not scientific/medical/technical.

Other Information

Ideally subjects should be aged over 50 years of age as the radiation risks are lower.

Children as subjects will require special justification by the IR(ME)R Practitioner.

Pregnant, or potentially pregnant, individuals must not be used as subjects in a research project involving the use of ionising radiation unless the pregnancy is central to the aims of the project.

In the case of studies involving radioactive administration, subjects who are breastfeeding should be excluded unless their participation is essential.

Procedures must be selected to ensure the dose of radiation is as low as reasonably practicable, consistent with the intended outcome.

The individuals concerned must participate voluntarily in the research programme and must be fully informed in advance about the risks of the exposure. A comparative risk assessment will be carried out and the level of risk specified as Trivial (<0.1mSv), Minor (0.1 to 1mSv), Intermediate (1 to 10 mSv) or Moderate (> 10 mSv). Patient Information Sheets must be produced appropriate to the level of risk – for Intermediate levels of risk and higher the risk information must be more detailed. Exposure information for this Trust is required and a Trust application form for x-ray and nuclear medicine exposures must be completed fully for this purpose. This is addition to any NRES paperwork for multi-centre trials

Declarations

Once the IRAS Form has been completed, declarations need to be made by the CRE/MPE. This is done electronically using their IRAS logins.

2. Participating Site

As a participating site we supply the main site with information regarding doses for the proposed examination. We will also be supplied with Part C of the IRAS application form- the Site-Specific Assessment (SSA).

Part C is completed by the local Principal Investigator (PI). Question 18 which relates to the use of ionising radiation is populated automatically from a previous part of the form.

Local approval is necessary to demonstrate compliance with IR(ME)R, and is the same whether we are a participating site or the sole or main centre. In this way we demonstrate that we are able to perform the required exposures within the ethically approved dose.

A local IR(ME)R Practitioner and MPE must be identified, even though the justification and risk assessment for the trial as a whole comes from the main site. This ensures compliance with the requirement that each exposure is individually justified.

The process is as follows:-

1. Feasibility in Principle must be agreed for the trial and this will include Nuclear Medicine when applicable. The IR(ME)R team will consult an IR(ME)R Practitioner and the leads for the area (radiographer or technologist), who will agree the project in principle and consider the imaging guidelines in relation to this site. For Nuclear Medicine exposures this must be the Nuclear Medicine IR(ME)R Practitioner i.e. the ARSAC licence holder.

2. An IR(ME)R practitioner and an MPE are identified locally – consult the IR(ME)R Team for this (these may be the same CRE/MPE as used for the ethics approval if we were the sole or main centre).

3. Complete the form ‘Application For Research Projects Involving Ionising Radiation for Diagnostic Purposes’ and/or ‘Application For Research Projects Involving Nuclear Medicine Therapeutic Exposures’. They are available in Appendix 5. Ideally this should be completed electronically. Whoever is completing this form should make it clear to the MPE on which Trust site(s) the patients will be imaged, to ensure the correct dose calculations are carried out.

4. Provide a brief summary of the project, in particular identifying all exposures or scans and highlight those which are part of routine care and those which are additional. Also indicate the duration of the trial and frequency of procedures (per year) for an individual.

5. Provide a copy of any imaging guidelines and Part B, Section 3 from the original IRAS application form, the Patient Information Sheet and the trial imaging protocol (as .pdf files if possible).

6. Return these to the MPE along with a paper copy of the application form

7. The Quality and Safety Team will consult with an MPE to have an effective dose calculated for the exposure(s). The MPE provides a dose notification for this Trust with a recommendation that the Main Centre has to refer it back to the REC if we cannot perform the imaging within the ethically approved effective dose. Otherwise, no further action will be required.

8. This report will also include local target doses/dose constraints as appropriate.

9. This information will then be taken back to the IR(ME)R Practitioner(s) by the Quality and Safety Team for final justification of the exposures.

10. The IR(ME)R Team will update their database accordingly, and the target dose and dose constraint values will be made available to the relevant Imaging staff

Notes

- Any exposure of an individual of childbearing potential will be carried out during the 10 days or 28 days following the onset of her LMP according to examination protocols found in the Medical Exposures Manual
- Approved Operators will always administer the radiation to the patient using appropriate optimisation.
- The IR(ME)R Practitioner's signature in the Declaration means the Practitioner has carried out the justification of the exposure and hence Authorises it to proceed. Once the project has been approved, a copy of this form is lodged with the x-ray/nuclear medicine department as proof that the procedure has been Authorised under IR(ME)R.
- The Principal Investigator for the project will be the Referrer for the examinations. Under IR(ME)R they must, therefore, be a registered medical or dental practitioner or other healthcare professional. For Nuclear Medicine the referrer must be a medical practitioner.
- If a referral is for research purposes then "Research" must be prominently marked on the referral form. This will not apply in the case of a referral that is part of a patient's normal treatment or diagnosis.
- Every x-ray or nuclear medicine procedure involving radiation carried out as part of the project must have a written evaluation even if the results are normal.
- NOTE: This procedure only applies for imaging performed in ESHT departments.

3. Monitoring Compliance with the Document

Element to be Monitored	**Lead**	**Tool for Monitoring**	**Frequency**	**Responsible Individual /Group** **Group for review of results/report**	**Responsible individual/group** **Group for acting on recommendations action plan**	**Responsible individual/group for ensuring action plan/lessons learnt are Implemented**
Radiation Incidents	Risk Lead	DATIX	Monthly	Risk Group	Radiation Protection Group	Radiation Protection Supervisor
Reporting Timeframe	Radiology Services Manager	Information Team Database	Monthly	Risk Group	Radiation Protection Group	Radiology Clinical Lead
Unreported Volume	PACS Team	HSS CRIS	Monthly	Risk Group	Radiation Protection Group	Radiology Clinical Lead
Equipment	RPSs	Maintenance Reports	Quarterly	Radiation Protection Group	Radiation Protection Group	Radiology Clinical Service Manager
Training	Modality Leads	ESR	Annual	Risk Group	Radiation Protection Group	Radiology Clinical Service Manager

4. References

The Ionising Radiation Regulations 2017, SI 2017/1075 HMSO

The Ionising Radiation (Medical Exposure) Regulations 2017, SI 2017/1322

The Ionising Radiation (Medical Exposure)(Amendment) Regulations 2018, SI 2006/2523

COREC Approval for research involving ionising radiation. V1 December 2006

Medical and Dental Guidance Notes, 2002, IPEM

Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources, Administration of Radioactive Substances Advisory Committee (ARSAC), February 2023

British Institute of Radiology - Guidance on using shielding on patients for diagnostic radiology applications March 2020

Appendix A: Equality Impact Assessment Form

1. Cover Sheet

Please refer to the accompanying guidance document when completing this form.

Strategy, policy or service name	IR(ME)R 2017 Employers Procedures Manual
Date of completion	September 2023
Name of the person(s) completing this form	Ian Diton
Brief description of the aims of the Strategy/ Policy/ Service	To ensure the health and safety of employees, of contractors working on Trust premises and of members of the public who may be exposed to the hazards arising from the use of ionising radiations, lasers, ultra-violet and other time-varying electric or magnetic fields is maintained at all times.
Which Department owns the strategy/ policy/ function	Radiology Department
Version number	V13
Pre Equality analysis considerations	Click here to enter text.
Who will be affected by this work? **E.g. staff, patients, service users, partner organisations etc.**	Staff and Patients
Review date	September 2023
If negative impacts have been identified that you need support mitigating please escalate to the appropriate leader in your directorate and contact the EDHR team for further discussion.	To whom has this been escalated? Name: Click here to enter text. Date: Click here to enter a date.
Have you sent the final copy to the EDHR Team?	Choose an item.

2. EIA Analysis

<table>
<tr><td></td><td>☺ 😐 ☹</td><td>Evidence:</td></tr>
<tr><td>Will the proposal impact the safety of patients', carers' visitors and/or staff?

Safe: Protected from abuse and avoidable harm.</td><td>Choose:
Positive
Neutral
Negative</td><td>Click here to enter text.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td>Choose:
Positive
Neutral
Negative</td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
<tr><td>Gender reassignment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr>
<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>Is the proposal of change effective?

Effective: Peoples care, treatment and support achieves good outcomes, That staff are enabled to work in an inclusive environment. That the changes are made on the best available evidence for all involved with due regards across all 9 protected Characteristics</td><td>Yes</td><td>Click here to enter text.</td></tr>
</table>

<table>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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</td></tr>
<tr><td>What impact will this have on people receiving a positive experience of care?</td><td>Choose:
Positive
Neutral
Negative</td><td>Click here to enter text.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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<tr><td>Gender reassignment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr>
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<tr><td>Does the proposal impact on the responsiveness to people's needs?</td><td>Choose:
Positive
Neutral
Negative</td><td></td></tr>
</table>

<table>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
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<tr><td>What considerations have been put in place to consider the organisations approach on improving equality and diversity in the workforce and leadership?</td><td>Choose:
Positive
Neutral
Negative</td><td>Click here to enter text.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
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</td></tr>
<tr><td colspan="3">Access
Could the proposal impact positively or negatively on any of the following:</td></tr>
<tr><td>• Patient Choice</td><td>Choose:
Positive
Neutral
Negative</td><td></td></tr>
</table>

<table>
<tr><td>• Access</td><td>Choose:
Positive
Neutral
Negative</td><td></td></tr>
<tr><td>• Integration</td><td>Choose:
Positive
Neutral
Negative</td><td></td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><th>Race</th><th>Gender</th><th>Sexual orientation</th><th>Age</th><th>Disability & carers</th></tr>
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<table>
<tr><td>Engagement and Involvement
How have you made sure that the views of stakeholders, including people likely to face exclusion have been influential in the development of the strategy / policy / service:</td><td>Choose:
Positive
Neutral
Negative</td><td></td></tr>
<tr><td>Equality Consideration Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
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</td></tr>
</table>

Duty of Equality **Use the space below to provide more detail where you have identified how your proposal of change will impact.**	Choose: Positive Neutral Negative	
Characteristic	***Rating*** ☺ ☹ 😐	***Description***
Race	Choose: Positive Neutral Negative	
Age	Choose: Positive Neutral Negative	
Disability and Carers	Choose: Positive Neutral Negative	
Religion or belief	Choose: Positive Neutral Negative	
Sex	Choose: Positive Neutral Negative	
Sexual orientation	Choose: Positive Neutral Negative	
Gender re-assignment	Choose: Positive Neutral Negative	

Pregnancy and maternity	Choose: Positive Neutral Negative	
Marriage and civil partnership	Choose: Positive Neutral Negative	

Human Rights

Please look at the table below to consider if your proposal of change may potentially conflict with the Human Right Act 1998

Articles		Y
A2	Right to life	Y/
A3	Prohibition of torture, inhuman or degrading treatment	Y/
A4	Prohibition of slavery and forced labour	Y/
A5	Right to liberty and security	Y/
A6 &7	Rights to a fair trial; and no punishment without law	Y/
A8	Right to respect for private and family life, home and correspondence	Y/
A9	Freedom of thought, conscience and religion	Y/
A10	Freedom of expression	Y/
A11	Freedom of assembly and association	Y/
A12	Right to marry and found a family	Y/
Protocols		
P1.A1	Protection of property	Y/
P1.A2	Right to education	Y/
P1.A3	Right to free elections	Y/

Appendix 1 – New Referrer Application Form

The Ionising Radiations (Medical Exposure) Regulations, 2017 require that all patients x-rayed or administered with radioactive substances at East Sussex Healthcare NHS Trust are referred by a registered medical practitioner, dental practitioner or other health care professional that have been granted entitlement by the Trust. Application is made to the Radiation Protection Committee, and the following information is required.

Full Name inc. Title:	
Staff payroll number (ESHT staff):	
Signature:	
Employer:	
Work Address (Including Department):	
Contact Phone Number:	
Work Email Address:	
Profession:	
Clinical Qualifications:	
Registration Body & Number:	
Intended Protocol(s):	
Protocol Lead:	
Reason for Application:	
Date of Application:	
Name of Supervising Clinician:	
Signature of Supervising Clinician:	
Contact Details of Supervising Clinician if different to work address above:	

*I agree that I have read, understood, and will practice within the scope of the protocol listed above. I understand that if I have any clinical queries regarding the scope or practice within the protocol, I will raise them with my Supervising Consultant or protocol lead.

(Signature) …….

(Date) …….

You will only be entitled to refer once this application has been received with its supporting documentation, signed and approved by the lead IR(ME)R Practitioner and you have received an e-mail confirming entitlement.

On completion, please either scan or photograph all the pages of the application and send to the following email address:-

esht.radiologyreferrers@nhs.net

If you have any queries about this form, or what information to include to support your application, please contact the non-medical radiological imaging team on esht.radiologyreferrers@nhs.net

Notes for Applicants

- Referral Criteria MUST be clearly stipulated as part of the agreed Protocol for Referral
- The purpose of Referral Criteria is to ensure the Practitioner at the Hospital has sufficient information to justify the requested procedure.
- Referral Criteria must be complied with, otherwise the request form will be returned to you to be completed correctly.
- Staff returning a request form will be acting under Procedures laid down by the Trust.
- Repeated failure to comply with Referral Criteria will result in the entitlement to refer to this Trust for imaging being removed.

Applications from Outside ESHT

Please write to the Radiology Quality Manager who will present your case to the Radiation Protection Committee with:

- Stipulate the examinations, modalities you wish to refer for and for what clinical indications.
- Ensure you have clearly outlined who will be medically responsible for the patient's care.
- Provide details of Registered Practice Address
- Please complete the attached documentation to the best of your knowledge and provide all certificates of training.

Application to become a Referrer – Additional Supporting Information

1. **Have you undertaken the ½ day inhouse IR(ME)R 2017 training provided by the ESHT Radiology department?**

   YES / NO*
   If **yes,** please supply evidence of that training with dates and location below.

   If **no,** contact radiology for dates of forthcoming training

2. **Are you applying to act as a referrer under an existing agreed referral protocol?**

   YES / NO

   If **yes,** please state the full title of the protocol and revision level below.

   ……

   If **no,** please contact the Radiology Quality Manager for further advice

3. **Who is the Supervising Clinician (Medically Qualified) for this agreed protocol?**

   Name:…….

   Post:……

   Signature:……..

The Supervising Clinician must ensure that the Clinical protocol under which you are applying to become a referrer is up to date and reflects best practice.
They must also sign your application.

Application to become a Referrer – Outcome of Application

Name of applicant……

Application **agreed** by East Sussex Healthcare NHS Trust Radiation Protection Committee

DATE:……

SIGNED:……..

POSITION:……..

REFERRAL CRITERIA SENT TO APPLICANT:……..

Application **refused** by East Sussex Healthcare NHS Trust Radiation Protection Committee

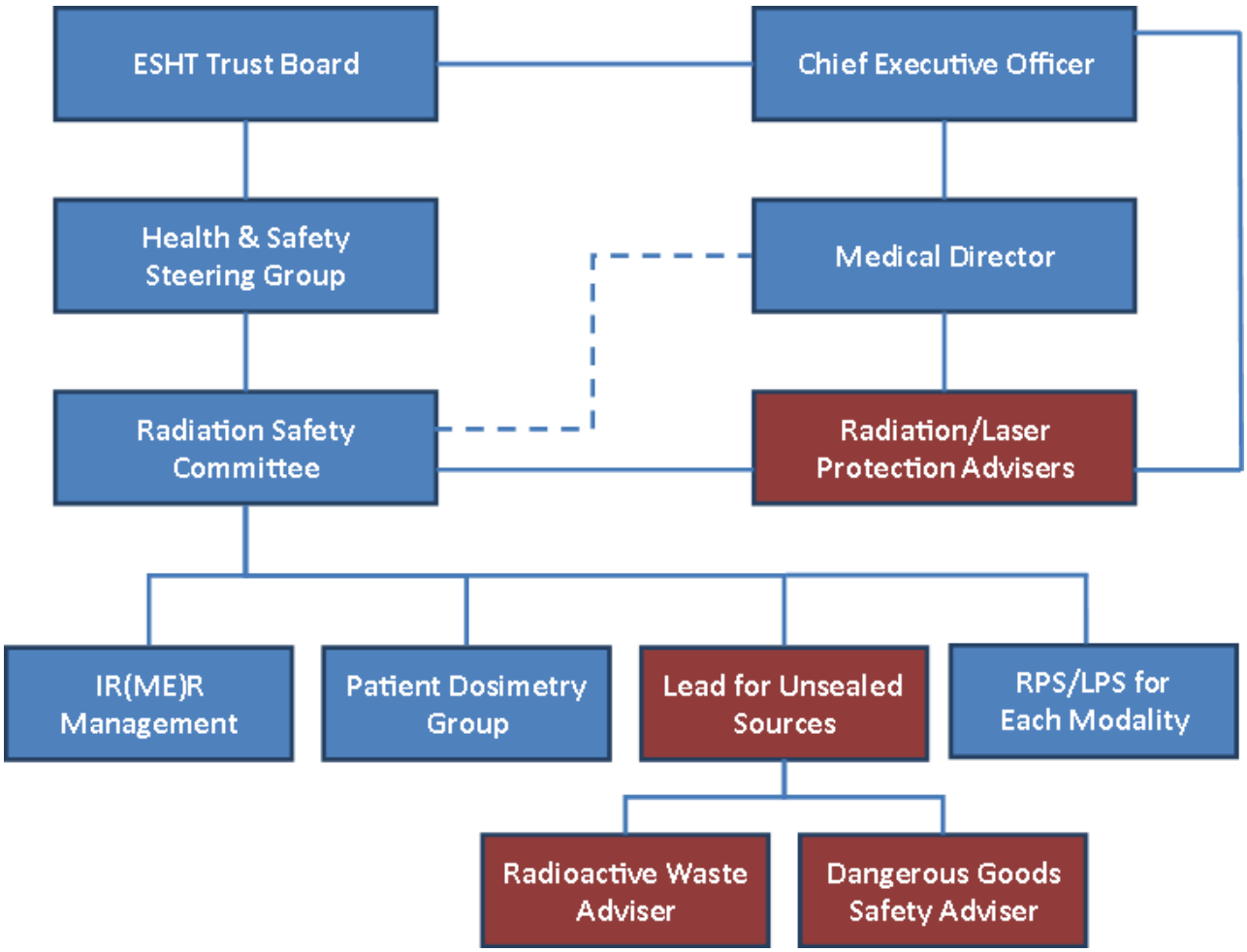
DATE:……

SIGNED:……..

POSITION:……..

REASONS FOR REFUSAL:

Appendix 2 - Governance Structure



Appendix 3 - Radiation Safety Committee Terms of Reference

1. Purpose

- The committee is to monitor co-ordinate and advise on all matters regarding ionising radiation safety and promote good radiation working practice; and report radiation protection issues as appropriate to the Health & Safety Steering Group.

2. Objectives

1. To advise the Trust on the implementation of legislation and guidelines on issues of radiation safety, for both ionising and non-ionising radiations (including lasers).
2. To monitor the Trust's radiation protection performance by:

   a. receiving reports and guidance from the appointed RPA and LPA on issues of radiation and laser safety including the outcome of audit visits.

   b. receiving reports from Divisions and Departments on radiation safety risk assessments, Ionising Radiation (Medical Exposures) Regulations 2017 compliance, training, reports on incidents and associated action plans, internal and external audits and inspections, issues of cooperation between employers and other radiation safety issues
3. To review and monitor the Trust Radiation Safety Policy.
4. To develop and review Trust level procedures in support of the implementation of the Radiation Safety Policy.
5. To monitor the implementation of all radiation and laser safety related policies and procedures.
6. To monitor the identification and management of radiation risks.
7. To ensure that the relevant CQC Outcomes are being managed and provide any additional monitoring in areas of low compliance.
8. To support continual improvement in radiation protection culture and practice.
9. To receive and act on advice for the Trust's Medical Physics Experts and Radioactive Waste Advisor(s).
10. To review and maintain all relevant quality assurance programmes.
11. To review the Groups Terms of Reference on an annual basis and if necessary make recommendations for amendment.
12. To facilitate a close working relationships between the management of radiation safety and other areas of risk management.

3. Membership:

- Clinical Lead for Radiology (Chair).
- Radiation Protection Adviser (via UHSussex).
- Laser Protection Adviser (via UHSussex).
- Radiology Services Manager.
- Radiation Protection Supervisors for each area.
- Laser Protection Supervisors for each area.
- Other representatives of services/departments with radiation facilities.
- Representatives of other external agencies, other Site Users and/or internal Departments / functions may also be invited to attend, as required.

- CSD Divisional Governance Manager
- Trust Health & Safety representative.
- Trust Risk management representative.
- Trust executive representative

4. Constitution

Attendance will be monitored at each meeting. No business shall be conducted unless the Radiation Protection Committee is quorate. The quorum is four members, provided that this includes;

- the chair or suitably delegated individual.
- at least one RPS.
- the Radiation Protection Adviser or their delegate.
- the Laser Protection Adviser or their delegate.

5. Accountability and Reporting arrangements

- Secretarial support will be provided for the provision of meeting minutes.
- The Chair shall provide quarterly reports to the Trust Health & Safety Steering Group for the last radiation protection meeting of each calendar quarter.
- The Chair attends the Trust Health & Safety Steering Group as its Radiation Safety Representative.
- The Chair of the Group shall draw to the attention of the Trust Health & Safety Steering Group and The ESHT Trust Board any issues that require disclosure to the full Board, or require executive action.
- A nominated Risk Safety Group member shall attend the Trust Health & Safety Steering Group as appropriate to progress investigations and actions associated with radiation incidents.
- No Annual Report will be produced; however radiation incidents are submitted annually together with outcomes by the Clinical Governance Facilitator responsible for Radiology Risk meetings

6. Mapped Relationships

- Health & Safety Steering Group (Quarterly Reports)
- CSD Divisional H & S Group
- Trust Emergency Preparedness Committee (NAIR Coordinator)

7. Frequency

- Meetings shall be held quarterly.

Date of Next Review - December 2023
Date of Approval by the Trust Health & Safety Steering group – TBC

Appendix 4 - Information for Carers and Comforters

Information for Carers and Comforters in Diagnostic Radiology

(separate information is available for Nuclear Medicine and Radiotherapy exposures)

Under the Ionising Radiation (Medical Exposures) Regulations 2017, Carers and Comforters are defined as 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 a radiation exposure.

Any person supporting a patient or imaging plate must wear protective clothing, and stand as far from the main radiation beam as possible.

A light beam from the x-ray machine usually shows where the main radiation beam will be during the taking of the x-rays. You must not put any part of your body in this beam. This will ensure that you are exposed to scattered radiation only, which will be a very low dose. Please note that the light will usually turn off before the exposure happens but you should follow the instructions of the staff member directing you.

The Lead IRMER Practitioner has justified the very small additional exposure of carers and comforters to scattered radiation (ie not the main radiation beam) within general imaging where supporting an individual undergoing a radiation exposure is required to produce diagnostic quality images.

('Justified' means that it has been determined that the benefits significantly outweigh any potential risk from the scattered radiation.)

If the above rules, and any other instructions given to you by the radiographer, are followed, it is most unlikely that you would receive more than a trivial additional dose.
We would not expect anyone acting as a carers or comforter in x-ray to receive the equivalent of more than 24 hours of natural background radiation and often much less. Everyone is exposed to some radiation from the natural environment every day.

In some situations you may be provided with a personal dosemeter to wear under a lead apron. If so, please use it as instructed and ensure that it is handed back when you remove the apron at the end of the procedure.

If you have previously acted as a Carer and Comforter (holding patient or cassette during patient x-rays) please let us know as the small doses you receive each time will add up and a dose assessment may be required.

N.B. This document will be scanned and retained on the patient's record

Carer and Comforter Name ……

Relationship to Patient ……

Date of x-ray ……..

Previously acted as Carer and Comforter
(Y/N Including date(s) if known) ……...

Pregnancy status (If applicable) ..……

I have read and understood this document regarding the implications of acting as a Carer and Comforter:

Appendix 5 – Incident Data Proforma

In the event of an inappropriate exposure the following should be completed as fully as possible in order to provide sufficient information to carry out a dose calculation. Additional sheets should be used where appropriate. If you do not have accurate information, give a best estimate. **As Medical Physics need to estimate the effective dose of both the intended and total exposures, please give details of both the exposure(s) given in error and the intended exposure(s) given making clear which details refer to which exposure.**

Please e-mail completed documents to uhsussex.mpe@nhs.net

Patient Name				Hospital Number		Hospital	
Date of Incident		Date of LMP if pregnancy is possible		Room		Tube Number	
Datix Reference		Patient Average Size & Weight? (Yes) If no, please comment, e.g. BMI++, BMI--, tall, short, etc.					

Radiography/Fluoroscopy:

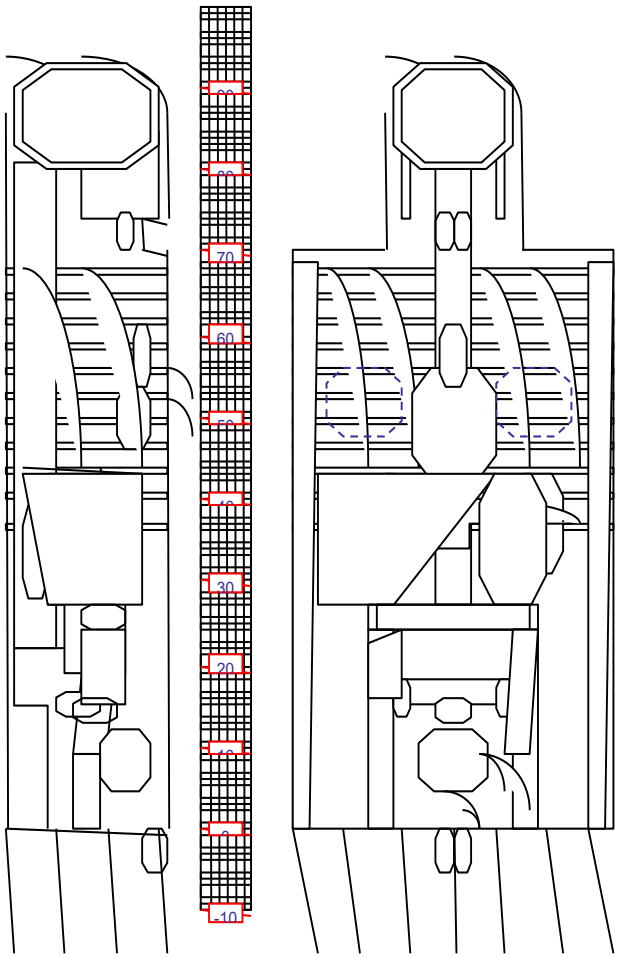
Examination (include view as well as L or R)	Tick if *non* standard coverage	kV	mAs	Time	Post Exposure mAs	AEC or Manual Exposure?	EI	Intended Exp Yes/No	Plate Size	Focus to *Skin* dist cm (estimate)	Actual DAP Number	DAP units	Shielding? Where?

* Please also state amount of additional copper used if applicable to radiography exposures.

For fluoroscopy:

Estimated Intensifier Field Size (or mag field used)	cm	Screening Time (Estimate)		Screening mA (Estimate)		Screening kV (Estimate)	
How Much Additional Copper in Beam*	mm						
Number of video runs		Duration of each run					

Computed Tomography - Mark areas irradiated on diagram



Area 1 Helical / Sequential (delete as appropriate)

kV = mA = Rot. Time (s) =

Pitch (helical) = Increment (seq) =

Collimation (total irradiated beam width e.g. 20 mm) = mm Number of slices =

Detector combination (e.g. 8 x 2.5 mm) =

DLP (mGy.cm) = Total mAs displayed =

Area 2 Helical / Sequential (delete as appropriate)

kV = mA = Rot. Time (s) =

Pitch (helical) = Increment (seq) =

Collimation (total irradiated beam width e.g. 20 mm) = mm Number of slices =

Detector combination (e.g. 8 x 2.5 mm) =

DLP (mGy.cm) = Total mAs displayed =

Displayed CTDIw =

mA modulation used: yes / no

max mA Noise setting

NB: Please give details of both the exposure(s) given in error and the intended exposure(s) given, making clear which details refer to which exposure

Appendix 6 – Local Application For Research Projects Involving Ionising Radiation for Diagnostic Purposes

The purpose of the form is to provide the information required to calculate the dose to the subject and assess the risk from this dose. If we are the Main Co-ordination Centre for the trial, patient information may be attached.

This is in addition to the IRAS application form – the appropriate sections of that form must be completed as well.

The Principal Investigator/Research Co-ordinator only need complete the sections in white. DO NOT complete shaded sections.

Project Details

Please give the title and a brief, legible outline of the aims of the project. Also include any IRAS Patient Information, dose calculations and risk estimates. It is particularly important to include imaging guidelines and a copy of IRAS form Part B, Section 3.

Give the name of the Principal Investigator.

Describe the normal radiological management of the volunteer.

Describe the additional views you are proposing and the frequency at which you would like these carried out. Please state if the project is time limited or if the exposures are to be continued indefinitely. Please be as accurate and as clear as you can about your proposals.

General

Please answer these questions as appropriate, but only if we are the Main Co-ordinating Centre. It is particularly important if there will be a medical benefit to the participants.

X-Rays

Please list each view you are proposing, giving both location on the body (e.g. lumbar spine) and projection (e.g. AP, Lateral). The factors and doses will be entered by others.

Nuclear Medicine

This data will be completed by others.

Details of subjects

Please enter the information as requested. The total dose per subject will be entered by the MPE.

Doses

If we are the Main Co-ordinating Centre these doses, in conjunction with national data, will be used to assess risk and to produce information for the Patient Information Sheet.

If we are a participating centre, the doses will be returned to the Main Co-ordinating Centre with the Site Specific Assessment to inform them of the doses that will be received at this site. If they are within the target dose/dose constraint set by the Main Co-ordinating Centre, no further action is required. However if the doses are higher, then they must be referred back to the approving Ethics Committee (by the Main Centre) for further ethical approval.

Risk Assessment

This will be completed by the MPE for project where the Trust is the co-ordinating centre. Information will then be provided for the Patient Information Sheet.

Research Application form for research trials Involving Ionising Radiation for Diagnostic Purposes

This form must be completed for all research trials that involve ANY exposures to ionising radiation.

Information contained in this form will be used by Radiological Science staff and the Medical Physics Expert (MPE) at UHSussex for dose calculation and risk estimation, and then by the IR(ME)R Practitioner for justification of the exposure. N.B. if MRI/US included in the trial, there is no need to complete a separate research application form as these details can be added to this form.

DO NOT FILL IN SHADED SECTIONS, these sections are for Imaging staff and/or MPEs to complete.

Project Details *(Please complete electronically)*

Short title of Project:- **IRAS Number:-**

Full title of Project and Brief Details:-

WHEN SUBMITTING THIS FORM TO THE MPE EMAIL ADDRESS [redacted]) PLEASE ALSO ATTACH THE PATIENT INFORMATION SHEET, TRIAL PROTOCOL, AND PART B, SECTION 3 OF THE IRAS APPLICATION FORM

Name of Principal Investigator **and** Research Co-ordinator

Contact details of Person completing form

Name of IR(ME)R Practitioner Justifying Exposure (completed by Imaging)

Ionising Radiation Procedure (body part + view) e.g. PA Chest x-ray, AP Lumbar Spine, CT abdomen, bone scan, whole body DEXA	**Total number of procedures**	**Number of routine procedures**	**Number of additional procedures**	**Timing of each procedures**

If appropriate, state over what time period will these examinations be carried out (e.g. if until disease progression or similar, please give typical time period for this):-

If any imaging aspects of protocol will not be performed locally please provide details below:-

Indicate which sites procedures will be performed at:- **EDGH** **CONQUEST**

N.B. :- **Routine** procedures are those that would be given in the normal radiological management of this type of patient
Additional procedures are those that you propose to give above the routine procedures, for patients on this research trial.

General

Have pregnant patients/volunteers (except in exceptional circumstances) been excluded?	Yes / No
Have breast-feeding volunteers (for studies involving radionuclides) been excluded?	Yes / No
Does the project involve medical benefit for the participants? **IMPORTANT**	Yes / No
Does the information to patients/volunteers make it clear that some additional exposure to ionising radiation is involved and the consequent risk?	Yes / No

X-Rays

Research Nurse	**Medical Physics Expert**
Procedure / scan / x-ray	**Typical Effective Dose per View (mSv)**

Nuclear Medicine

Research Nurse	**Medical Physics Expert**					
Scan Type	Radionuclide	Chemical form	Route of Administration	Activity (MBq)	Number of Administrations Per subject	Effective Dose per Administration

Non-Ionising Radiation

Please list all non-ionising exposures (e.g. MR and/or ultrasound) required by the trial protocol:-

Non-Ionising Radiation Procedure e.g. MR chest	**Total number of procedures**	**Number of routine procedures**	**Number of additional procedures**	**Timing of each procedures**

Details of Subjects To Be Studied

Research Nurse or Chief/Principal Investigator						Medical Physics Expert
Trial Arm (if appropriate)	Anticipated Number of Subjects	Age Range	Sex	Clinical Condition	Name, Number and Frequency of Examinations	Typical Total Effective Dose per Subject (mSv)

Local Target Dose/Dose Constraint

Target Dose	Applies only to subjects receiving some benefit from the exposure (i.e. normal care exposures). Procedure must aim not to exceed this dose. If dose exceeded, a comment is required on CRIS.
Dose Constraint	Applies only to subjects ***not*** receiving any benefit from the exposure.(i.e. additional care exposures). If the constraint is exceeded a Datix report must be completed.

Procedure	Target or Constraint?	Value	Approx. Effective Dose (mSv)

Is Patient Information Sheet acceptable? Yes No

(to be circled by the MPE – this is regarding the explanation of the radiation risks only)

Declarations

Declaration by the Chief/Principal Investigator

I will communicate the risk to the volunteers as a condition of the project and a legal requirement of Ionising Radiation (Medical Exposure) Regulations, 2017.

Signature	Print Name	Date

Additional Declaration by the Principal Investigator in the case of Nuclear Medicine exposures when the Principal Investigator is not the ARSAC Certificate holder (or ARSAC applicant)

I will act in accordance with the ARSAC Certificate holder's written instructions

Signature	Print Name	Date

Once the research nurse and Chief/Principal Investigator have completed all of the above relevant sections of this form, the form must be emailed to uhsussex.mpe@nhs.net

The Radiological Science staff and the MPE will then estimate the typical effective doses of each research exposure listed and complete the form with these values, together with relevant Target Doses and/or Dose Constraints, and the MPE(s) will sign below.

Radiological Science will also produce a Dose Notification document for the trial detailing how the ESHT typical doses compare to the nationally ethically approved doses in the IRAS form.

This form and the Dose Notification document will then be emailed by Radiological Science to the Clinical Modality Managers - Quality and Safety who will arrange for the IR(ME)R Practitioner to review these. If happy with the doses and exposures, and the Participant Information Sheet, the IR(ME)R Practitioner will sign below to authorise the research exposures under IR(ME)R.

Declaration by the Medical Physics Expert(s)

I am satisfied that the values indicated above is a reasonable estimate of the radiation dose to which the subjects will be exposed.

Signature	Print Name	Date
1)		
2)		
3)		

Declaration by the IR(ME)R Practitioner(s)

I am satisfied that the legal requirements of the Ionising Radiation (Medical Exposure) Regulations, 2017 will be fulfilled and that these exposures are justified. I Authorise them to proceed.

Signature	Print Name	Date
1)		
2)		

Appendix 7 – Staff Signatures

I have read and understood the IR(ME)R documentation in the Medical Exposures Procedures Manual, and I agree to abide by it.

Name (Print)	Designation	Signature	Date

Name (Print)	Designation	Signature	Date

Appendix 8 – EP-03 Referral Criteria. Organisations requesting outside of the Trust.

Sussex Musculoskeletal Partnership East (SMSKPE) Nuclear Medicine Referrals

SMSKPE Nuclear Medicine requests are only made by appropriately qualified consultants within the SMSKPE system, namely NHS consultants that are working in SMSKPE community clinics.

SMSKPE requests are created using a password protected / smart card protected login to the electronic requesting software System one. This means only authorised consultants can create these requests. The requests come with the name of the requesting consultant but not the electronic signature. The SMSKPE requests provide an audit trail of who created the request and contact details should the radiology team want to contact SMSKPE to discuss the request.

East Sussex Healthcare NHS Trust

Policy for the Safe Use of Ionising and Non-Ionising Radiations

Document ID Number	676
Version:	V7
Ratified by:	Patient documentation and Policy Ratification Group (chairs action)
Date ratified:	11 November 2021
Name of author and title:	[redacted], Radiation Protection Advisor, UHSussex, [redacted], Clinical Scientist, UHSussex
Date originally written:	May 2005
Date current version was completed	August 2021
Name of responsible committee/individual:	Radiation Protection Committee
Date issued:	11 November 2021
Review date:	November 2024
Target audience:	Employees and contractors
Compliance with CQC Fundamental Standard	Safe Care and Treatment Good Governance
Compliance with any other external requirements (e.g. Information Governance)	Health and Safety Executive Ionising Radiation Regulations
Associated Documents:	IR(ME)R 2017 Employers Procedures Manual. Health and Safety Management – New and Expectant Mothers Policy Arrangements

Did you print this yourself?
Please be advised the Trust discourages retention of hard copies of the procedural document and can only guarantee that the procedural document on the Trust website is the most up to date version

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1 2005180	July 2005	[redacted]	New document	
V2 2008055	April 2008	[redacted]		
V3 2011217	July 2011	[redacted]		
V4 2014186	August 2014	Radiology Services Manager and Medical Physics Expert	Update and reformatting to new Trust template	Flowcharts Responsibilities Review of procedures
V 5.0	October 2017	[redacted] and [redacted] (BSUH)	Updated	Major review and edit
V 6.0	November 2019	[redacted] and [redacted] (BSUH)	Updated	Review and minor edits to references etc.
V 7.0	August 2021	[redacted] and [redacted] (UHSussex)	Reviewed and Updated	Section 10.5 Annual reporting function changed to 'when required'. Brighton & Sussex University Hospitals NHS Trust (BSUH) changed to University Hospitals Sussex NHS Foundation Trust (UHSussex). Personnel changes (page 14).

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
[redacted]	Radiation Protection Advisor	16.06.2014
Dr Neil Barlow	Radiology Clinical Lead	16.06.2014
[redacted]	Radiology – Clinical Service Manager	16.06.2014
[redacted]	Radiation Protection Advisor	October 2017
Dr Justin Harris	Radiology – Clinical Lead	October 2017
Amanda Isted	Radiology – Clinical Service Manager	October 2017
Chris Salt	Nuclear Medicine Team Lead	October 2017
Radiation Protection Committee		December 2017
Radiation Protection Committee		November 2019
Policy Ratification Group		Not required due to minor changes to this revision (Dec 2019).
Radiation protection Committee		November 2021
Policy ratification group		Not required due to minor changes to this revision (Nov 2021)

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

East Sussex Healthcare NHS Trust (hereafter the Trust) will ensure, as far as is reasonably practicable, that the health and safety of its employees, of contractors working on Trust premises and of members of the public who may be exposed to the hazards arising from the use of ionising radiations, lasers, ultra-violet and other time-varying electric or magnetic fields is maintained at all times.

As a general principle, the Trust is committed to a policy of keeping exposures to ionising and non-ionising radiations as low as reasonably achievable, consistent with the intended purpose.

The Trust is committed to complying with current regulations concerning the use of ionising and non-ionising radiation and general health and safety. These regulations include the Ionising Radiations Regulations 2017 (hereafter IRR17) for which the Health and Safety Executive is responsible, the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017) for which the Care Quality Commission is responsible, and the Environmental Permitting (E&W) Regulations 2016 (EPR16) for which the Environment Agency is responsible.

This policy specifies how the risks from ionising, non-ionising radiation and electromagnetic fields are to be managed within the Trust at all sites to ensure compliance with all relevant regulations and official guidance. It outlines the responsibilities of staff and the processes in place to ensure that safe practice is maintained.

2. Rationale

The trust is committed to providing a safe environment and meeting its responsibility for the control of both ionising and non-ionising radiation.

This policy specifies the required organisation, communication and nominated responsible officers for the implementation and compliance with relevant legislation and guidance pertaining to ionising and non-ionising radiation.

3. Scope

This policy is for the health and safety of its employees, members of the public and contractors working on the premises.

4. Definitions

Ionising
The process of an atom or molecule acquiring a negative or positive charge by gaining or losing electrons to form ions.

Non-Ionising
Any type of electromagnetic radiation that does not carry enough energy to ionise atoms or molecules, i.e. to completely remove an electron from an atom or molecule.

Radiation
The emission of energy as electromagnetic waves or as having subatomic particles, especially high-energy particles which cause ionisation.

Local rules
These are rules in place to cover all procedures using ionising radiation and areas where hazardous exposure to non-ionising radiations could occur.

Dosimetry
A device that monitors the dose to all staff working with ionising radiation by means of whole body dosemeters, extremity dosemeters and/or environmental monitoring.

Risk Assessments
An evaluation of the area where radiation is used. The outcome of the assessment will indicate if the control measures are effective or further mitigating action needs to be taken.

Quality Assurance tests
Tests that are carried out at regular intervals on all equipment involved in patient exposure with ionising radiation, as defined within IR(ME)R2017.

Optical Radiation
Term covering ultraviolet radiation, visible light or Infrared radiation.

5. Accountabilities

5.1 Chief Executive, Executive Lead for Radiation Safety and Trust Board

The Employer (Chief Executive) is ultimately responsible for ensuring compliance with the Regulations and holds overall responsibility for ensuring that systems are in place to manage risks arising from the use of ionising and non-ionising radiation.

Authority for this is however delegated to the Medical Director (Executive Lead for Radiation Safety).

The Trust Board delegates authority for approving radiation safety policies to the Radiation Protection Committee.

5.2 Chair of the Radiation Protection Committee

The Chair of the Radiation Protection Committee is responsible for ensuring that the radiation safety structure and implementation programme as outlined in this policy is kept under review, and all issues escalated and resolved as necessary.

The Chair reports quarterly to the Health and Safety Steering Group.

The Chair also reports to the Medical Director (Executive Lead for Radiation Safety) for any issue related to radiation safety and has access to the Medical Director and Chief Executive as required.

5.3 Radiation Protection Adviser

The Radiation Protection Adviser (RPA) is appointed in writing by the Employer to provide advice on the observance of the regulations, and in any health and safety matter in connection with ionising radiation. However, responsibility for compliance with the regulations cannot be delegated to the RPA, and this remains at all times with the Employer.

The Employer must notify the RPA in writing of the appointment, with details of the scope of the advice that is required. The RPA must be provided with adequate information and facilities to enable their work to be carried out effectively.

The RPA should make regular visits to all the areas under their jurisdiction where ionising radiations are used, and work in close consultation with Radiation Protection Supervisors and Heads of Department to ensure all necessary protective measures are being complied with in order to keep exposure to radiation as low as reasonably practicable.

5.4 Medical Physics Experts (MPEs)

MPEs are provided by the Brighton & Sussex University Hospitals NHS Trust (Now University Hospitals Sussex NHS Foundation trust UHSussex) Medical Physics Department (Radiological Science section) and can be consulted for advice on all matters relating to dose optimisation and radiation protection, in both X-ray and nuclear medicine settings.

5.5 MR Safety Expert (MRSE)

The MRSE is responsible for the provision of advice to managers, departmental heads and staff on MRI safety matters and on practical implementation of this policy and compliance of Local Rules.

The MRSE can provide scanning advice on contraindicated devices along with physics expertise for protocol development.

5.6 Laser Protection Advisor (LPA)

The Laser Protection Adviser (LPA) is appointed by the Employer to provide advice on the observance of the Regulations, and in any health and safety matter in connection with artificial optical radiation. However, responsibility for compliance with the Regulations cannot be delegated to the LPA, and this remains at all times with the Employer.

The Employer must notify the LPA in writing of the appointment, with details of the scope of the advice that is required. The LPA must be provided with adequate information and facilities to enable their work to be carried out effectively.

The LPA should make regular visits to all the areas under their jurisdiction where optical radiations are used, and work in close consultation with Laser Protection Supervisors and Heads of Department to ensure all necessary protective measures are being complied with in order to keep exposure to radiation as low as reasonably practicable.

5.7 Heads of Department

Each of Head of Department is responsible for the organisation of radiation protection requirements within their area of responsibility in accordance with the Regulations, Approved Codes of Practice, Guidance Notes and Local Rules.

In consultation with the RPA they must nominate suitably qualified Radiation Protection Supervisors who will be appointed by the chair of the Radiation Protection Committee.

The RPA, RPS and Occupational Health Department must be informed of the impending employment of a person who may be designated as a Classified Worker, in order that a suitable medical examination may be carried out prior to designation.

Any changes in procedure, equipment or environment, which may affect the radiation safety of the department, must be reported in writing to the RPA.

Any changes in procedure, equipment or environment, which may affect the laser safety of the department, must be reported in writing to the LPA.

5.8 Radiation Protection Supervisors & Laser Protection Supervisors

Radiation Protection Supervisors (RPSs) and Laser Protection Supervisors (LPSs) have supervisory roles in assisting the Employer to comply with the Regulations, and are responsible to their Heads of Department in all matters regarding radiation and laser protection/safety.

The RPS/LPS should supervise staff in their assigned area so as to ensure that the Local Rules are complied with.

The RPS should report any repeated infringements of radiation protection principles to their Head of Department, and also has direct access to the RPA as required.

As with the RPA, responsibility for compliance with the Regulations cannot be delegated to the RPS/LPS, and this remains with the Employer.

The employer commits to said persons sufficient resources to carry out their duties effectively.

5.9 Employees

Employees have a general responsibility under the Regulations such that they shall not knowingly expose themselves or any person to ionising radiation to an extent greater than is reasonably necessary for the purpose of their work, and they shall exercise all reasonable care while carrying out such work.

The employee is also required to make full and proper use of any personal protective equipment and monitoring devices, and report to the employer any defect he/she discovers in such equipment or devices.

All employees must read, understand and comply with any Local Rules, operating instructions and systems of work applicable to their working environment.

An employee must report to the RPS and their line-manager (or most senior person on duty) any instances of suspected over-exposure to themselves or others, including significant over-exposures to patients as a result of radiation equipment malfunction or defect. Guidance will be provided to all staff regarding the latest advice on what constitutes a “significantly greater” exposure to patients.

No employee shall intentionally or recklessly misuse or interfere with an ionising or non-ionising radiation producing piece of equipment.

An employee who is knowingly or suspects to be pregnant must inform (in writing) their manager and RPS as soon as is practical, so that appropriate measures can be put in place if required. For these measures, please refer to the Health and Safety Management – New and Expectant Mothers Policy Arrangements which is available on the Extranet.

Each department will comply with the Trust policy to ensure that staff who become pregnant are not involved in any situation where a significant dose may be received and do not receive a radiation exposure which could result in a foetal dose above 1 mSv. These arrangements will depend on the staff involved and the options for rotation to different areas. Some staff may be required to work under a restricted schedule especially areas where there is a greater potential for radiation exposure. There may be a requirement for more vigorous monitoring of radiation dose to be undertaken where the RPA deems this appropriate.

5.10 Responsible Officers

Trust-wide Responsible Officers overseeing a number of areas of implementation and/or expertise are itemised in Appendix A.

Departmental Responsible Officers are listed within the Local Rules for each area.

6. Procedures for Managing Radiation Safety

6.1 The Trust will maintain a management structure (see Appendix C) and implementation programme to ensure radiation safety requirements are met. A key element of this structure is the provision of a Radiation Protection Committee whose role is to oversee the provision and effectiveness of radiation protection strategies (see Appendix B for the full terms of reference of the committee).

6.2 A Radiation Protection Adviser (RPA, appointed in writing) will advise on all matters concerning the use of ionising radiation.

6.3 A Laser Protection Advisor (LPA, appointed in writing) will advise on all matters relating to the use of lasers.

6.4 Medical Physics Experts (MPEs) are provided by the UHSussex Medical Physics Department (Radiological Science section) and can be consulted for advice on all matters relating to dose optimisation and radiation protection, in both X-ray and nuclear medicine settings.

6.5 Provision of Radioactive Waste Advisor(s) will be via the UHSussex Medical Physics Department (Radiological Science section).

6.6 In support of the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) as amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018, the Trust maintains the *"IR(ME)R 2017 Employers Procedures Manual"*. This top level document describes the Trust-wide approach to IR(ME)R and is further supported by Speciality Documents (e.g. written clinical protocols) for each clinical department.

6.7 In support of the Ionising Radiations Regulations 2017, Local Rules and risk assessments are in place and cover all work involving ionising radiation. The Local Rules will contain written arrangements designed to minimise radiation doses to staff and members of the public.

6.8 Risk assessments will be carried out, acted upon and reviewed at appropriate intervals, including prior risk assessments (IRR17 Reg. 8) for proposed new activities or facilities. Responsibility for ensuring risk assessments are performed, reviewed and any findings implemented lies with the Clinical Modality Manager.

6.9 All new and replacement radiation facilities will be designed to meet the requirements of relevant regulations and codes of practice so as to ensure that doses to members of the public and staff are significantly below relevant dose limits. Such design will be carried out in consultation with the appointed RPA.

6.10 No item of radiographic imaging equipment, or radioactive source (other than smoke detectors), will be acquired by the Trust without advice being sought from the Chair of the Radiation Protection Committee and the Radiation Protection Adviser. This includes loan equipment, charitable, donated or research equipment. The Supplies and Capital Development & Estates Departments will not process a purchase without confirmation that appropriate advice has been sought.

6.11 All equipment involved in patient exposure shall be:

- Covered by appropriate valid service agreements and subject to regular maintenance in accordance with the manufacturer's instructions.
- Included in an up-to-date inventory of all radiation equipment used within the Trust to comply with the requirements of IR(ME)R17 Regulation 15(2). Ultimate responsibility its maintenance lies with the Clinical Modality Manager.
- Replaced in accordance with a written equipment replacement programme. The minimising of radiation doses to patients, consistent with the desired clinical outcome, will be a prime factor to be taken into consideration in the selection of equipment.
- Subject to a written quality assurance programme consistent with national and professional standards.
- Subject to Quality Assurance tests, carried out at regular intervals on all equipment involved in patient exposure with ionising or non-ionising radiation. Time scales will be within those required by current legislation and accompanying guidance. The RPA/LPA or MRSE can be consulted for advice on all Quality Assurance issues.
- Subject to procedures for handover and receipt of radiation equipment to external contractors to ensure the safety of contractors, Trust staff and patients.

6.12 The use of radioactive materials on Trust premises, and the disposal of radioactive waste arising from such use, is governed by permits from the Environment Agency (EA) under the Environmental Permitting (E&W) Regulations 2016 (EPR16), or Registrations and Authorisations respectively under the Radioactive Substances Act 1993 (RSA93).

6.13 The Trust will ensure compliance with The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 and ADR 2017 (Accord Européen Relative au Transport International des Marchandises Dangereuses Par Route).

6.14 Departmental managers of departments using radioactive materials are required to ensure that the terms of any Environment Agency Permits are complied with by:

- Ensuring that receipts, transfers and disposals of radioactive materials are recorded in a timely manner, and such records are made available to the EA on request.
- Reporting to the Radiation Waste Advisor as necessary on the disposal of radioactive wastes made from Trust premises to enable reporting to the EA.
- Keeping an inventory of closed sources kept on Trust premises, and undertaking biennial "wipe testing" of those sources to confirm the integrity of their containment.
- Notifying the police and the EA Regulator if there is strong suspicion that a source has been lost or stolen, and carrying out a full investigation into each such occurrence

6.15 Radiation doses to all staff working with ionising radiation will be monitored by means of whole body and/or other dosimeters as deemed appropriate by the employer, after consultation with the RPA and in line with the relevant prior risk assessment.

6.16 Appropriate Employer's Procedures will be maintained relating to the exposure of patients.

6.17 Medical procedures involving the use of ionising or non-ionising radiation will only be carried out where there is sufficient medical justification.

6.18 Responsibility for the justification and optimisation of every medical exposure will lie with the individual duty holder, clearly identified in the employer's procedures.

6.19 Radiation doses from diagnostic examinations will be kept as low as can reasonably be achieved without compromising the diagnostic potential.

6.20 Staff working with ionising and non-ionising radiation will be trained commensurate with the work being performed and the degree of hazard involved.

6.21 The Trust is responsible for ensuring that the radiation safety programme is implemented and reviewed, and that appropriate organisational arrangements are in place to facilitate it.

6.22 Incidents must be reported according to the Trust Incident Reporting Policy. Ionising radiation incidents must also be reported to the RPA as soon as possible, who will advise the Trust on the need for external reporting.

6.23 The Radiation Protection Committee will be responsible for ensuring that clinical audit is undertaken to confirm that good standards of radiological practice are demonstrated and to improve the quality and outcome of patient care. The Trust also undertakes to perform regular audit and review of its IR(ME)R Employer's Procedures to monitor their effectiveness.

6.24 There will be annual RPA, LPA, MPE and RWA audits of radiation departments that will include the RPS/LPS and management representatives and will include a review of the outcome of audit.

6.25 The outcome of audit will be reported to the Trust Radiation Protection Committee.

6.26 Exposures carried out for the purposes of research studies require the authorisation of a Medical Physics Expert, prior to the study starting. It is the responsibility of the Chief or Principal Investigator to obtain such authorisation.

6.27 Procedures for the governance of radiation within research are held by the Research & Development Department. Chief and Principal Investigators are responsible for ensuring that these procedures are followed.

6.28 All new members of staff must receive appropriate instruction on radiation protection and safety procedures as part of their induction training.

7. Implementation

7.1 This policy aims to ensure a safe environment for staff, patients and the public. Appendix 3 outlines the Trust's governance and reporting structure for implementing the policy and ensuring Trust compliance with regulatory requirements and national directives.

7.2 The Chair of the Radiation Protection Committee monitors compliance through the participation of the Group members representing each functional area. The terms of reference for the Radiation Protection Committee can be found in Appendix B.

7.3 Where procedures are not being followed, the Chair will take action as necessary, including instigation of formal disciplinary proceedings if warranted.

7.4 All staff actively involved with ionising or non-ionising radiation are made aware of this policy as part of their induction programme. The policy is available on the Trust website.

7.5 Regular radiation safety training forms part of the Trust's Statutory and Mandatory training framework for appropriate staff groups. Suitable online training may also be employed, under the advice of the RPA/LPA.

7.6 Where additional specific legislation and training requirements are required, these are advised and monitored within individual departments via local procedures and record keeping.

8. Evidence Base/References

Regulations as noted in section 1.

9. Competencies and Training Requirements

See section 7.

10. Monitoring Arrangements

10.1 The management structures reporting into the committee, together with feedback from the Radiation Protection, Laser Protection and Radioactive Waste Advisers, provide the necessary information and advice so as to ensure that regulatory compliance is resourced and maintained.

10.2 Where there are instances of non-compliance and/or “near-miss”, the Trust’s on-line reporting system, Datix, is utilised. Any major incidents which are required to be reported to external bodies must also be reported to the Chair of the committee.

10.3 Reportable radiation incidents, and general incident trends, are monitored and discussed by the committee, with corrective actions followed up and lessons learnt shared between speciality sub-groups.

10.4 The monitoring of this policy will occur by internal audit and through inspections by a number of external agencies associated with relevant legislation. Internal inspections will be performed by the RPA/LPA/RWA/MPE/MRSE, conducted in a similar vein to those performed by external agencies.

10.5 Each sub-group and the RPA will provide updates at the radiation protection committee meeting and annual reports when required.

10.6 This policy is reviewed and ratified every two years.

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Radiation incidents and trends	Radiology Clinical Services Manager	DATIX	Quarterly	Radiation Protection Committee	Radiation Protection Committee	Radiology Clinical Services Manager Health and Safety Steering Group
Equipment QA Testing	Modality Managers	QA Tests	Annual	Radiation Protection Committee	Radiation Protection Committee	Modality Managers Health and Safety Steering Group
IRMER Compliance	RPA	QA Tests	As per IRR17	Radiation Protection Committee	Radiation Protection Committee	RPS Health and Safety Steering Group
Compliance with Local Rules	RPS	Local Rules	Annual	Radiation Protection Committee	Radiation Protection Committee	RPS Health and Safety Steering Group
IRR17 Compliance	RPA	Review	As per IRR17	Radiation Protection Committee	Radiation Protection Committee	RPS Health and Safety Steering Group

11. Equality and Human Rights Statement

An Equality and Human Rights analysis has been completed for this document. It has considered the potential impact of this document and recognises the Equality and Human Rights of all employees and patients (see Appendix D).

Appendix A: RESPONSIBLE OFFICERS

Area of Responsibility	Substantive Post/Role	Responsible Officer
Delegated responsibility for radiation safety compliance across the Trust	*Executive Lead for Radiation Safety* Medical Director	[redacted]
Chair of Ionising Radiation Protection Committee	Radiologist & IR (me) R Practitioner	Dr Neil Barlow
Scientific advice on the safe use of ionising radiation	Radiation Protection Adviser / Medical Physics Expert	[redacted]
Sealed and unsealed sources	*Lead for Unsealed Sources* Nuclear Medicine Physics Lead	[redacted] contracted to UHSussex
	Radioactive Waste Adviser	[redacted] *Contracted to UHSussex*
	Source Custodian Radiation Protection Committee Chair	Dr Neil Barlow
	Source keeper Nuclear Medicine	Chris Salt
Carriage of dangerous goods by road	Dangerous Goods Safety Adviser	[redacted] *Contracted to UHSussex*
Lasers	Laser Protection Advisor	[redacted]
Magnetic Resonance Imaging	Magnetic Resonance Safety Expert	Dr. Lisa Harris
IR(ME)R & IRR17 (Imaging)	*Overall responsibility* Imaging Services Manager	Nansi Botros
Risk Assessments	Relevant Modality Leads	
Medical Supervision	Occupational Health Department	

Appendix B: RADIATION PROTECTION COMMITTEE

TERMS OF REFERENCE

1. Purpose

- The group is to monitor, co-ordinate and advise on all matters regarding ionising radiation safety and promote good radiation working practice; and report radiation protection issues as appropriate to the Health & Safety Steering Group.

2. Objectives

1. To advise the Trust on the implementation of legislation and guidelines on issues of radiation safety, for both ionising and non-ionising radiations (including lasers).
2. To monitor the Trust's radiation protection performance by:
   a. receiving reports and guidance from the appointed RPA and LPA on issues of radiation and laser safety including the outcome of audit visits.

   b. receiving reports from Divisions and Departments on radiation safety risk assessments, Ionising Radiation (Medical Exposures) Regulations 2017 compliance, training, reports on incidents and associated action plans, internal and external audits and inspections, issues of cooperation between employers and other radiation safety issues
3. To review and monitor the Trust Radiation Safety Policy.
4. To develop and review Trust level procedures in support of the implementation of the Radiation Safety Policy.
5. To monitor the implementation of all radiation and laser safety related policies and procedures.
6. To monitor the identification and management of radiation risks.
7. To ensure that the relevant CQC Outcomes are being managed and provide any additional monitoring in areas of low compliance.
8. To support continual improvement in radiation protection culture and practice.
9. To receive and act on advice for the Trust's Medical Physics Experts and Radioactive Waste Advisor(s).
10. To review and maintain all relevant quality assurance programmes.
11. To review the Groups Terms of Reference on an annual basis and if necessary make recommendations for amendment.
12. To facilitate a close working relationships between the management of radiation safety and other areas of risk management.

3. Membership:

- Clinical Lead for Radiology (Chair).
- Radiation Protection Adviser (via UHSussex).
- Laser Protection Adviser (via UHSussex).
- Radiology Services Manager.
- Radiation Protection Supervisors for each area.
- Laser Protection Supervisors for each area.
- Radiology Quality Manager
- Other representatives of services/departments with radiation facilities.
- Representatives of other external agencies, other Site Users and/or internal Departments / functions may also be invited to attend, as required.
- DAS Divisional Governance Manager
- Trust Health & Safety representative.
- Trust Risk management representative.
- Trust executive representative

4. Constitution

Attendance will be monitored at each meeting. No business shall be conducted unless the Radiation Protection Committee is quorate. The quorum is four members, provided that this includes;

- the chair or suitably delegated individual.
- at least one RPS.
- the Radiation Protection Adviser or their delegate.
- the Laser Protection Adviser or their delegate.

5. Accountability and Reporting arrangements

- Secretarial support will be provided for the provision of meeting minutes.
- The Chair shall provide quarterly reports to the Trust Health & Safety Steering Group for the last radiation protection meeting of each calendar quarter.
- The Chair attends the Trust Health & Safety Steering Group as its Radiation Safety Representative.
- The Chair of the Group shall draw to the attention of the Trust Health & Safety Steering Group and The ESHT Trust Board any issues that require disclosure to the full Board, or require executive action.
- A nominated Risk Safety Group member shall attend the Trust Health & Safety Steering Group as appropriate to progress investigations and actions associated with radiation incidents.
- No Annual Report will be produced; however radiation incidents are submitted annually together with outcomes by the Clinical Governance Facilitator responsible for Radiology Risk meetings

6. Mapped Relationships

- Health & Safety Steering Group (Quarterly Reports)
- Core Services Divisional H & S Group
- Trust Emergency Preparedness Committee (NAIR Coordinator)

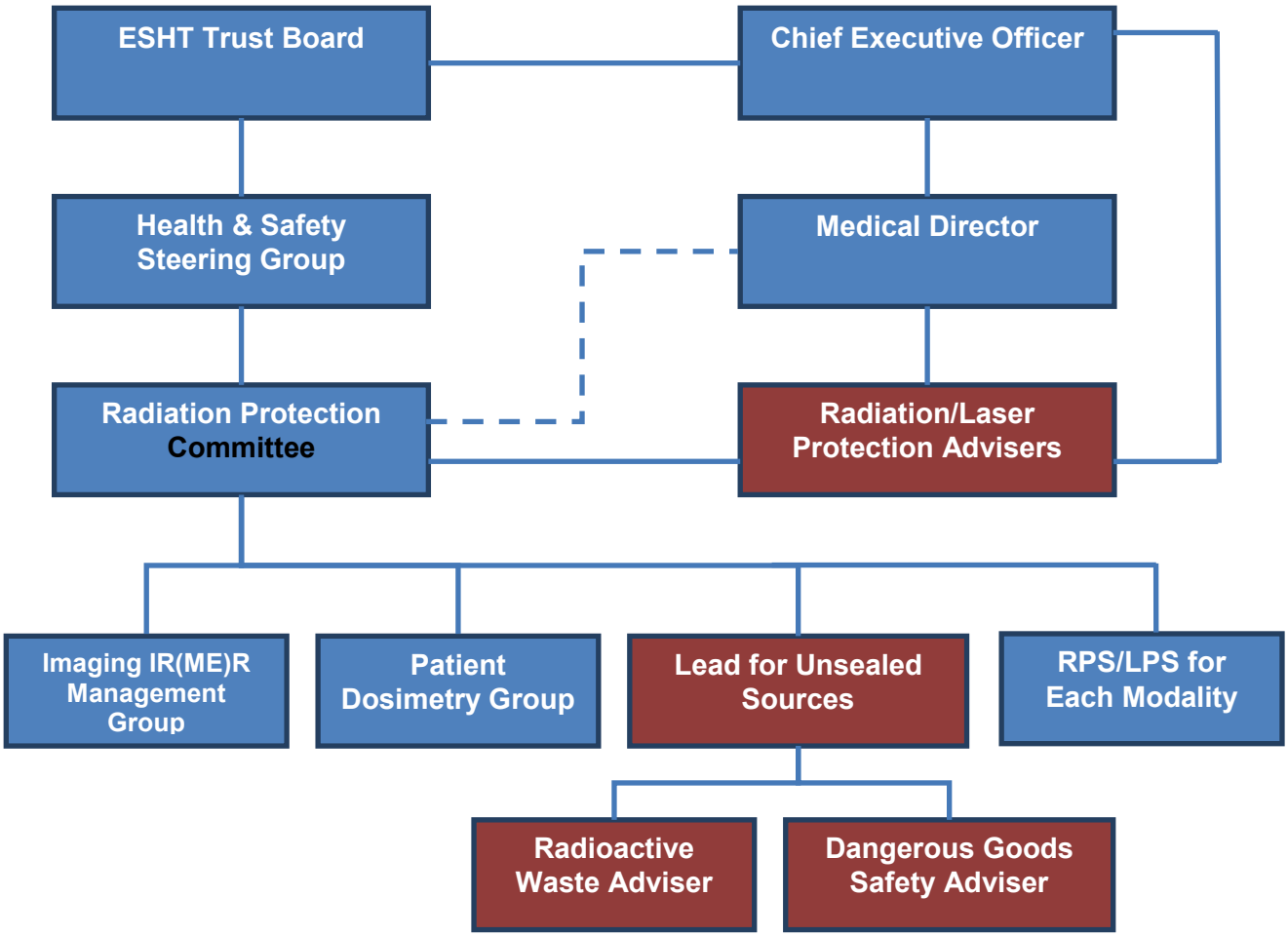
7. Frequency

- Meetings shall be held quarterly.

Date of Next Review – August 2023

Date of Approval by the Trust Policy Ratification group – Not required as only minor changes to this revision.

Appendix C: GOVERNANCE AND REPORTING STRUCTURE



Appendix D – EHRA Form

Due Regard, Equality and Human Rights Analysis

Title of document: **Policy for the Safe Use of Ionising and Non-Ionising Radiations**
Who will be affected by this work? E.g. staff, patients, service users, partner organisations etc. Staff, patients and other service users
Please include a brief summary of intended outcome: To ensure the health and safety of its employees, of contractors working on Trust premises and of members of the public who may be exposed to the hazards arising from the use of ionising radiations, lasers, ultra-violet and other time-varying electric or magnetic fields is maintained at all times.

		Yes/No	Comments, Evidence and Link to main content
1.	**Does the work affect one group less or more favourably than another on the basis of:** (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)		
	• Age	No	
	• Disability (including carers)	No	
	• Race	No	
	• Religion & Belief	No	
	• Gender	No	
	• Sexual Orientation (LGBT)	No	
	• Pregnancy & Maternity	Yes	There is an increase health and safety risk for pregnant women and extra measures are required. See section 5.9
	• Marriage & Civil Partnership	No	
	• Gender Reassignment	No	
	• Other Identified Groups	No	
2.	**Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?**	Yes	Unborn babies may be at increased risk of side effects of ionising and non-ionising radiation and so more mitigation measures need to be put in place. See section 5.9
3.	**What are the impacts and alternatives of implementing / not implementing the work / policy?**	All staff, contractors and service users will be at risk.	
4.	**Please evidence how this work / policy seeks to "eliminate unlawful discrimination, harassment and victimisation" as per the Equality Act 2010?**	N/A	

5.	**Please evidence how this work / policy seeks to "advance equality of opportunity between people sharing a protected characteristic and those who do not" as per the Equality Act 2010?**	N/A
6.	**Please evidence how this work / policy will "Foster good relations between people sharing a protected characteristic and those who do not" as per the Equality Act 2010?**	N/A
7.	**Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)**	N/A
8.	**Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?**	N/A
9.	**Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).**	No

East Sussex Healthcare NHS Trust

Clinical Process for the Communication of Critical or Significant Unexpected Radiological Findings

Document ID Number:	1015
Version:	V2.2
Ratified by:	Core Services Division Quality and Safety Group
Date ratified:	April 2022
Name of author and title:	Emma Owens & Justin Harris, Consultant Radiologists
Date originally written:	February 2009
Date current version was completed:	April 2022
Name of responsible committee/individual:	Medical Director, Clinical Unit and Clinical Radiology Leads. Clinical Support Services Manager CSD Quality and Safety Group Radiology Audit Leads
Date issued:	01 June 2022
Review date:	September 2023
Target audience:	Radiologists, referrers to radiology, medical secretaries and Admin team.
Compliance with CQC outcome	N/A
Compliance with NHSLA	Diagnostic testing procedures standard 5.7
Compliance with any other external requirements (e.g. Information Governance)	Royal College of Radiology Guidelines IRMER regulations
Associated Documents:	Royal College of Radiology 'Standards for communication of critical, urgent and unexpected significant radiological findings Second edition, 2012' Royal College of Radiology 'Standards for communication of radiological reports and fail-safe alert notification, 2016.' IRMER Regulations Information Governance Policy

Did you print this yourself?
Please be advised the Trust discourages retention of hard copies of procedural documents and can only guarantee that the procedural document on the Trust website is the most up to date version

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1 2009027	February 2009	David Hughes	New document	
V1.1 2014119	January 2014	Neil Barlow	New PACS system and Royal College guidance	ALERT communication system and logbook, blue dot system included
V1.2	29 April 2020	Neil Barlow	Un-archived this version Extension to review date due to covid19	Extended review date from June 2015 to 31 July 2020
V2	17 April 2021	Justin Harris Ian Diton	Review post wave 2 of Covid	Agreed General and Specific alert process.
V2.1	11 April 2022	Justin Harris Ian Diton Emma Owens	Review and update. Provisional release pending the introduction of order comms.	Agreed General and Specific alert process.
V2.2	18 May 2023	Ian Diton	Extension to review date due to system roll out	Extended the review date from April 2023 to September 2023

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Justin Harris	Clinical Radiology Lead	April 2022
Nansi Botros	Radiology – Clinical Service Manager	April 2022
Ian Diton	Radiology Quality Manager	April 2022
[redacted]	Medical Director	April 2022
Emma Owens	Radiology Consultant	April 2022

This information may be made available in alternative languages

and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

Until the Philips/CRIS radiology reporting system is able to electronically communicate with referring clinicians any urgent, critical or significant unexpected radiological findings (with feedback to confirm acknowledgement), these guidelines have been formulated to address the need for a formalised process. The aim is to ensure that the Radiology Department fulfils its responsibility for timely and reliable communication and have in place safety net procedures.

The ability to deliver these standards is dependent on adequate radiologist staffing levels, functional IT systems and secretarial support.

2. Rationale

It is clear from the NPSA Safer Practice Notice 16 that it remains the responsibility of the referring health professional to ensure that the results of any investigation requested are viewed, recorded and acted upon accordingly

NHSLA Criterion 5.7 compliance rationale states “The failure to access, acknowledge and act upon the results of diagnostic tests may result in an inappropriate delay and lack of timely treatment resulting in harm to patients. Organisations should have in place clear clinical risk management systems that identify guidance to reduce this risk. These should include the ability to record timely and accurate data; ensure that staff are trained in the use of software systems that support diagnostic functions; enable communication channels that are consistent across the organisation; provide known pathways that assist in the tracking of patients; and advise patients on how their test results will be communicated to them.”

Analysis of claims on the NHSLA database shows that a failure or delay in interpreting or acting on test results is one of the most common factors in relation to claims.”

3. Scope

- Reporting Staff – Radiologists, Radiographers & Sonographers
- Radiology Administration, IT/PACS and Secretaries.
- Clinicians who refer their patients for radiological studies.
- AHP’s, Nurses and Administrators involved in receiving radiological reports

4. Definitions and abbreviations

CRIS/RIS: HSS software Radiology Information System which is used to report and review and disseminate radiological investigation reports.

Critical : Where emergency action is required

Feedback: Means by which the radiology department can confirm receipt of a Radiological Report

PACS: Picture Archiving and Communication system and is used by Radiologists to view and report radiological investigations.

Receiver: The person who takes the call and report from the radiology team forms part of the ALERT process.

Significant unexpected findings: A finding on an outpatient imaging study which needs to be conveyed urgently to a referring clinician to avoid delay in diagnosis or treatment.

Urgent: Where medical evaluation is required within 24 hours

Validation: The point where the radiologist verifies the report and it becomes visible/available to the referring clinician.

Voice Recognition: Electronic system integrated into PACS which allows speech to be converted immediately into text.

5. Accountabilities

The Radiology Lead and General Manager are responsible for monitoring that this procedure is followed. Relevant incidents logged on DATIX will be reviewed monthly at the risk meeting.

6. Process

To avoid repetition the text below refers to reporting radiologists. The guidelines do however also apply equally to Reporting Radiographer and Sonographers.

6.1. Critical/Urgent

For Critical findings, the reporting radiologist should seek immediate contact with the referring doctor or his/her senior via telephone.

The name and grade of the contacted doctor, nurse or administrator should be added to the radiology report. The receiver should record the time/date contact was made within the patients' health record and sign/date their name in full.

If possible, voice recognition will be used to report the case to ensure immediate validation by the reporting radiologist.

If a critical or urgent finding, such bowel obstruction, is found out of hours whilst reporting routine imaging then the reporter should immediately alert the appropriate on call team. Please note that oncology does not have an out-of-hours on call team and as such, the reporting radiologist will need to inform the on call surgical or medical team depending on the acute finding encountered.

6.2. Urgent and Significant Unexpected Findings – Non Critical

General points

The ALERT process for these types of findings is designed to notify requesting physicians or their teams of a significant unexpected finding on a scan requested from an elective outpatient or GP setting. It should not be required in the primary reporting of Inpatient or Emergency department scans CT or MRI scans as requesting inpatient teams have a duty of care to check reports on their admitted patients. For ED plain films or addendums to existing reports please see the guidelines below.

It may be difficult to determine from the request form whether a finding is unexpected.

The reporting radiologist should review any available relevant old reports to see if this finding is significant and unexpected.

The ALERT process should only be reserved for significant unexpected findings. For example, progressive disease in a patient with known cancer is not a significant unexpected finding. A new recurrence of previously treated cancer or a new significant finding such as acute renal obstruction in a known cancer patient should however be alerted.

The reporter will include the word 'ALERT' (any combination of upper or lower case) in the body of the report plus the action or destination according to current local policy:

e.g.:

- ALERT bring this report to the urgent attention of the referring clinician,
- ALERT MRI unit recall for specific imaging

The designated radiology secretarial or administration staff members will then send the ALERT via NHS encrypted email to the referring clinician named on the report and their department secretarial generic email account. An Alert template is used rather than the whole report sent in order to maintain data protection.

The Radiology Secretarial/Admin team maintain an Alerts Excel spreadsheet which is generated by the Stat run from CRIS. The admin staff will update the spreadsheet with the action taken.

The receiver should record the time/date contact was made and the signature of the person writing in the health report/case record.

Radiologists should alert the secretaries immediately if they have dictated an alerted report not using VR so that it can be picked up by the secretary in a timely manner as typing reports is no longer a regular part of the secretaries' role.

Specific Types of Alert

- **Acute plaques in MS** – Enhancing MS related lesions noted on an MRI should be alerted to the requesting team as a significant unexpected finding due to urgency to commence steroid treatment in these patients.
- **AAA** – Patients with an Abdominal Aortic Aneurysm measuring > 5.5cm and not known to vascular surgeons should be alerted and urgent vascular opinion recommended. The local AAA referral policy is included in Appendix B for reference.
- **Emergency Department Films** – As we are not reporting these on the same day and the patient may have left the department we have agreed to alert abnormal ED films to ensure findings are picked up. This process will change to a digital system once the new PACS system is in place.
- **CXR with possible lung cancer** - suggested terminology - "Alert: This may represent a malignancy, urgent CT is advised. Please send a request for this investigation. In the meantime we will book an appointment for this test. Copy report to Respiratory Secretaries."
- **Addendums to SPR or Medica reports** – any addendum that significantly changes the outcome of the initial report and/or details a significant finding or error

in the initial report must be communicated to the requesting team. The reporting radiologist adding the addendum must assess the degree of importance of the error or new findings to determine whether the severity requires immediate contact via telephone or a standard alert via the secretarial team.

- **Malignant Spinal Cord Compression (MSCC)** - Patients with impending cord compression or cord compression require urgent alerting to both the clinical team and the acute oncology team (AOT). There is no local AOT out of hours and a referral to the Brighton oncology registrar on call needs to be made out of hours. The local MSCC guidance is included in Appendix C for reference.

6.3. GP or other outside referrers

Include the word 'ALERT' (any combination of upper or lower case) in the body of the report, preferably at the end of the report with the conclusion and advice on urgency.

In the rare instance (such as VR failure) that a report is typed by the secretaries, it should be typed within 1 working day of dictation and the report called or emailed to the GP. The radiologist should indicate whether he/she authorises the sending of the report to the referrer prior to validation.

6.4. Hospital Referrers

This refers to clinicians including non-medical referrers signed off to refer for diagnostic imaging.

The Radiologist or reporter will include the word 'ALERT' (any combination of upper or lower case) in the body of the report plus the action or destination.

The designated radiology secretarial or administration staff members will then send the ALERT via NHS encrypted email to the referring clinician named on the report and their department secretarial generic email account. An Alert template is used rather than the whole report sent in order to maintain data protection.

The Radiology Secretarial/Admin team maintain an Alerts Excel spreadsheet which is generated by the Stat run from CRIS. The admin staff update the spreadsheet with the action taken.

6.5. The Blue Dot System

Cancer Patients on a fast track GP referral for suspected cancer need to be treated within 62 days of the original GP referral. It is therefore essential that these patients' diagnostic requests are prioritised and undertaken with minimum delay, particularly as some of these patients will need subsequent referral to tertiary providers, and the clock remains ticking all the time.

In order for the relevant diagnostics departments to identify these requests in the most timely and appropriate manner, the agreed ESHT system is that they should have a "Blue Dot" attached to the request form at source. It is essential that this takes place for all relevant patients as, if the requests are not highlighted, they will not be fast tracked through the department, thus slowing down the patient's results. When a request is "blue dotted" it must come directly to Radiology without delay to ensure that the department has adequate notice to appoint.

Blue dots are used for:

- **All** requests for diagnostics for patients on a 2 week wait GP referral pathway until treatment or until a non-cancer diagnosis is obtained.
- For **all** requests for diagnostics where the consultant has upgraded a patient with suspected cancer onto a fast track cancer pathway.
- For **all** requests for further diagnostics on patients referred in from the Screening Service

When blue dots should NOT be used:

They should not be used to expedite any non-cancer patient **except**:

- Where upgraded by a consultant on suspicion of cancer
- When a diagnostic test reveals an incidental finding of cancer for a patient on a non-cancer pathway.

Misuse of the blue dot system for patients who are urgent but who are not suspected of having cancer is not acceptable as it makes it impossible for the receiving departments to prioritise cancer patients. If any individual is found to be misusing the system, the matter will be brought to the attention of the Trust executive. The process will be randomly audited by the receiving Departments and the Cancer Advisory Team in order to maintain a robust service.

6.6. Multi-Disciplinary Meeting (MDM) Referrals

Radiologist or reporter will include the word 'ALERT' (any combination of upper or lower case) in the body of the report plus the action or destination:

e.g.:

- ALERT Colorectal MDM,
- ALERT Gynae MDM
- ALERT Respiratory MDM

- The designated radiology secretarial or administration staff members will then send the ALERT via NHS encrypted email to the referring clinician named on the report and department secretarial generic email account.

- In addition, the ALERT will be sent to the relevant Patient Pathway Coordinator. This is another failsafe process. The relevant team members will be alerted to the report and the patient will be added to the MDM where appropriate at the request of the alerted team.

- If ALERT MDM is used with no specific MDM mentioned, or it is not clear which MDM is to be alerted, this will be sent to a generic email address: esht.cancerppcalerts@nhs.net

- An ALERT template is used rather than the whole report sent in order to maintain data protection.

6.7. Specifics of the 'ALERT process'.

1. An automated electronic system will be included as part of the ongoing PACS procurement exercise. This will add better automation to the process, improving patient care. Assurance of receipt is via an acknowledgements system and there are procedures in place to ensure that any ALERT reports are followed up within two working days.

2. As an interim measure the ALERT process above will be managed manually by the radiology secretaries and administration team (as in 3. below)

3. In the case of internal Trust and external referrers a twice daily CRIS statistical search for all ALERTS will be run by the Radiology Secretarial/Administrative Team preferably automatically as batch jobs between 9-10am and 2-3 pm.

4. ALERTS will be emailed to the requestor and generic secretarial email account for that group or individual. Cancer ALERTS will also be sent to the relevant PPC.

5. Emails containing an ALERT will be titled "A Critical Urgent or Unsuspected Finding is now available on ESearcher/ICE". Emails are marked as "important" and a read receipt is requested.

6. Read receipts are currently printed off, marked on the spreadsheet and filed when received. Read receipt returns can be poor and will be addressed with future digital systems.

7. Any e-mail that fails to be acknowledged (by read receipt) will be re-sent the following working day.

8. If no acknowledgement is received by day two a phone call will be made to the referrer or a member of their team and a record made of this in the 'ALERT Diary'.

7. Evidence Base/References

NPSA Safer Practice Notice 16
An Organisation wide Policy for the Management of Diagnostic and Screening Testing Procedures(NHSLA Criterion 5.7)– Template document for the management of diagnostic testing procedures V.2

8. Competencies and Training Requirements

Members of staff will require training in the setup of the ALERT process and diary recording. A written procedure will be available as a reference aid for staff.

9. Monitoring Arrangements

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/ action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Incidents relating to urgent results non-communication	Risk Lead	DATIX	Monthly	Radiology Risk Group	Risk Group Member, Senior radiology managers and professional leads	Trust Risk Lead patient safety and clinical improvement group
Alert Process Detection	Secretary Manager	CRIS	Daily	Secretary Manager	Secretary Manager	Radiology Services Manager
Blue dot process	Manager/ Lead clinician	Audit tool	Random min annual	Cancer team manager	Clinical leads and clinical unit managers	Relevant clinical unit manager
Function of the Core Services Division Quality and Safety Group	Chair	Minutes and reports	Monthly	Trust Board	Core Services Division Quality and Safety Group lead	Core Services Division Quality and Safety Group and the Board

Appendix A: EHRA Form

A Due Regard, Equality and Human Rights Analysis form must be completed for all procedural documents used by East Sussex Healthcare NHS Trust. Guidance for the form can be found on the Equality and Diversity Extranet page.

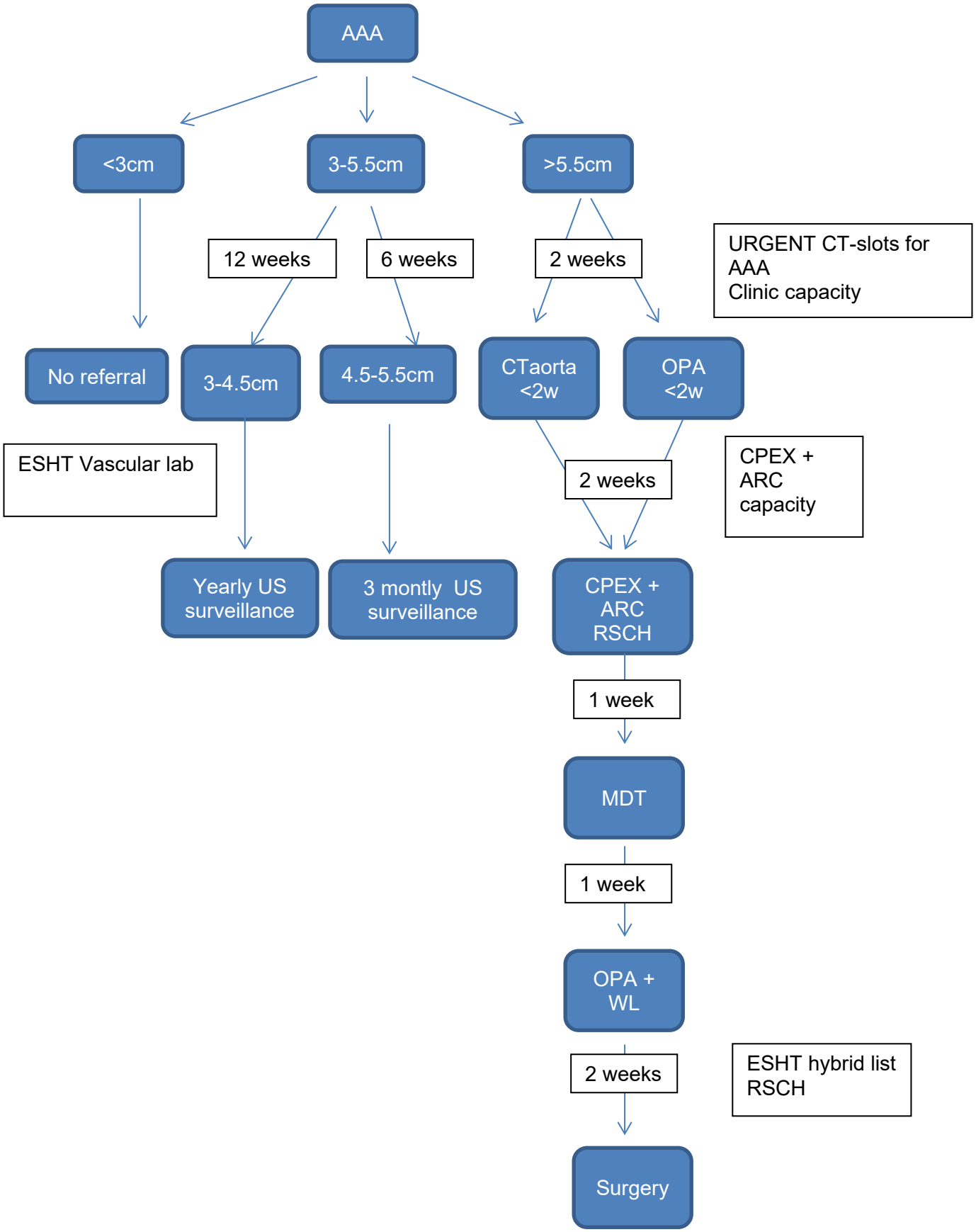
Due Regard, Equality and Human Rights Analysis

Title of document: Clinical Process for the Communication of Critical, Urgent and Unsuspected Radiological Findings
Who will be affected by this work? E.g. staff, patients, service users, partner organisations etc. Staff
Please include a brief summary of intended outcome:

		Yes/No	Comments, Evidence and Link to main content
1.	**Does the work affect one group less or more favourably than another on the basis of:** (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)		
	• Age		
	• Disability (including carers)		
	• Race		
	• Religion & Belief		
	• Gender		
	• Sexual Orientation (LGBT)		
	• Pregnancy & Maternity		
	• Marriage & Civil Partnership		
	• Gender Reassignment		
	• Other Identified Groups		
2.	**Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?**		(Ensure you comment and link to main policy with page/paragraph number)
3.	**What are the impacts and alternatives of implementing / not implementing the work / policy?**	(Ensure you comment and link to main policy with page/paragraph number)	
4.	**Please evidence how this work / policy seeks to "eliminate unlawful discrimination, harassment and victimisation" as per the Equality Act 2010?**	(Ensure you comment and link to main policy with page/paragraph number)	
5.	**Please evidence how this work / policy seeks to "advance equality of opportunity between people sharing a protected characteristic and those who**	(Ensure you comment and link to main policy with page/paragraph number)	

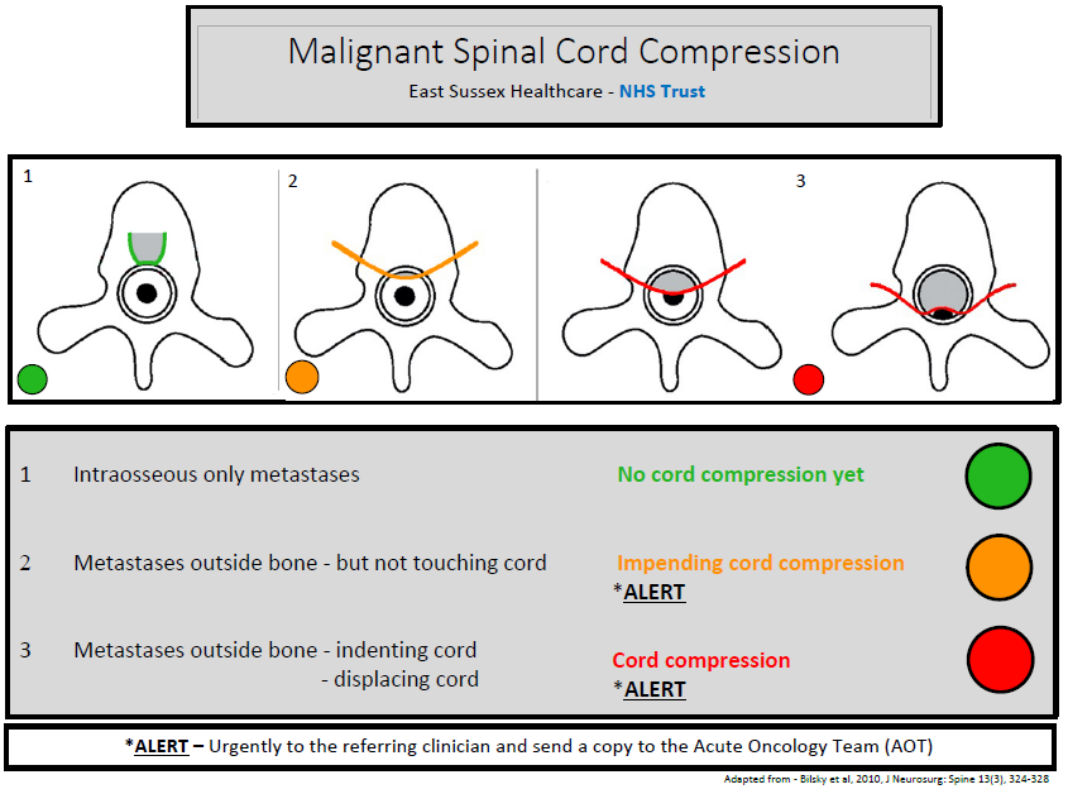
	do not" as per the Equality Act 2010?	
6.	**Please evidence how this work / policy will "Foster good relations between people sharing a protected characteristic and those who do not" as per the Equality Act 2010?**	(Ensure you comment and link to main policy with page/paragraph number)
7.	**Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)**	(Ensure you comment and link to main policy with page/paragraph number)
8.	**Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?**	(Ensure you comment and link to main policy with page/paragraph number)
9.	**Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).**	(If yes ensure you comment and link to main policy with page/paragraph number)

Appendix B: ESHT AAA pathway



Appendix C: Malignant Spinal Cord Compression

- Malignancy location - no need to grade
  - Intraosseous only
  - Outside bone, but not touching cord – impending cord compression
  - Outside bone and displacing/indenting cord – cord compression



East Sussex Healthcare NHS Trust

Practitioner Guidelines for a requesting a Mammogram

Document ID Number	1421
Version:	1.0
Ratified by:	Radiation Protection Committee
Date ratified:	11TH September 2024
Name of author and title:	Lauren Head Lead Interventional Mammographer/ Deputy Modality Manager Mammography
Date originally written:	11th September 2024
Date current version was completed	11th September 2024
Name of responsible committee/individual:	Radiation Protection Group
Division/Speciality:	CORE services
Date issued:	17th February 2025
Review date:	11th September 2027
Target audience:	•Medical referrers holding current GMC registration working within the Breast team at East Sussex Healthcare. •Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate working within the Breast team at East Sussex Healthcare.
Compliance with CQC Fundamental Standard	Safe Care and Treatment.
Compliance with any other external requirements (e.g. Information Governance)	IR(ME)R Guidelines 2017 Information Governance
Associated Documents:	N/A

Did you print this yourself?
Please be advised the Trust discourages retention of hard copies of the procedural document and can only guarantee that the procedural document on the Trust website is the most up to date version.

Version Control Table

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V1.0	11th Sep 2024	Lauren Head	New Document	New Document

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Dr Ulle Raudsepp	Consultant Radiologist	Sep 2024
Professor Howlett	Consultant Radiologist	Sep 2024
Dr Yesim Akan	Consultant Radiologist	Sep 2024
Lauren Head	Lead Interventional Mammographer / Deputy Modality Manager	Sep 2024
Dr Neil Barlow	Consultant Radiologist / IRMER Lead	Sep 2024

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1. Introduction

This procedural document outlines the referral guidelines for requesting a mammogram, a diagnostic imaging tool used to detect and evaluate breast abnormalities. It includes criteria for patient selection, as well as the indications and contraindications for the procedure.

Additionally, the document provides an overview of the procedural steps and the referral process. Adhering to these guidelines ensures the appropriate use of mammographic imaging, optimising patient outcomes and supporting accurate diagnosis.

2. Purpose

The purpose of practitioner guidelines for requesting mammograms is to provide clear and consistent criteria for healthcare professionals when requesting mammographic imaging.
These guidelines help ensure that mammograms are used appropriately, identifying patients who will benefit most from the procedure.
They also aim to:

- Ensure early detection and accurate diagnosis of breast abnormalities.
- Minimise unnecessary imaging or exposure to radiation.
- Optimise patient outcomes by guiding the timely and appropriate use of mammograms.
- Standardise the referral process to enhance clinical decision-making and improve healthcare efficiency.

By following these guidelines, healthcare providers can improve patient care while using diagnostic resources effectively.

2.1. Rationale

The guidance in this document has been developed based on policies from NHS England, Royal College of Radiologists, NICE (National Institute for Health and Care Excellence), and East Sussex Healthcare Trust (ESHT).
It ensures that all symptomatic breast care pathways in England follow the recognised gold standard of care, known as the Triple Assessment ***therefore Mammogram referrals will only be accepted from the Breast team within ESHT.***

2.2. Principles

The principles of these referral guidelines are designed to ensure appropriate, ethical, and effective use of the procedure. These principles include:

IR(ME)R 2017 Regulations
Appropriate Indication
Patient Safety
Informed Decision-Making
Multidisciplinary Collaboration
Ethical Considerations
Evidence-Based Practice

2.3. Scope

This Policy and Procedure document is available to all ESHT employees but in particular relevant to:

- Medical referrers holding current GMC registration working within the Breast team at East Sussex Healthcare.

- Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate working within the Breast team at East Sussex Healthcare.

3. Definitions

NMR – Non medical Referrer
IR(ME)R – Ionising Radiation (Medical Exposure) Regulations

4. Accountabilities and Responsibilities

- Entitlement to refer will automatically be withdrawn should the Referrer terminate their employment with East Sussex Healthcare Trust.

Clinical Indications Referral Guidelines:
This guidance specifies that only patients meeting certain criteria will be accepted for a Mammogram, These criteria include:

Age Criteria

- **Ages 40 +** Patients over the age of 40. Mammography is the first line Imaging modality of choice in females 40 years or over (with the addition of Ultrasound if indicated)

However with male patients, Ultrasound may be a better modality of choice (e.g,. Query Gynaecomastia P2 referrals will have an Ultrasound scan only as stated below in the symptomatic criteria section.

- **Under 40 Years Old:** Generally, Mammograms are not recommended for women under 40 due to the density of breast tissue, which makes mammograms less effective. However, exceptions will be made if there is a significant family history, genetic risk, or a clinical concern of P4/ P5 and must be discussed with a Radiologist.

Symptomatic Criteria

- **Presence of Breast Symptoms:** Patients aged 40 + presenting with any of the following symptoms are eligible for diagnostic mammography:

- New or persistent breast lump(s)
- Unexplained breast pain. Please note
- Patients **over 40** years old with non-specific breast pain and no focal tenderness or palpable abnormality require a mammogram only.
- If the patient is **under 40** years old and has persisting focal tenderness or a palpable area of concern, they require an Ultrasound only in the first instance.
- **Under 40** years old with general pain, require no imaging at all.

- Nipple symptoms, nipple discharge (bloody or clear)
- Skin changes such as dimpling, thickening, or redness
- Nipple retraction or inversion
- Palpable axillary lymph nodes
- Noticeable asymmetry between the breasts, especially if new or accompanied by other symptoms.
- Gynaecomastia: There is specific guidance for patients with query gynaecomastia, which is as follows: **Please note all requests for Gynaecomastia must state a P Value.**

The **P-value** in breast imaging is used to classify the level of clinical concern based on imaging findings. It helps guide clinical decision-making regarding whether further action, such as a biopsy or additional imaging, is required. **P5** represents the highest level of concern (suggesting a strong likelihood of cancer), while **P1** represents normal or benign findings.

Under 50 years of age
P value of 1 or 2. Patient has no imaging at all.
P value of 3, 4, 5. Ultrasound scan prior to Mammogram.

Over 50 years of age
P value of 1, 2, 3. Ultrasound first prior to Mammogram.
P Value 4 or 5. Mammogram first then Ultrasound**.**

High-Risk Factors

Patients with significant risk factors may require earlier or additional screening beyond routine recommendations. Clinical indications include:

- **Family History:** A strong family history of breast cancer, particularly in first-degree relatives (e.g., mother, sister), may require earlier and more frequent screening. **Please note all family history patients need to be assessed in Family History clinic first before being sent for imaging.**
- **Genetic Predisposition:** Patients with known BRCA1, BRCA2 mutations, or other hereditary breast cancer syndromes should be referred for earlier and more frequent imaging (including MRI in addition to mammography).
- **Previous Breast Cancer:** Patients with a history of breast cancer may require annual surveillance imaging.
- **Previous Chest Radiation:** Women who received radiation therapy to the chest (e.g., for Hodgkin's lymphoma) between the ages of 10 and 30 years will require Mammography at an earlier age.

Incidental Findings

Abnormal Imaging from Other Modalities: Incidental findings from imaging performed for other reasons (e.g., chest CT, MRI) that raise concern for breast pathology should be referred to the breast MDM for additional discussion and breast-specific imaging.

Follow-Up of Previously Identified Abnormalities

- **Short-Term Follow-Up:** For patients with previously identified benign findings that require interval imaging follow-up mammography at recommended intervals is indicated as per MDM recommendations.
- **Post Marker Clip insertion:** Imaging may be required to evaluate post-clip insertion areas that mark a lesion prior to neo-adjuvant chemotherapy, or where biopsies were performed to ensure placement and monitor recurrence or residual disease.
- **Post-Treatment Monitoring**: Patients who have undergone breast cancer surgery or treatment will usually need follow-up mammograms to monitor for recurrence or a new tumour.

Contraindications:

The following are contraindications for Mammography, which outline the contraindications where a Mammogram may not be appropriate, or where alternative imaging options should be considered:

- **Below the Age of 40** unless there is a significant family history or genetic risk or another clinical indication and must be discussed with a Radiologist.
- **Recent Mammogram (Within 6 - 12 Months)** unless the patient is symptomatic and then usually only the affected side should be imaged.
- **Breastfeeding**: Lactating breasts are denser, making mammography less effective in detecting abnormalities. Ultrasound is typically the preferred imaging method during breastfeeding. Mammograms are usually deferred until after breastfeeding has concluded depending on the clinical concern.
- **Post-Surgery (Less Than 1 Year)** Mammography is postponed until at least one year after surgery to allow healing and resolution of post-surgical change.
- **Injury or Damage to the Breast** Recent trauma or injury to the breast such as a biopsy can cause bruising, swelling, or haematomas, which may complicate mammogram interpretation and be painful for the patient. In such cases, it may be best to delay the mammogram until the injury has healed or consider alternative imaging.
- **Query Ruptured Implant** In cases of a query ruptured implant the initial imaging of choice is Ultrasound. Mammography is not performed routinely. If, following the Ultrasound, it is felt that a Mammogram is required for further evaluation, this decision must be discussed and agreed upon between the referrer and the breast radiology team. MRI is not used routinely in the initial evaluation of suspected implant rupture it is used as a problem-solving tool to provide additional diagnostic clarity.

  Patients need to be fully informed of the potential risk of implant damage during Mammography (albeit the risk is low) and this discussion and patient agreement should be documented on the request form.

5. Evidence Base/References

NHS England 2019 - https://www.nhs.uk
NICE Guidelines - Find guidance | NICE

RCR Guidelines - Guidance on screening and symptomatic breast imaging, Fourth edition | The Royal College of Radiologists (rcr.ac.uk)

6. Competencies and Training Requirements

Referrals will only be accepted from medical referrers holding current GMC registration ***working within the Breast team at East Sussex Healthcare*** and Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate ***working within the Breast team at East Sussex Healthcare***.

7. Monitoring Arrangements

- This policy and procedure will be reviewed every three years. Where review is necessary due to legislative change, this will happen immediately.

- Variations of the protocol must be fully agreed by all parties and authorised by East Sussex Healthcare Trust's Radiation Protection Committee after which it can be amended accordingly.

8. Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Referral guidelines are being adhered to and appropriate patients are being selected and referred for a biopsy.	Individual divisions and departments	CRIS, Sectra PACs Clinical Governance Risk Management Framework	Every 3 Years	As required	Divisional Governance process	Governance Lead

Appendix A: Equality and Health Inequalities Impact Assessment (EHIA) template

Undertaking EHIA helps us to make sure that our services and polices do not inadvertently benefit some groups more than others, ensuring that we meet everyone's needs, and our legal and professional duties.

This is important because:

- Assessing the potential for services and policies to impact differently on some groups compared with others is a legal requirement.
- People who find it harder to access healthcare services are more likely to present later when their disease may be more progressed, have poorer outcomes from treatment, and need more services than other groups who have better access.

The Equality Act 2010 legally protects people from discrimination in the workplace and in wider society. It is against the law to discriminate against anyone because of:

- age
- gender reassignment
- being married or in a civil partnership
- being pregnant or on maternity leave
- disability
- race including colour, nationality, ethnic or national origin
- religion or belief
- sex
- sexual orientation.

These are called 'protected characteristics'. The Act requires that public sector organisations meet specific equality duties in respect of these protected characteristics. This is known as the public sector equality duty.

Public Sector Equality Duty

Public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees.

Public bodies must have due regard to the need to:

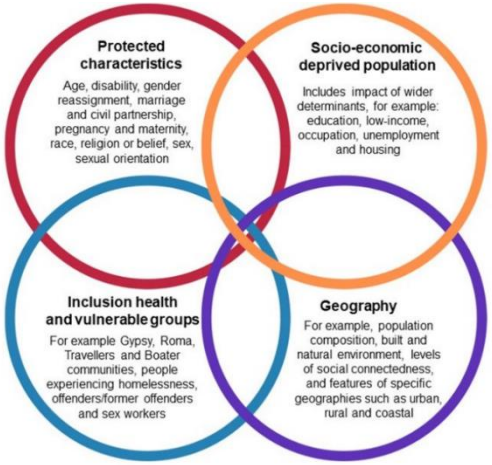
- eliminate discrimination
- advance equality of opportunity
- foster good relations.

Armed Forces Covenant Duty
The new Covenant Duty raises awareness of how Service life can impact on the Armed Forces community, and how disadvantages can arise due to Service when members of that community seek to access key local services. The Duty requires organisations to pay due regard to the Covenant principles when exercising functions in healthcare. “Due regard” means that we need to consciously consider the unique obligations and sacrifices made by the Armed Forces; that it is desirable to remove disadvantages faced by the Armed Forces community; and that special provision may be justified in some circumstances.

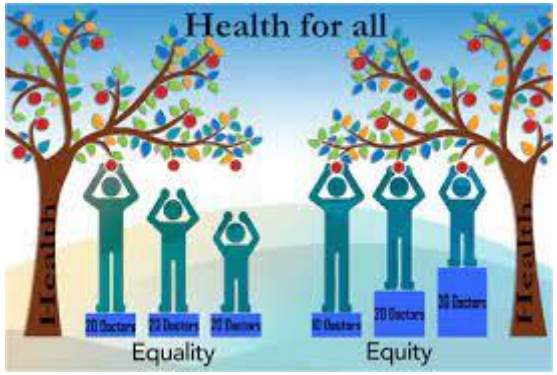
Health Inequalities Duties- Equity for all
In addition to our legal duties in relation to Protected Characteristics, the Health and Social Care Act and other legislation, NHS Planning Guidance and sector specific recommendations require the NHS to have regard to the need to address health inequalities (or differences in access to or outcomes from healthcare) and take specific action to address them.

Figure 1 shows the different population groups, factors associated with where we live, or our individual circumstances, which separately, or when combined, influence access to and outcomes from health care.

Getting equal outcomes may require different inputs (or services). In completing an EHIA its important to think about whether a one size fits all approach will generate the same good outcomes for everyone, or whether we might need to make some tweaks or adjustments to enable everyone to benefit equally. The health tree diagram shows that unless we think about the needs of different people, equal services might generate unequal outcomes.



The Health Tree[1]



The following principles, drawn from case law, explain what we must do to fulfil our duties under the Equality Act:

- **Knowledge:** everyone working for the Trust must be aware of our equality duties and apply them appropriately in their work.
- **Timeliness:** the duty applies at the time of considering policy options and/or before a final decision is taken – not afterwards.

[1] https://www.researchgate.net/figure/Equality-and-equity-of-medical-resources-distribution_fig2_323266914

- **Real Consideration:** the duty must be an integral and rigorous part of your decision-making and influence the process.
- **Sufficient Information:** you must assess what information you have and what is needed to give proper consideration.
- **No delegation:** the Trust is responsible for ensuring that any contracted services which provide services on our behalf can comply with the duty, are required in contracts to comply with it, and do comply in practice. It is a duty that cannot be delegated.
- **Review:** the equality duty is a continuing duty. It applies when a policy/process is developed/agreed, and when it is implemented/reviewed.
- **Proper Record Keeping:** to show that we have fulfilled our duties we must keep records of the process and the impacts identified.

NB: Filling out this EHIA in itself does not meet the requirements of the equality and health inequalities duties. All the requirements above must be fulfilled or the EHIA (and any decision based on it) may be open to challenge. Properly used, an EHIA can be a tool to help us comply with our equality and health inequalities duty and as a record that to demonstrate that we have done so. It is advised that you complete the short EHIA training session on MyLearn before completing this EHIA.

SECTION A ADMINISTRATIVE INFORMATION

This form is a central part of how the Trust makes sure and can demonstrate to others that we are meeting our legal duties; and how we can assure ourselves that all patients will get the best outcome for them from our services.

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal. **Function/policy/service name and number:**	N/A		
Main aims and intended outcomes of the function/policy/service and summary of the changes you are making (if existing policy/service):	To ensure that Mammography imaging is utilised appropriately, minimising unnecessary exposures while ensuring prompt and accurate diagnosis of breast abnormalities by adhering to established guidelines.		
How will the function/policy/service change be put into practice?	N/A		
Who will be affected/benefit from the policy?	N/A		
State type of policy/service	Policy ☐	Service ☐	
	Business Case ☐	Function ☐	Existing
Is an EHIA required? NB :Most policies/functions will require an EA with few exceptions such as routine procedures	Yes ☐		
	No ☐ (If no state reasons)		

Accountable Director: (Job Title)	N/A	
Assessment Carried out by:	Name:	
Contact Details:	N/A	
Date Completed:	N/A	

SECTION B ANALYSIS AND EVIDENCE

Analysis of the potential impact – Equality and Health Inequalities Duties
For this section you will need to think about all the different groups of people who are more likely to experience poorer access or have poorer outcomes from health and care services. For each group please describe in the first column the potential impact you have identified, in the second column explain how you have arrived at this conclusion and what information you used to identify the potential impact, and in the third column say what you are going to do to prevent it from happening, or which elements of a service or policy specifically address the potential impact. Key things to remember.

- Everyone has protected characteristics but some groups who share one or more protected characteristics may be more likely to have poorer outcomes or access compared with others – and it is this potential that the EHIA process seeks to identify and address.
- The information included here should be proportionate to the type and size of the policy/service/change.
- An update to a policy should demonstrate that you have considered the potential for the policy to impact differently on different groups and taken steps to address that.
- A minor policy update is likely to need to be much less comprehensive than an EHIA for a major service change.
- You will need to know information about who uses or could use your service/policy will apply to (the population). You can use information about current patients or staff, and about the general population the Trust serves.

3. PROTECTED CHARACTERISTICS - Main potential positive or negative impact of the proposal for protected characteristic groups summarised

Please write in the box below a brief summary of the main potential impact (positive or negative) Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below, but make sure you include information on how you know there will be no impact.**

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Age: older people; middle years; early years; children and young people.	N/A		
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	N/A		
Gender Reassignment and/or people who identify as Transgender	N/A		
Marriage & Civil Partnership: people married or in a civil partnership.	N/A		
Pregnancy and Maternity: before and after childbirth and who are breastfeeding.	N/A		
Race:	N/A		
Religion and belief: people with different religions/faiths or beliefs, or none.	N/A		

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Sex:	N/A		
Sexual orientation	N/A		
Veterans/Armed Forces Communities	N/A		

4. HEALTH INEQUALITIES -Potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). **If the policy/procedure is unrelated to patients, this sections does not require completion.**

Please state none if you have assessed that there is not an impact, but please make sure you complete the 'how do you know this' column to demonstrate that you have considered the potential for impact**. If you identify the potential for impact for one or more of these groups please complete the full assessment in Appendix A**

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
This includes all groups of people who may have poorer access to or outcomes from healthcare services. It includes: People who have experienced the care system; carers; homeless people; people involved in the criminal justice system; people who experience substance misuse or addiction; people who experience income or other deprivation; people with poor health literacy; people living in rural areas with limited access to services; refugees or asylum seekers; people in or who have been in the armed force; other groups who you identify as potentially having poorer access and outcomes.	*N/A*	*N/A*	*N/A*

SECTION C ENGAGEMENT

5. Engagement and consultation

a.Talking to patients, families and local communities can be a rich source of information to inform health care services. If you are making substantial changes, it's likely that you'll have to undertake specific engagement with patients. For smaller changes and policies your may have undertaken some engagement with patient groups, gained insight from routine sources e.g. patient surveys, PALS or Complaints information or information from Healthwatch, you may also have looked at relevant engagement that others have undertaken in the Trust, or locally
Have any engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	**No**

b. If yes, please ensure all stakeholders are listed in the consultation table at the beginning of the policy.

SECTION D SUMMARY OF FINDINGS

Reflecting on all the information included in your review-

6. EQUALITY DUTIES: Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please **add an x** to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?			
Uncertain whether the proposal will support?			

7. HEALTH INEQUALITIES: Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?		
The proposal may support?		
Uncertain if the proposal will support?		

8. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1		
2		
3		

9. EHIA sign-off: (this section must be signed)

Person completing the EHIA:	**Lauren Head**	**Date: 28.11.2024**
Line Manager of person completing:	**Louise Richards**	**Date: 28.11.2024**

Breakdown of Groups who are more likely to experience health inequalities:

Groups who face health inequalities[3]	**Summary explanation of the potential positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
Looked after children and young people			
Carers of patients			

Groups who face health inequalities[3]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.			
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.			
People with addictions and/or substance misuse issues			
People or families on a low income			
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).			
People living in deprived areas			
People living in remote, rural and island locations			
Refugees, asylum seekers or those experiencing modern slavery			
People who have served in the Armed Forces			
Other groups experiencing health inequalities (please describe)			

EHIA Resources
Sources of Information on the East Sussex population and sources of community or patient insight.

Population Data
State of the County 2021 Focus on East Sussex

East Sussex JSNA

Community Insight

Further Reading on Equality and Health Inequalities

Training

East Sussex Healthcare NHS Trust

Practitioner Guidelines for requesting a Stereotactic Breast biopsy

Document ID Number	1422
Version:	1.0
Ratified by:	Radiation Protection Committee
Date ratified:	11th September 2024
Name of author and title:	Lauren Head Interventional Mammographer/ Deputy Modality Manager Mammography
Date originally written:	11th September 2024
Date current version was completed	11th September 2024
Name of responsible committee/individual:	Radiation Protection Group
Division/Speciality:	CORE services
Date issued:	17th February 2025
Review date:	11th September 2027
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Compliance with CQC Fundamental Standard	Safe Care and Treatment.
Compliance with any other external requirements (e.g. Information Governance)	IR(ME)R Guidelines 2017 Information Governance
Associated Documents:	Lidocaine Patient Group Directive Nov 2022

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Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Dr Ulle Raudsepp	Consultant Radiologist	Sep 2024
Professor Howlett	Consultant Radiologist	Sep 2024
Dr Yesim Akan	Consultant Radiologist	Sep 2024
Lauren Head	Lead Interventional Mammographer / Deputy Modality Manager	Sep 2024
Dr Neil Barlow	Consultant Radiologist / IRMER Lead	Sep 2024

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Appendix A: Equality and Health Inequalities Impact Assessment (EHIA) template 9

1. Introduction

This procedural document outlines the referral guidelines for requesting a stereotactic breast biopsy, a minimally invasive procedure used to diagnose breast abnormalities. It includes the criteria for patient selection, as well as the indications and contraindications for the procedure.

Additionally, the document provides an overview of the procedural steps and referral process. Adherence to these guidelines ensures the appropriate use of mammographic imaging in stereotactic breast biopsies, optimizing patient outcomes and supporting accurate diagnosis

2. Purpose

To ensure that Stereotactic breast biopsies are utilised appropriately, minimising unnecessary procedures while ensuring prompt and accurate diagnosis of breast abnormalities by adhering to established guidelines.

3. Rationale

The professional frameworks that provide the foundation for the guidelines Stereotactic Breast Biopsy are as follows: NHS England, NICE Guidelines, Breast Radiology.org, Gov.UK.

4. Principles

The principles of these practitioner guidelines are designed to ensure appropriate, ethical, and effective use of the procedure. These principles include:

IR(ME)R 2017 Regulations
Appropriate Indication
Patient Safety
Informed Decision-Making
Multidisciplinary Collaboration
Ethical Considerations
Evidence-Based Practice

5. Scope

This Policy and Procedure document is available to all ESHT employees but relevant to:

- Medical referrers holding current GMC registration working within the Breast team at East Sussex Healthcare.
- Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate working within the Breast team at
- East Sussex Healthcare.

6. Definitions

NMR – Nonmedical Referrer
IR(ME)R – Ionising Radiation (Medical Exposure) Regulations

7. Accountabilities and Responsibilities

- Each NMR must complete the trusts application process for non-medical referrer's outlines in the 'Principles' section above and have a named Supervising Consultant.

- This protocol must be adhered to by all the referrers within the breast teams at EDGH and Conquest.

- The Referrer is responsible for informing East Sussex Healthcare Trust's Radiation Protection Committee of any relevant training that they might undertake and any changes to their name or designation. This should be notified via the IR(ME)R Lead.

- The Supervising Consultant and/or East Sussex Healthcare Trust's Radiation Protection Committee have the right to withdraw the Referrers ability to request x-rays.

- Entitlement to refer will automatically be withdrawn should the Referrer terminate their employment with East Sussex Healthcare Trust.

Clinical Indications Referral Guidelines:

This guidance specifies that only patients meeting certain criteria will be accepted for a Mammogram, these criteria include:

- Micro calcifications:
  Suspicious Micro calcifications: When mammography reveals micro calcifications that are clustered, linear, or have irregular patterns, which could indicate conditions such as ductal carcinoma in situ (DCIS) or other abnormalities.

- Uncertain Classification:
  Micro calcifications that are not clearly benign or malignant on initial imaging studies and require further evaluation to determine their significance.

- Abnormal Mammographic Findings:
  Asymmetries or Density Changes: Areas of increased density or asymmetry on mammograms that do not have a corresponding palpable abnormality or are not clearly characterised by other imaging modalities.

- Non-Palpable Lesions: Lesions that are detected on mammography but are not palpable on physical examination, making them difficult to sample using conventional methods.

- All requests must be discussed at Breast MDM.

4 Contraindications:

Some patients may not be suitable candidates for this procedure due to certain contraindications. These contraindications can be classified into **absolute** and **relative** categories

Absolute Contraindications

Absolute contraindications are conditions where the procedure should not be performed under any circumstances due to high risks.

- Active Infective Reason:
  An active infection at the biopsy site or systemic infection can increase the risk of complications, such as spreading the infection.

- Severe Coagulopathy
  Patients with uncontrolled bleeding disorders or those on anticoagulation therapy that cannot be temporarily discontinued are at high risk for excessive bleeding during and after the procedure.

- Allergy to Anaesthetics
  An allergy to local anaesthetics used during the procedure can lead to severe allergic reactions, making the biopsy unsafe.

Relative Contraindications

Relative contraindications are conditions where the procedure may be performed if the benefits outweigh the risks and appropriate precautions are taken.

- Patients on anticoagulation therapy.
  All patients on anticoagulation therapy should consult a haematologist or cardiologist to consider discontinuing.

  The instructions for safe biopsy practice for patient taking anticoagulation drugs are as follows:

- New anticoagulants such as Rivaroxaban, Clopidogrel, Apixaban - stop for 3 days before biopsy

- Aspirin - Stop for 1 day before biopsy

- Warfarin - Stop for 5 days before biopsy and an INR blood test must be performed 24-48 hours prior to the biopsy date. Result must be 1.5 or below in order to proceed.

- LMW Heparin – Stop for 3 days before biopsy

- Large Breast Size or Very Small Breasts
  Extremely large or very small breasts can make positioning and accessing the target area challenging. Alternatives or modifications may be needed.

- Proximity to Chest Wall
  Lesions located very close to the chest wall may be difficult to access safely without risking damage to underlying structures.

- Implants or Previous Breast Surgery
  The presence of breast implants or extensive scar tissue from previous surgeries can complicate the biopsy process. Special techniques or imaging adjustments may be required.

- Pregnancy
  Although the radiation exposure in stereotactic biopsy is minimal, it is generally avoided during pregnancy unless necessary. Alternative biopsy methods, such as ultrasound-guided biopsy, are preferred.

- Inability to Comply with Instructions
  Reason: Patients who cannot remain still during the procedure due to severe anxiety, cognitive impairment, or other factors may not be suitable candidates. Sedation or alternative biopsy methods may be considered.

- Unstable Medical Conditions
  Patients with unstable cardiovascular, respiratory, or other serious medical conditions may not be suitable candidates due to the potential for complications

8. Evidence Base/References

NHS England 2019 - https://www.nhs.uk
NICE Guidelines - Find guidance | NICE
RCR Guidelines - Guidance on screening and symptomatic breast imaging, Fourth edition | The Royal College of Radiologists (rcr.ac.uk)

9. Competencies and Training Requirements

Referrals will only be accepted from medical referrers holding current GMC registration ***working within the Breast team at East Sussex Healthcare*** and Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate ***working within the Breast team at East Sussex Healthcare***.

10. Monitoring Arrangements

- This policy and procedure will be reviewed every three years. Where review is necessary due to legislative change, this will happen immediately.

- Variations of the protocol must be fully agreed by all parties and authorised by East Sussex Healthcare Trust's Radiation Protection Committee after which it can be amended accordingly.

11. Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Referral guidelines are being adhered to and appropriate patients are being selected and referred for a biopsy.	Individual divisions and departments	CRIS, Sectra PACs Clinical Governance Risk Management Framework	Every 3 Years	As required	Divisional Governance process	Governance Lead

Appendix A: Equality and Health Inequalities Impact Assessment (EHIA) template

Undertaking EHIA helps us to make sure that our services and polices do not inadvertently benefit some groups more than others, ensuring that we meet everyone's needs, and our legal and professional duties.

This is important because:

- Assessing the potential for services and policies to impact differently on some groups compared with others is a legal requirement.
- People who find it harder to access healthcare services are more likely to present later when their disease may be more progressed, have poorer outcomes from treatment, and need more services than other groups who have better access.

The Equality Act 2010 legally protects people from discrimination in the workplace and in wider society. It is against the law to discriminate against anyone because of:

- age
- gender reassignment
- being married or in a civil partnership
- being pregnant or on maternity leave
- disability
- race including colour, nationality, ethnic or national origin
- religion or belief
- sex
- sexual orientation.

These are called 'protected characteristics'. The Act requires that public sector organisations meet specific equality duties in respect of these protected characteristics. This is known as the public sector equality duty.

Public Sector Equality Duty

Public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees.

Public bodies must have due regard to the need to:

- eliminate discrimination
- advance equality of opportunity
- foster good relations.

Armed Forces Covenant Duty

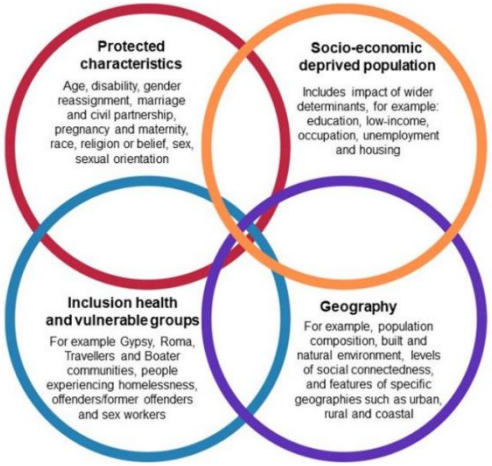
The new Covenant Duty raises awareness of how Service life can impact on the Armed Forces community, and how disadvantages can arise due to Service when members of that community seek to access key local services. The Duty requires organisations to pay due regard to the Covenant principles when exercising functions in healthcare. "Due regard" means that we need to consciously consider the unique obligations and sacrifices made by the Armed Forces; that it is desirable to remove disadvantages faced by the Armed Forces community; and that special provision may be justified in some circumstances.

Health Inequalities Duties- Equity for all

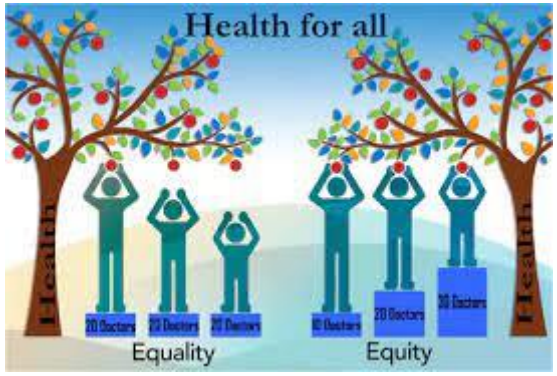
In addition to our legal duties in relation to Protected Characteristics, the Health and Social Care Act and other legislation, NHS Planning Guidance and sector specific recommendations require the NHS to have regard to the need to address health inequalities (or differences in access to or outcomes from healthcare) and take specific action to address them.

Figure 1 shows the different population groups, factors associated with where we live, or our individual circumstances, which separately, or when combined, influence access to and outcomes from health care.

Getting equal outcomes may require different inputs (or services). In completing an EHIA its important to think about whether a one size fits all approach will generate the same good outcomes for everyone, or whether we might need to make some tweaks or adjustments to enable everyone to benefit equally. The health tree diagram shows that unless we think about the needs of different people, equal services might generate unequal outcomes.



The Health Tree[1]



The following principles, drawn from case law, explain what we must do to fulfil our duties under the Equality Act:

- **Knowledge:** everyone working for the Trust must be aware of our equality duties and apply them appropriately in their work.
- **Timeliness:** the duty applies at the time of considering policy options and/or before a final decision is taken – not afterwards.

[1] https://www.researchgate.net/figure/Equality-and-equity-of-medical-resources-distribution_fig2_323266914

- **Real Consideration:** the duty must be an integral and rigorous part of your decision-making and influence the process.
- **Sufficient Information:** you must assess what information you have and what is needed to give proper consideration.
- **No delegation:** the Trust is responsible for ensuring that any contracted services which provide services on our behalf can comply with the duty, are required in contracts to comply with it, and do comply in practice. It is a duty that cannot be delegated.
- **Review:** the equality duty is a continuing duty. It applies when a policy/process is developed/agreed, and when it is implemented/reviewed.
- **Proper Record Keeping:** to show that we have fulfilled our duties we must keep records of the process and the impacts identified.

NB: Filling out this EHIA in itself does not meet the requirements of the equality and health inequalities duties. All the requirements above must be fulfilled or the EHIA (and any decision based on it) may be open to challenge. Properly used, an EHIA can be a tool to help us comply with our equality and health inequalities duty and as a record that to demonstrate that we have done so. It is advised that you complete the short EHIA training session on MyLearn before completing this EHIA.

SECTION A ADMINISTRATIVE INFORMATION

This form is a central part of how the Trust makes sure and can demonstrate to others that we are meeting our legal duties; and how we can assure ourselves that all patients will get the best outcome for them from our services.

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal. **Function/policy/service name and number:**	N/A		
Main aims and intended outcomes of the function/policy/service and summary of the changes you are making (if existing policy/service):	To ensure that stereotactic breast biopsy is utilised appropriately, minimising unnecessary procedures while ensuring prompt and accurate diagnosis of breast abnormalities by adhering to established guidelines.		
How will the function/policy/service change be put into practice?	N/A		
Who will be affected/benefit from the policy?	N/A		
State type of policy/service	Policy ☐	Service ☐	
	Business Case ☐	Function ☐	Existing
Is an EHIA required? NB :Most policies/functions will require an EA with few exceptions such as routine procedures	Yes ☐		
	No ☐ (If no state reasons)		

Accountable Director: (Job Title)	N/A	
Assessment Carried out by:	Name:	
Contact Details:	N/A	
Date Completed:	N/A	

SECTION B ANALYSIS AND EVIDENCE

Analysis of the potential impact – Equality and Health Inequalities Duties
For this section you will need to think about all the different groups of people who are more likely to experience poorer access or have poorer outcomes from health and care services. For each group please describe in the first column the potential impact you have identified, in the second column explain how you have arrived at this conclusion and what information you used to identify the potential impact, and in the third column say what you are going to do to prevent it from happening, or which elements of a service or policy specifically address the potential impact. Key things to remember.

- Everyone has protected characteristics but some groups who share one or more protected characteristics may be more likely to have poorer outcomes or access compared with others – and it is this potential that the EHIA process seeks to identify and address.
- The information included here should be proportionate to the type and size of the policy/service/change.
- An update to a policy should demonstrate that you have considered the potential for the policy to impact differently on different groups and taken steps to address that.
- A minor policy update is likely to need to be much less comprehensive than an EHIA for a major service change.
- You will need to know information about who uses or could use your service/policy will apply to (the population). You can use information about current patients or staff, and about the general population the Trust serves.

3. PROTECTED CHARACTERISTICS - Main potential positive or negative impact of the proposal for protected characteristic groups summarised

Please write in the box below a brief summary of the main potential impact (positive or negative) Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below, but make sure you include information on how you know there will be no impact.**

Protected characteristic groups	**Summary explanation of the *potential* positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
Age: older people; middle years; early years; children and young people.			
Disability: physical, sensory and learning			

Protected characteristic groups	**Summary explanation of the *potential* positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
impairment; mental health condition; long-term conditions.			
Gender Reassignment and/or people who identify as Transgender			
Marriage & Civil Partnership: people married or in a civil partnership.			
Pregnancy and Maternity: before and after childbirth and who are breastfeeding.			
Race:			
Religion and belief: people with different religions/faiths or beliefs, or none.			
Sex:			
Sexual orientation			

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Veterans/Armed Forces Communities			

4. HEALTH INEQUALITIES -Potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). **If the policy/procedure is unrelated to patients, this sections does not require completion.**

Please state none if you have assessed that there is not an impact, but please make sure you complete the 'how do you know this' column to demonstrate that you have considered the potential for impact**. If you identify the potential for impact for one or more of these groups please complete the full assessment in Appendix A**

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
This includes all groups of people who may have poorer access to or outcomes from healthcare services. It includes: People who have experienced the			

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
care system; carers; homeless people; people involved in the criminal justice system; people who experience substance misuse or addiction; people who experience income or other deprivation; people with poor health literacy; people living in rural areas with limited access to services; refugees or asylum seekers; people in or who have been in the armed force; other groups who you identify as potentially having poorer access and outcomes.			

SECTION C ENGAGEMENT

5. Engagement and consultation

a. Talking to patients, families and local communities can be a rich source of information to inform health care services. If you are making substantial changes it's likely that you'll have to undertake specific engagement with patients. For smaller changes and policies your may have undertaken some engagement with patient groups, gained insight from routine sources e.g. patient surveys, PALS or Complaints information or information from Healthwatch, you may also have looked at relevant engagement that others have undertaken in the Trust, or locally
Have any engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	No

b. If yes, please ensure all stakeholders are listed in the consultation table at the beginning of the policy.

SECTION D SUMMARY OF FINDINGS

Reflecting on all of the information included in your review-

6. EQUALITY DUTIES: Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please **add an x** to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?			
Uncertain whether the proposal will support?			

7. HEALTH INEQUALITIES: Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?		
The proposal may support?		
Uncertain if the proposal will support?		

8. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1		
2		
3		

9. EHIA sign-off: (this section must be signed)

Person completing the EHIA:	**Lauren Head**	**Date: 28.11.2024**

Line Manager of person completing:	**Louise Richards**	**Date: 28.11.2024**

Breakdown of Groups who are more likely to experience health inequalities:

Groups who face health inequalities[3]	**Summary explanation of the potential positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
Looked after children and young people			
Carers of patients			
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.			
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.			
People with addictions and/or substance misuse issues			
People or families on a low income			

Groups who face health inequalities[3]	**Summary explanation of the potential positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).			
People living in deprived areas			
People living in remote, rural and island locations			
Refugees, asylum seekers or those experiencing modern slavery			
People who have served in the Armed Forces			
Other groups experiencing health inequalities (please describe)			

EHIA Resources
Sources of Information on the East Sussex population and sources of community or patient insight.

Population Data
State of the County 2021 Focus on East Sussex

East Sussex JSNA

Community Insight

Further Reading on Equality and Health Inequalities

Training

East Sussex Healthcare NHS Trust

Practitioner Guidelines for requesting a Vacuum assisted Breast Biopsy / Excision

Document ID Number	1423
Version:	1.0
Ratified by:	Radiation Protection Committee
Date ratified:	11th September 2024
Name of author and title:	Lauren Head Interventional Mammographer/ Deputy Modality Manager Mammography
Date originally written:	11th September 2024
Date current version was completed	11th September 2024
Name of responsible committee/individual:	Radiation Protection Group
Division/Speciality:	CORE services
Date issued:	17th Feb 2025
Review date:	11th September 2027
Target audience:	•Medical referrers holding current GMC registration working within the Breast team at East Sussex Healthcare. •Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate working within the Breast team at East Sussex Healthcare.
Compliance with CQC Fundamental Standard	Safe Care and Treatment.
Compliance with any other external requirements (e.g. Information Governance)	IR(ME)R Guidelines 2017 Information Governance
Associated Documents:	Lidocaine with Adrenaline Patient Group Directive Sep 2023 Bupivacaine hydrochloride Patient Group Directive Mar 2024 Xylocaine PGD mammography Mar 2024

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1.0	11th Sep 2024	Lauren Head	New Document	New Document

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Dr Ulle Raudsepp	Consultant Radiologist	Sep 2024
Professor Howlett	Consultant Radiologist	Sep 2024
Dr Yesim Akan	Consultant Radiologist	Sep 2024
Lauren Head	Lead Interventional Mammographer / Deputy Modality Manager	Sep 2024
Dr Neil Barlow	Consultant Radiologist / IRMER Lead	Sep 2024

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

This procedural document outlines the referral guidelines for Vacuum-Assisted Breast Biopsy (VAB) and Vacuum-Assisted Breast Excision (VAE), a minimally invasive technique used to diagnose breast abnormalities.
It covers the criteria for patient selection, indications, and contraindications for the procedure.

The document provides an overview of the procedural steps and referral process.
Understanding these guidelines ensures appropriate use of VAB, optimising patient outcomes and ensuring accurate diagnosis.

2. Purpose

To ensure that vacuum-assisted breast biopsy (VAB) and vacuum-assisted breast excision (VAE) is utilised appropriately, minimising unnecessary procedures while ensuring prompt and accurate diagnosis of breast abnormalities by adhering to established guidelines.

2.1. Rationale

The professional frameworks that provide the foundation for the guidelines on VAB and VAE are as follows: NHS England, NICE Guidelines, Breast Radiology.org, Gov.UK.

2.2. Principles

The principles of these practitioner guidelines for VAB and VAE are designed to ensure appropriate, ethical, and effective use of the procedure. These principles include:

IR(ME)R 2017 Regulations
Appropriate Indication
Patient Safety
Informed Decision-Making
Multidisciplinary Collaboration
Ethical Considerations
Evidence-Based Practice

2.3. Scope

This Policy and Procedure document is available to all ESHT employees but in particular relevant to:

- Medical referrers holding current GMC registration working within the Breast team at East Sussex Healthcare.

- Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate working within the Breast team at East Sussex Healthcare.

3. Definitions

VAB – Vacuum Assisted Breast biopsy
VAE – Vacuum Assisted Breast Excision
NMR – Non medical Referrer
IR(ME)R – Ionising Radiation (Medical Exposure) Regulations

4. Accountabilities and Responsibilities

- Each NMR must complete the trusts application process for non-medical referrer's outlines in the 'Principles' section above and have a named Supervising Consultant.

- This protocol must be adhered to by all the referrers within the breast teams at EDGH and Conquest.

- The Referrer is responsible for informing East Sussex Healthcare Trust's Radiation Protection Committee of any relevant training that they might undertake and any changes to their name or designation. This should be notified via the IR(ME)R Lead.

- The Supervising Consultant and/or East Sussex Healthcare Trust's Radiation Protection Committee have the right to withdraw the Referrers ability to request x-rays.

- Entitlement to refer will automatically be withdrawn should the Referrer terminate their employment with East Sussex Healthcare Trust.

5. Process

Clinical Indications Referral Guidelines:

This guidance specifies that only lesions meeting certain criteria will be accepted for VABB, focusing on ensuring appropriate use. These criteria include:

- Micro calcifications that appear suspicious on mammograms that have a scattered appearance and a larger tissue sample is required to accurately assess their nature.

- Inconclusive Previous Biopsies:
  Inadequate Samples: When previous core needle biopsies or other sampling methods have not provided a clear diagnosis.

- All VABB requests must be discussed at Breast MDM.

Contraindications:

The same contraindications apply as in the Mammography Stereotactic biopsy service standard operating procedure.
There are also additional contraindications that may prevent some patients from being suitable candidates for this procedure.

These contraindications can be divided into absolute and relative categories.

Absolute Contraindications

Absolute contraindications are conditions where the procedure should not be performed under any circumstances due to high risks.

- Active Infection Reason:
  An active infection at the biopsy site or systemic infection can increase the risk of complications, such as spreading the infection.

- **Severe** Coagulopathy
  Patients with uncontrolled bleeding disorders or those on anticoagulation therapy that cannot be temporarily discontinued are at high risk for excessive bleeding during and after the procedure.

- Allergy to Anaesthetics
  An allergy to local anaesthetics used during the procedure can lead to severe allergic reactions, making the biopsy unsafe.

Relative Contraindications
Relative contraindications are conditions where the procedure may be performed if the benefits outweigh the risks and appropriate precautions are taken.

- Patients on anticoagulation therapy.
  All patients on anticoagulation therapy should consult a haematologist or cardiologist to consider discontinuing.
  The instructions for safe biopsy practice for patient taking anticoagulation drugs are as follows:

- New anticoagulants such as Rivaroxaban, Clopidogrel, Apixaban - stop for 3 days before biopsy

- Aspirin - Stop for 1 day before biopsy

- Warfarin - Stop for 5 days before biopsy and an INR blood test must be performed 24-48 hours prior to the biopsy date. Result must be 1.5 or below in order to proceed with VABB.

- LMW Heparin – Stop for 3 days before biopsy

- Large Breast Size or Very Small Breasts
  Extremely large or very small breasts can make positioning and accessing the target area challenging. Alternatives or modifications may be needed.

- Proximity to Chest Wall
  Lesions located very close to the chest wall may be difficult to access safely without risking damage to underlying structures.

- Proximity to retro areola area
  Lesions located very close to the nipple and retro areola may be difficult to access safely due to the anatomical complexity and potential complications associated with the retro areolar region, vacuum-assisted breast biopsy in this area is generally avoided.

- Implants or Previous Breast Surgery
  The presence of breast implants or extensive scar tissue from previous surgeries can complicate the biopsy process. Special techniques or imaging adjustments may be required.

- Pregnancy

Although the radiation exposure in stereotactic biopsy is minimal, it is generally avoided during pregnancy unless absolutely necessary. Alternative biopsy methods, such as ultrasound-guided biopsy, are preferred.

- Inability to Comply with Instructions
  Reason: Patients who cannot remain still during the procedure due to severe anxiety, cognitive impairment, or other factors may not be suitable candidates. Sedation or alternative biopsy methods may be considered.

- Unstable Medical Conditions
  Patients with unstable cardiovascular, respiratory, or other serious medical conditions may not be suitable candidates due to the potential for complications with the medication that is used during the procedure.

6. Evidence Base/References

NHS England 2019 - https://www.nhs.uk
NICE Guidelines - Find guidance | NICE
Guidelines for performing breast and axillary biopsies in patients on anticoagulant and antiplatelet therapy
https://breastradiology.org/media/1022/bsbr-anticoag-guidelines-august-2018.pdf

Lidocaine with Adrenaline Patient Group Directive Sep 2023
Bupivacaine hydrochloride Patient Group Directive Mar 2024
Xylocaine PGD mammography Mar 2024

Gov. UK https://www.gov.uk/government/publications/breast-screening-how-to-record-vacuum-assisted-excisions/breast-screening-how-to-record-vacuum-assisted-excisions

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Referrals will only be accepted from medical referrers holding current GMC registration ***working within the Breast team at East Sussex Healthcare*** and Non-medical referrers whom have had IR(ME)R training and agreed protocols between the Radiology Department and the appropriate directorate ***working within the Breast team at East Sussex Healthcare***.

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The Equality Act 2010 legally protects people from discrimination in the workplace and in wider society. It is against the law to discriminate against anyone because of:

- age
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- being married or in a civil partnership
- being pregnant or on maternity leave
- disability
- race including colour, nationality, ethnic or national origin
- religion or belief
- sex
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These are called 'protected characteristics'. The Act requires that public sector organisations meet specific equality duties in respect of these protected characteristics. This is known as the public sector equality duty.

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- foster good relations.

Armed Forces Covenant Duty

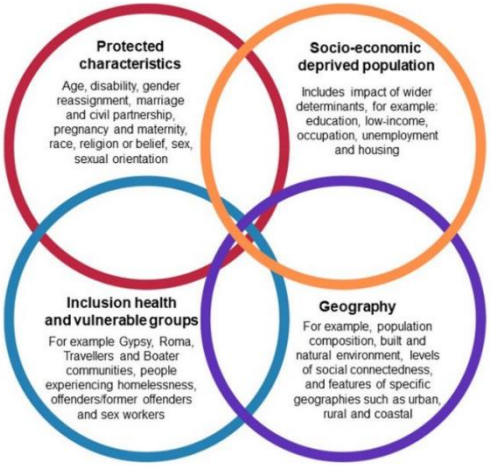
The new Covenant Duty raises awareness of how Service life can impact on the Armed Forces community, and how disadvantages can arise due to Service when members of that community seek to access key local services. The Duty requires organisations to pay due regard to the Covenant principles when exercising functions in healthcare. "Due regard" means that we need to consciously consider the unique obligations and sacrifices made by the Armed Forces; that it is desirable to remove disadvantages faced by the Armed Forces community; and that special provision may be justified in some circumstances.

Health Inequalities Duties- Equity for all

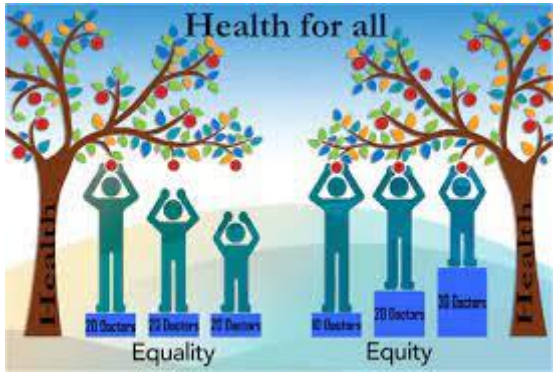
In addition to our legal duties in relation to Protected Characteristics, the Health and Social Care Act and other legislation, NHS Planning Guidance and sector specific recommendations require the NHS to have regard to the need to address health inequalities (or differences in access to or outcomes from healthcare) and take specific action to address them.

Figure 1 shows the different population groups, factors associated with where we live, or our individual circumstances, which separately, or when combined, influence access to and outcomes from health care.

Getting equal outcomes may require different inputs (or services). In completing an EHIA its important to think about whether a one size fits all approach will generate the same good outcomes for everyone, or whether we might need to make some tweaks or adjustments to enable everyone to benefit equally. The health tree diagram shows that unless we think about the needs of different people, equal services might generate unequal outcomes.



The Health Tree[1]



The following principles, drawn from case law, explain what we must do to fulfil our duties under the Equality Act:

- **Knowledge:** everyone working for the Trust must be aware of our equality duties and apply them appropriately in their work.
- **Timeliness:** the duty applies at the time of considering policy options and/or before a final decision is taken – not afterwards.

[1] https://www.researchgate.net/figure/Equality-and-equity-of-medical-resources-distribution_fig2_323266914

- **Real Consideration:** the duty must be an integral and rigorous part of your decision-making and influence the process.
- **Sufficient Information:** you must assess what information you have and what is needed to give proper consideration.
- **No delegation:** the Trust is responsible for ensuring that any contracted services which provide services on our behalf can comply with the duty, are required in contracts to comply with it, and do comply in practice. It is a duty that cannot be delegated.
- **Review:** the equality duty is a continuing duty. It applies when a policy/process is developed/agreed, and when it is implemented/reviewed.
- **Proper Record Keeping:** to show that we have fulfilled our duties we must keep records of the process and the impacts identified.

NB: Filling out this EHIA in itself does not meet the requirements of the equality and health inequalities duties. All the requirements above must be fulfilled or the EHIA (and any decision based on it) may be open to challenge. Properly used, an EHIA can be a tool to help us comply with our equality and health inequalities duty and as a record that to demonstrate that we have done so. It is advised that you complete the short EHIA training session on MyLearn before completing this EHIA.

SECTION A ADMINISTRATIVE INFORMATION

This form is a central part of how the Trust makes sure and can demonstrate to others that we are meeting our legal duties; and how we can assure ourselves that all patients will get the best outcome for them from our services.

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal. **Function/policy/service name and number:**	N/A		
Main aims and intended outcomes of the function/policy/service and summary of the changes you are making (if existing policy/service):	To ensure that vacuum-assisted breast biopsy is utilised appropriately, minimising unnecessary procedures while ensuring prompt and accurate diagnosis of breast abnormalities by adhering to established guidelines.		
How will the function/policy/service change be put into practice?	N/A		
Who will be affected/benefit from the policy?	N/A		
State type of policy/service	Policy ☐	Service ☐	
	Business Case ☐	Function ☐	Existing
Is an EHIA required? NB :Most policies/functions will require an EA with few exceptions such as routine procedures	Yes ☐		
	No ☐ (If no state reasons)		

Accountable Director: (Job Title)		
Assessment Carried out by:	Name:	
Contact Details:		
Date Completed:		

SECTION B ANALYSIS AND EVIDENCE

Analysis of the potential impact – Equality and Health Inequalities Duties
For this section you will need to think about all the different groups of people who are more likely to experience poorer access or have poorer outcomes from health and care services. For each group please describe in the first column the potential impact you have identified, in the second column explain how you have arrived at this conclusion and what information you used to identify the potential impact, and in the third column say what you are going to do to prevent it from happening, or which elements of a service or policy specifically address the potential impact. Key things to remember.

- Everyone has protected characteristics but some groups who share one or more protected characteristics may be more likely to have poorer outcomes or access compared with others – and it is this potential that the EHIA process seeks to identify and address.
- The information included here should be proportionate to the type and size of the policy/service/change.
- An update to a policy should demonstrate that you have considered the potential for the policy to impact differently on different groups and taken steps to address that.
- A minor policy update is likely to need to be much less comprehensive than an EHIA for a major service change.
- You will need to know information about who uses or could use your service/policy will apply to (the population). You can use information about current patients or staff, and about the general population the Trust serves.

3. PROTECTED CHARACTERISTICS - Main potential positive or negative impact of the proposal for protected characteristic groups summarised

Please write in the box below a brief summary of the main potential impact (positive or negative) Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below, but make sure you include information on how you know there will be no impact.**

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.

Protected characteristic groups	**Summary explanation of the *potential* positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
Age: older people; middle years; early years; children and young people.			
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.			
Gender Reassignment and/or people who identify as Transgender			
Marriage & Civil Partnership: people married or in a civil partnership.			
Pregnancy and Maternity: before and after childbirth and who are breastfeeding.			
Race:			
Religion and belief: people with different religions/faiths or beliefs, or none.			
Sex:			

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Sexual orientation			
Veterans/Armed Forces Communities			

4. HEALTH INEQUALITIES -Potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). **If the policy/procedure is unrelated to patients, this sections does not require completion.**

Please state none if you have assessed that there is not an impact, but please make sure you complete the 'how do you know this' column to demonstrate that you have considered the potential for impact**. If you identify the potential for impact for one or more of these groups please complete the full assessment in Appendix A**

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
This includes all groups of			

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
people who may have poorer access to or outcomes from healthcare services. It includes: People who have experienced the care system; carers; homeless people; people involved in the criminal justice system; people who experience substance misuse or addiction; people who experience income or other deprivation; people with poor health literacy; people living in rural areas with limited access to services; refugees or asylum seekers; people in or who have been in the armed force; other groups who you identify as potentially having poorer access and outcomes.			

SECTION C ENGAGEMENT

5. Engagement and consultation

a. Talking to patients, families and local communities can be a rich source of information to inform health care services. If you are making substantial changes it's likely that you'll have to undertake specific engagement with patients. For smaller changes and policies your may have undertaken some engagement with patient groups, gained insight from routine sources e.g. patient surveys, PALS or Complaints information or information from Healthwatch, you may also have looked at relevant engagement that others have undertaken in the Trust, or locally

Have any engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	**No**

b. If yes, please ensure all stakeholders are listed in the consultation table at the beginning of the policy.

SECTION D SUMMARY OF FINDINGS

Reflecting on all of the information included in your review-

6. EQUALITY DUTIES: Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please **add an x** to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?			
Uncertain whether the proposal will support?			

7. HEALTH INEQUALITIES: Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?		
The proposal may support?		
Uncertain if the proposal will support?		

8. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1		
2		

3		

9. EHIA sign-off: (this section must be signed)

Person completing the EHIA:	**Lauren Head**	**Date: 28.11.2024**
Line Manager of person completing:	**Louise Richards**	**Date:28.11.2024**

Breakdown of Groups who are more likely to experience health inequalities:

Groups who face health inequalities[3]	**Summary explanation of the potential positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
Looked after children and young people			
Carers of patients			
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.			
People involved in the criminal justice system: offenders in prison/on			

Groups who face health inequalities[3]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
probation, ex-offenders.			
People with addictions and/or substance misuse issues			
People or families on a low income			
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).			
People living in deprived areas			
People living in remote, rural and island locations			
Refugees, asylum seekers or those experiencing modern slavery			
People who have served in the Armed Forces			
Other groups experiencing health inequalities (please describe)			

EHIA Resources
Sources of Information on the East Sussex population and sources of community or patient insight.

Population Data
State of the County 2021 Focus on East Sussex

East Sussex JSNA

Community Insight

Further Reading on Equality and Health Inequalities

Training

East Sussex Healthcare NHS Trust

MRI Escalation Policy Controlled Document Radiology Department

Document ID Number	1951
Version:	V1.0
Ratified by:	Policy Ratification Group
Date ratified:	08th October 2019
Name of author and title:	Chris Brandt, Clinical Manager CT/MRI
Date originally written:	November 2018
Date current version was completed	September 2019
Name of responsible committee/individual:	Dr Justin Harris, Clinical Lead Consultant Radiologist
Date issued:	08th October 2019
Review date:	October 2022
Target audience:	All Clinical Staff in MRI
Compliance with CQC Fundamental Standard	Patient care diagnosis and treatment
Compliance with any other external requirements (e.g. Information Governance)	N/A
Associated Documents:	N/A

Did you print this yourself?
Please be advised the Trust discourages retention of hard copies of the procedural document and can only guarantee that the procedural document on the Trust website is the most up to date version

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1.0	November 2018	Chris Brandt	New Document	New Document
V1.0	September 2019	Chris Brandt	Updated format	New Document

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Dr Harris	Consultant Radiologist	May 2019
Dr Watson	Consultant Radiologist	May 2019
DAS Clinical Governance Group		January 2019

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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9. Monitoring Arrangements 5

Appendix A: EHRA Form 8

Appendix B: If the Radiographer suspects one of the following abnormalities use the "Emergencies" Procedure 10

Appendix C: If the Radiographer suspects Abnormalities Procedure 17

1. Introduction

In order to deliver safe and effective care all providers of diagnostics and healthcare must ensure that radiology imaging results are communicated and acted on appropriately. This encompasses:

- Ensuring the referrer provides adequate information about the patient, has tracking systems for checking results and a robust method for informing patients about the results.
- Ensuring that radiographers and reporting radiologists have adequate information about the referrer and patient and processes to inform them of urgent and abnormal results. In addition there must be processes in place to ensure that these have been followed up.
- Ensuring that services have the appropriate information systems throughout the organisation and its sub-contractors and that staff have training to use these systems.
- Ensuring that patients have information about when and where they can access their results.

2. Purpose

East Sussex Healthcare NHS Trust has routine processes in place for the transmission of results and reports to referrers. However there are times when the findings are such that the patient requires emergency care or urgent onward referral requiring additional actions by our staff.

The objectives of this policy are to ensure that:

- Serious findings which require immediate communication and/or treatment are identified by East Sussex Healthcare NHS Trust staff.
- East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives timely and appropriate care.
- Where appropriate actions have been implemented by East Sussex Healthcare NHS trust that there is follow up to ensure that the onward referral has been received and understood.

2.1. Rationale

To assist staff to recognise the common pathological signs when undertaking the MRI scan To allow them to either escalate the report and/or provide additional sequences with contrast as appropriate..

2.2. Principles

Staff should be aware of possible findings that will need to be raised appropriately.

2.3. Scope

The policy is for MRI staff undertaking imaging or for those supervising the scans.

3. Definitions

Escalation – The need to raise concerns that the Radiographer has seen something on the image which they feel needs urgent further advice from a Radiologist or that the Radiographer is concerned at the health of the patient.

4. Accountabilities and Responsibilities

East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives timely and appropriate care.

5. Process

During the normal working day the case should be discussed with the Consultant supervising the list. At other times the case should be marked as an Urgent report required and appropriately documented on CRIS. Cases can be highlighted for a particular Consultants attention. Patients may be referred to A/E or an appropriate ward if concerned.

6. Special Considerations

For oncology findings it may be advisable to inform the oncology nurse who can arrange the patient to be assessed prior to leaving the department.

7. Evidence Base/References

East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives timely and appropriate care.

8. Competencies and Training Requirements

Part of MRI training will include pathology and unexpected findings and what action should be taken at the time.

9. Monitoring Arrangements

This should be in the form of staff feedback communication and ongoing education. It may also form part of staff CPD education. Feedback from reporting Radiologists will also be beneficial.

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Compliance with Policy	Chris Brandt	Feedback	Continual	Radiology	Radiology	Division Governance Group

10. Equality and Human Rights Statement

The aim of this policy is to improve diagnosis and treatment for patients undergoing an MRI scan

A Due Regard, Equality and Human Rights Analysis form must be completed for all procedural documents used by East Sussex Healthcare NHS Trust. Guidance for the form can be found on the Equality and Diversity Extranet page.

Due Regard, Equality and Human Rights Analysis

Title of document: MRI Escalation Policy Controlled Document Radiology Department
Who will be affected by this work? Patients diagnosis treatment
Please include a brief summary of intended outcome: East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives timely and appropriate care.

		Yes/No	Comments, Evidence and Link to main content
1.	**Does the work affect one group less or more favourably than another on the basis of:** (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)		
	• Age	no	
	• Disability (including carers)	no	
	• Race	no	
	• Religion & Belief	no	
	• Gender	no	
	• Sexual Orientation (LGBT)	no	
	• Pregnancy & Maternity	no	
	• Marriage & Civil Partnership	no	
	• Gender Reassignment	no	
	• Other Identified Groups	no	
2.	**Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?**	no	(Ensure you comment and link to main policy with page/paragraph number)
3.	**What are the impacts and alternatives of implementing / not implementing the work / policy?**	none	
4.	**Please evidence how this work / policy seeks to "eliminate unlawful discrimination, harassment and victimisation" as per the Equality Act 2010?**	East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives timely and appropriate care.	
5.	**Please evidence how this work / policy seeks to "advance equality of opportunity between people sharing a protected characteristic and those who do not" as per the Equality Act 2010?**	East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives timely and appropriate care.	
6.	**Please evidence how this work / policy will "Foster good relations between people sharing a protected characteristic and those who do not" as per the Equality Act**	East Sussex Healthcare NHS Trust staff understands the appropriate actions required for different categories of serious findings to ensure that the patient receives	

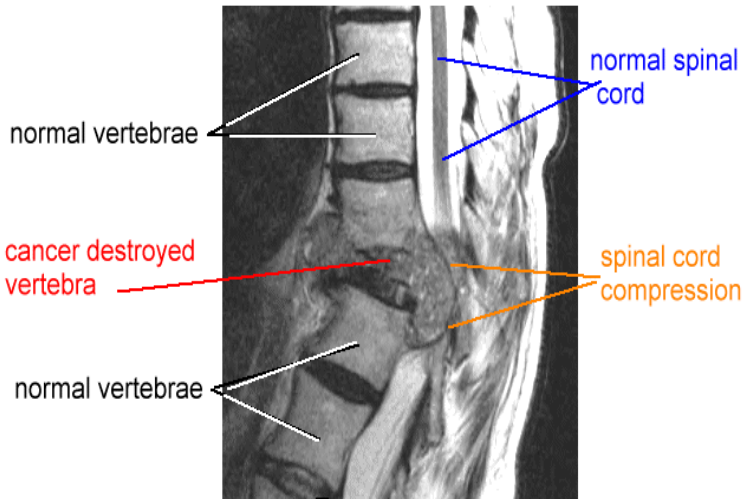
	2010?	timely and appropriate care.
7.	**Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)**	N/A
8.	**Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?**	N/A
9.	**Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).**	None

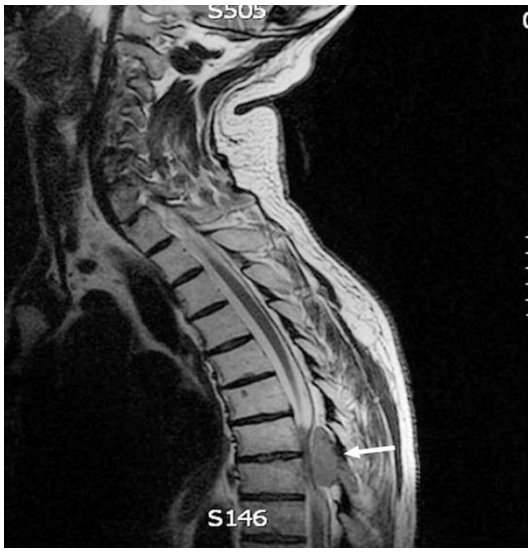
APPENDIX B

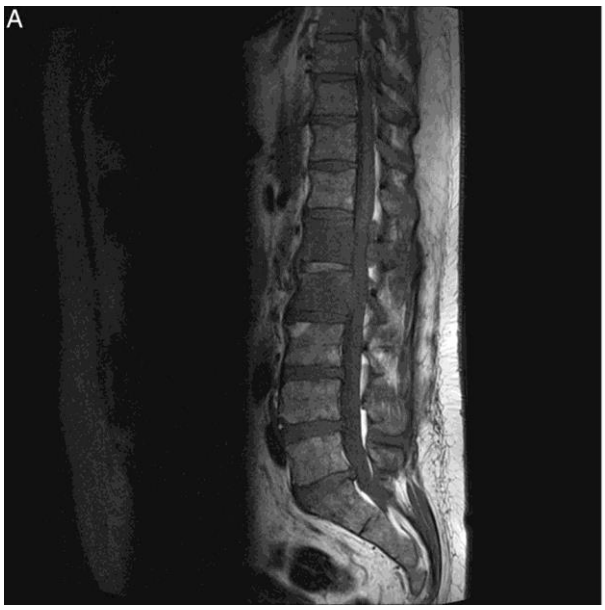
IF THE RADIOGRAPHER SUSPECTS ONE OF THE FOLLOWING ABNORMALITIES USE THE "EMERGENCIES" PROCEDURE

Malignant spinal cord compression

Compression of the spinal cord or cauda equine by direct pressure and or vertebral collapse which is causing or threatens to cause neurological disability



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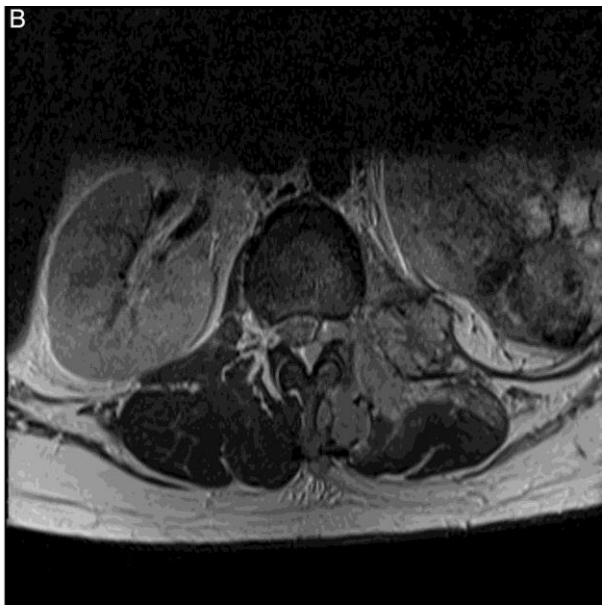
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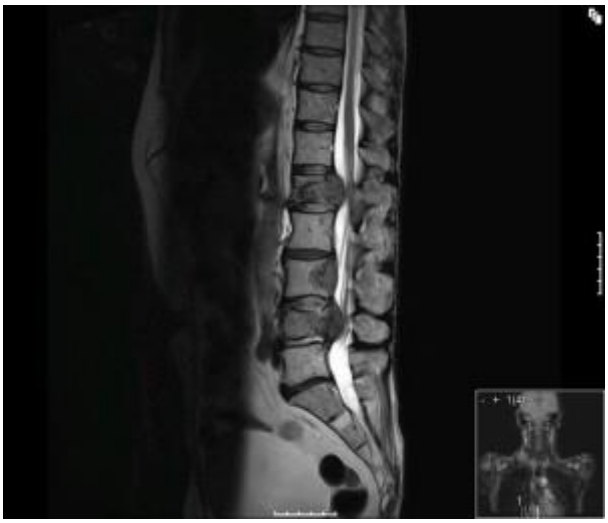
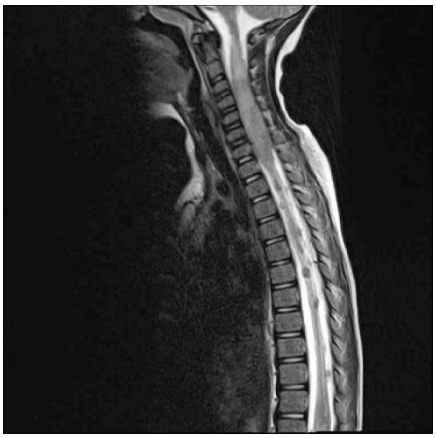
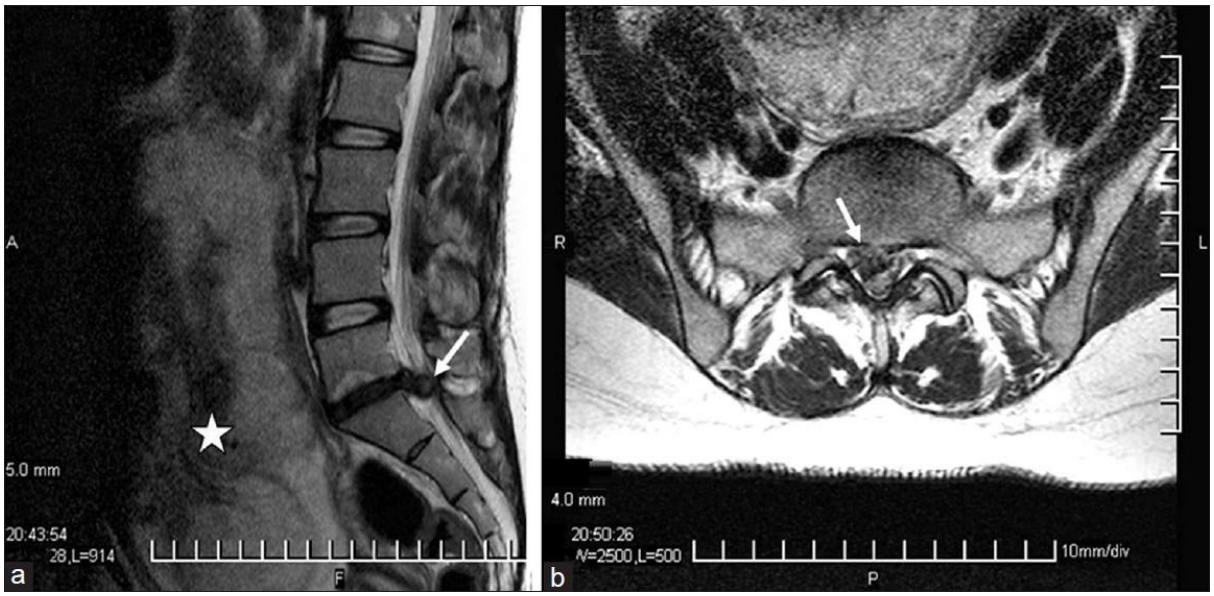
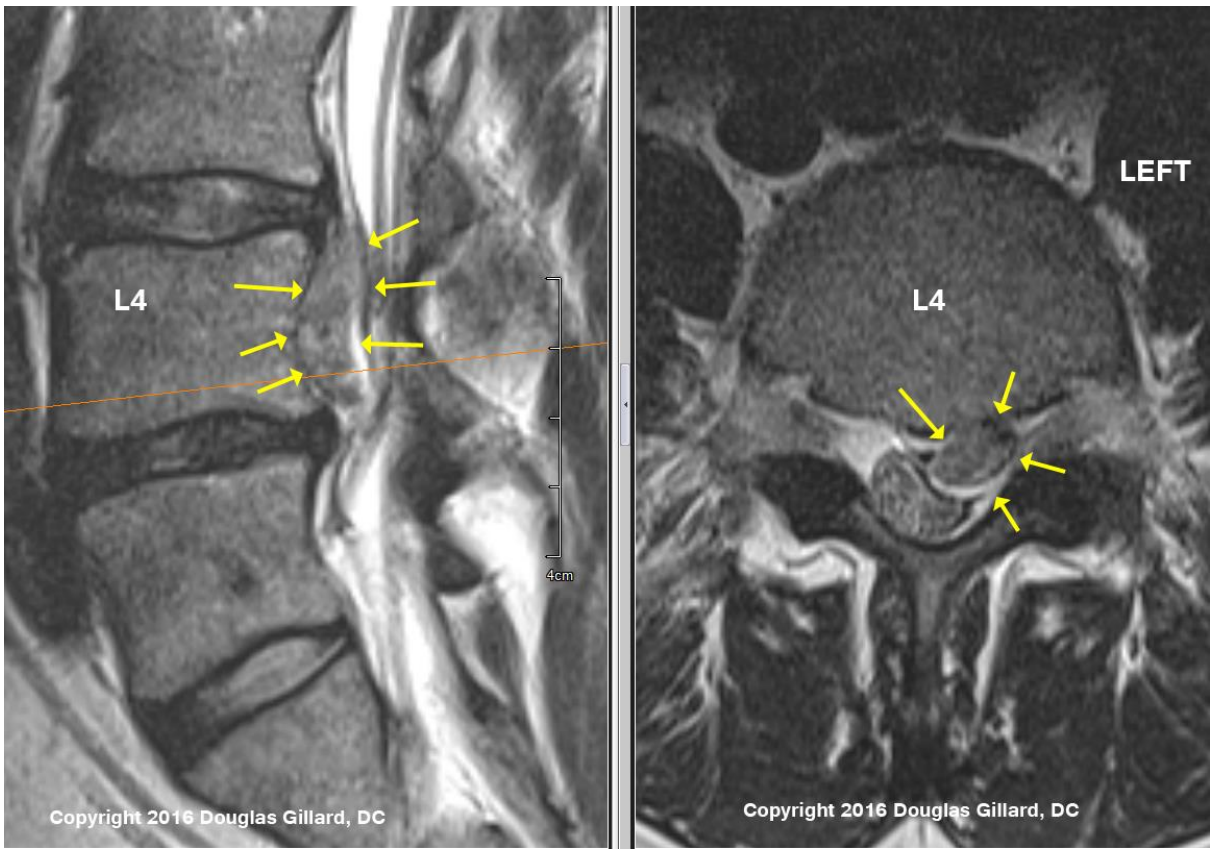




Disk prolapse

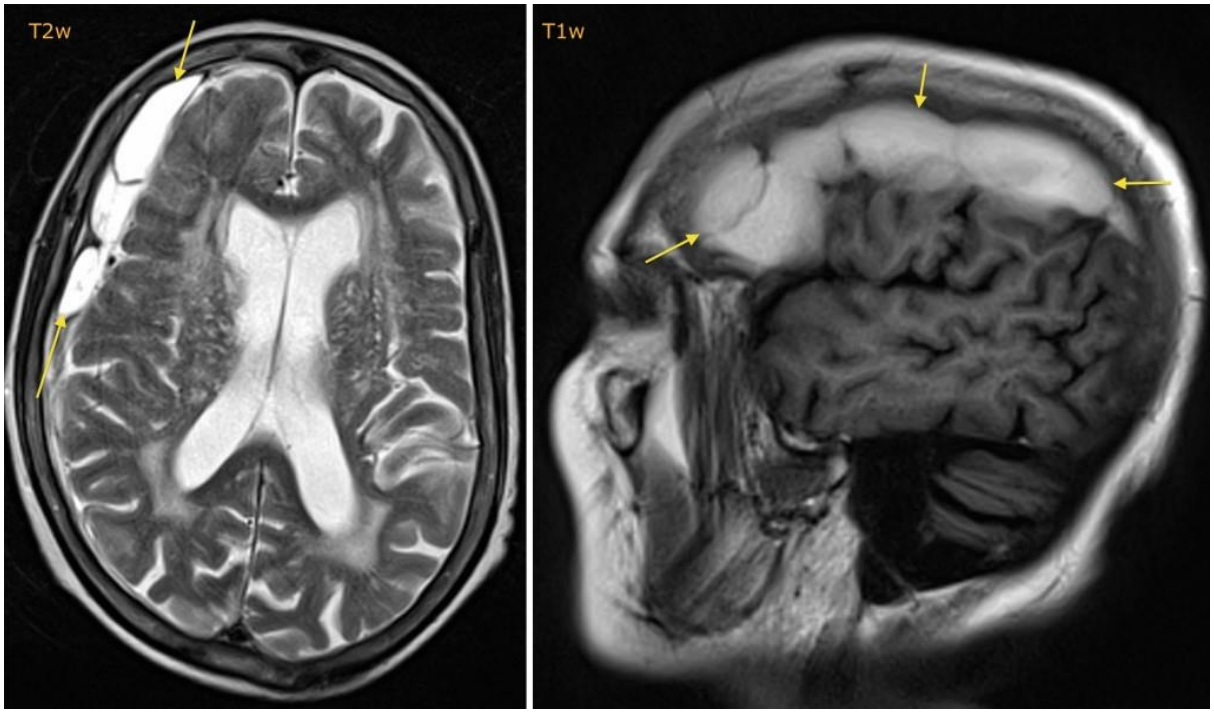
Disc prolapse or sequestration is the most severe degree of disc herniation, in which the nuclear material of the disc slips out and completely separates with the disc.





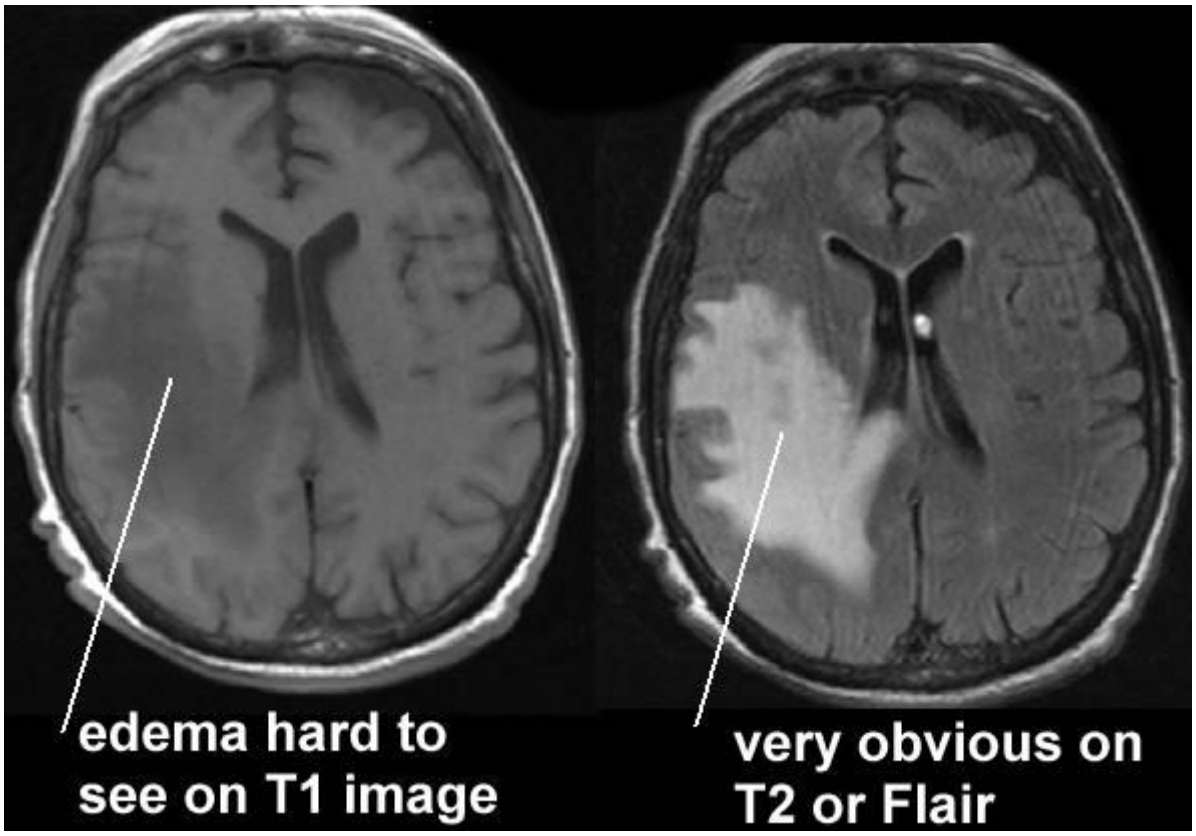
Acute or chronic subdural

Defined as bleeding between the dura and arachnoid mater, usually caused by movement of the brain relative to the skull resulting in injury to a vein or artery within or on the brain surface. As they are caused by injury to venous structures which bleed more slowly, development of clinical signs and symptoms can be delayed so you are more likely to see one on an OPD. Clinical presentation will vary depending on the amount of brain injury at the time so patients may be virtually asymptomatic or have altered consciousness or paralysis with many variations in between.

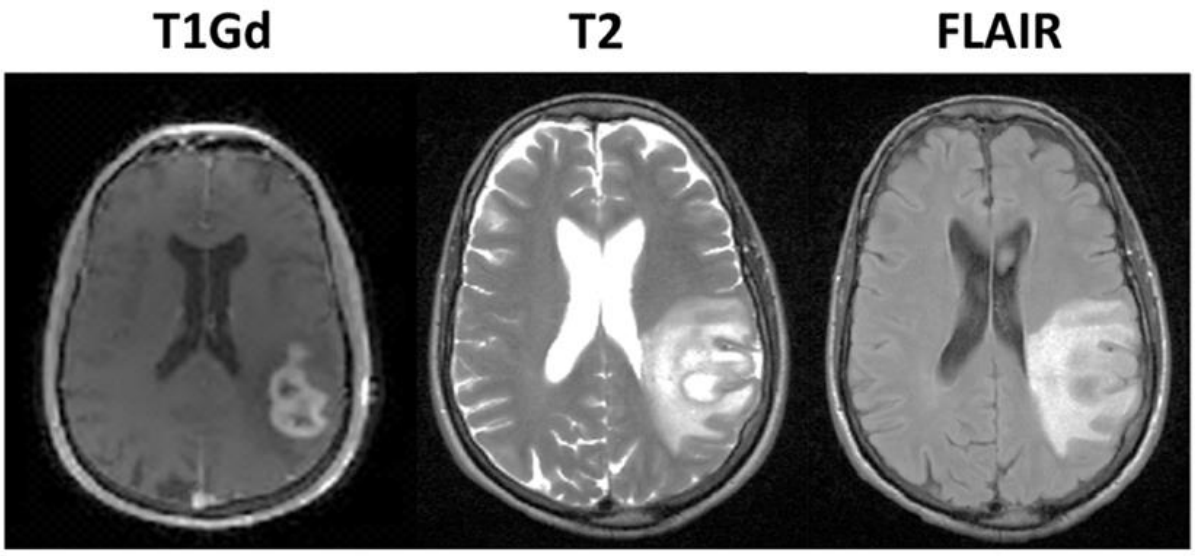


Oedema

Many brain tumours cause oedema which is a significant cause of patient morbidity and mortality. If a brain tumour with significant oedema is observed on the MRI scan, the patient should be carefully questioned whether they are currently experiencing the same severity of symptoms that promoted them to seek medical help, or if they feel their symptoms have got worse in the last 6 hours.

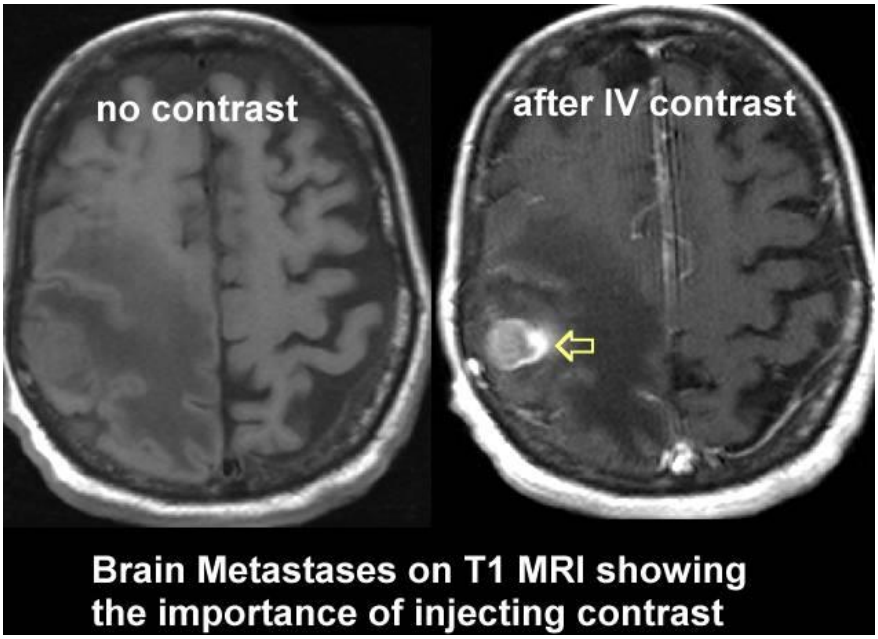


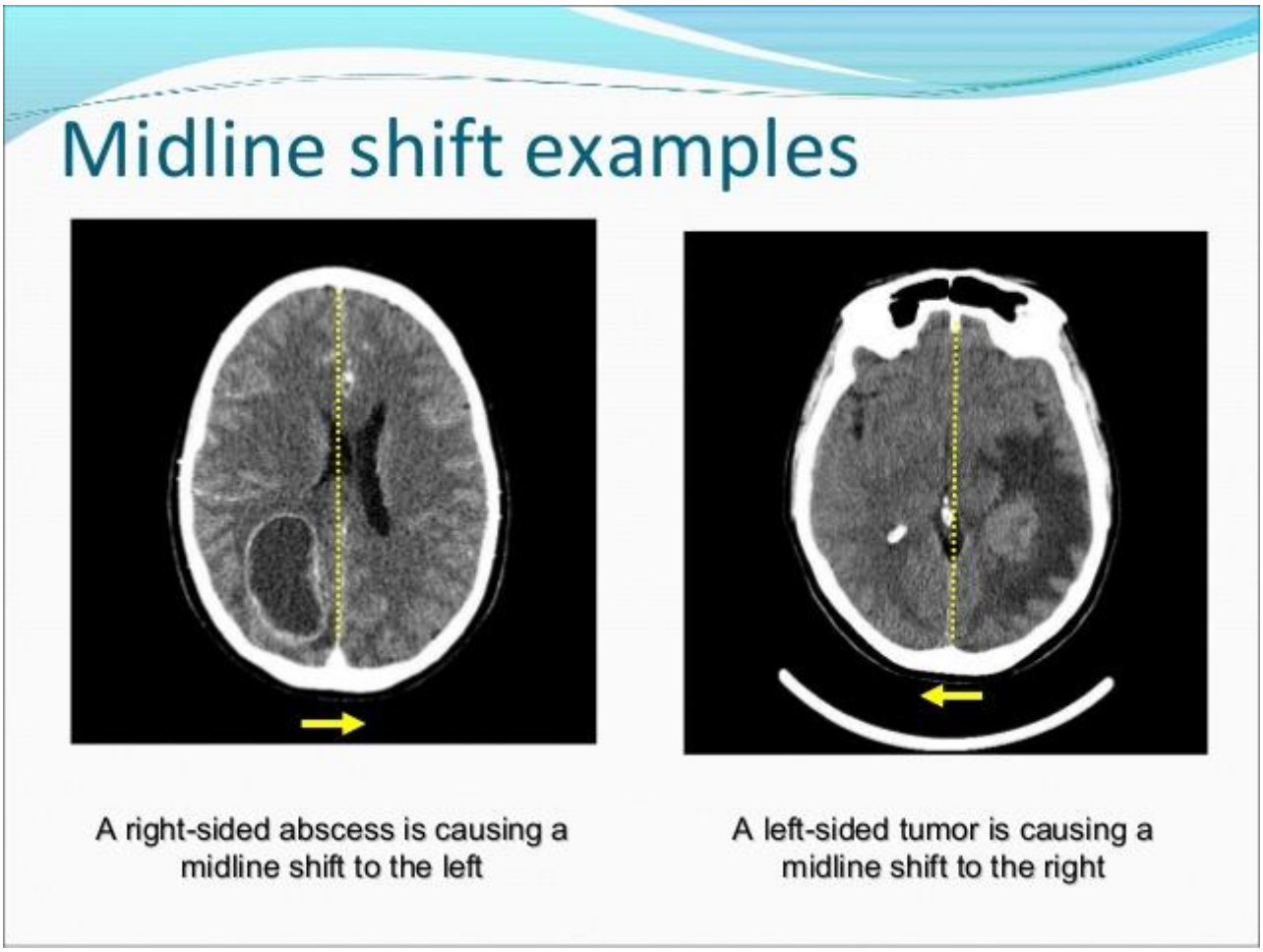
Oedema



Brain metastasis

May not be a clinical emergency if symptoms are stable but urgent follow up will be required.





Things to consider:

1. How well your patient is presenting, how is their mobility, how fast have symptom's progressed, how long have they had the symptoms? For example is the patient loosing sensation in the legs, more confused than previously or has altered bowel and urinary symptoms?

2. Think about advising them to seek urgent medical advice if the symptoms get worse or they are being sent home over a weekend for example.

3. Think about giving Gad whilst the patient is still in the scanner in line with your local PGD.

APPENDIX C

IF THE RADIOGRAPHER SUSPECTS ONE OF THE FOLLOWING ABNORMALITIES, USE THE URGENT FINDINGS PROCEDURE:

It is acknowledged that radiographers are not trained or qualified to diagnose and, subject to their experience, may not recognise all of the conditions listed below:

Region	Urgent Finding – MEDICALLY URGENT CONDITIONS
Head	New lesion with mass effect Infection Acute infarct Haemorrhage Large Hydrocephalus or SDH AA dislocation C1/C2 discloation Acute Cortical vein thrombosis Previously undiagnosed malignancy Dural sinus or cortical vein thrombosis
Spine	Perineural infection Fracture/Dislocation Cord compression with oedema Epidural Haemorrhage Osteomyelitis Previously diagnosed malignancy – primary or metastatic of axial skeleton or neural axis
Musculo-skeletal	Fracture/Dislocation Metastasis with likelihood of fracture Unsuspected Metastasis Osteomyelitis Septic Arthritis Soft Tissue infection Lytic lesion Suspected tumour – muscle, soft tissue or bone
Abdomen & Pelvis	Symptomatic renal stones Partial or complete obstruction Perforation of a viscus Abscess Hydronephrosis/obstruction in a single functioning kidney Haemorrhage Bowel infarction Gas in bowel wall Aortic Aneurysm with symptoms Foreign body Previously undiagnosed malignancy

A CRITICAL, URGENT AND UNEXPECTED FINDING:

Process:

- A twice daily Stat is run from the CRIS system.
- The Radiologist/reporting Radiographer/Sonographer identifies a critical, urgent and unexpected finding that he/she believes requires active clinical follow-up, clinical review and/or further investigation or, if there is an addendum added which requires the above actions.
- The Radiologist/reporting Radiographer will use the word ‘ALERT’ at the end of the report.
- The report containing the word ‘ALERT’ is to the stats template. This template is accessed by Radiology Administration twice daily for processing.
- Alerts are sent by email only to the referring clinician/General Practitioner and departmental secretaries.
- The email is sent as Urgent and a read receipt requested.
- Read receipts are printed and stored with all documentation in date order.
- All documentation is printed and stored securely within the department.
- An electronic copy on (W) drive is kept.
- All documentation is kept within the department for a minimum of 2 years.
- Other instructions given are followed if required, i.e. inform Patient Pathway Co-ordinators, copy of reports to other clinicians/General Practitioner or other Hospital, added to lists for discussion in MDM meetings.
- Other instructions, i.e. Clinician/Team have been contacted by phone by the reporting Radiologists/reporting Radiographer/Sonographer, it is necessary to incorporate this information in the body of the report to ensure an audit trail.

East Sussex Healthcare NHS Trust

Standard Operating Procedure For Videofluoroscopy

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Associated Documents:	Dysphagia Policy

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
1.0	September 2019	Anita Smith	New Document	
1.1	September 2019	Anita Smith	Updated protocol LOCSSIP compliance	MBSImP protocol included LOCSSIP information added
1.2	August 2020	Anita Smith	Updated information after Covid -19 pandemic	New prioritisation form Amended referral form with Covid-19 status Updated clinic checklist
1.3	Sept 2022	Anita Smith	Updated information after Covid -19 pandemic	Administration changes following SystmOne
V2	Oct 2022	Anita Smith	Format to new template	No changes to content

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

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This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

A bedside or clinical evaluation, regardless of how astute the observation, can only hypothesise about possible pharyngeal swallowing problems. Some components of the swallow cannot be accurately assessed on clinical evaluation alone. Only an instrumental examination such as videofluoroscopy or Fibre optic evaluation of swallowing (FEES) can give a true picture of pharyngeal dysphagia. Videofluoroscopy is also known as modified barium swallow (MBS), videofluorographic swallow study (VFSS) amongst other names. Videofluoroscopy has been defined as "the definitive test to identify aspiration and other abnormalities of swallowing" *(Haruka Tohara et al 2003),* although FEES is now more readily available.

According to Logemann (1998) Videofluoroscopy is the most frequently used procedure to assess the pharyngeal phase of the swallow. The VFS is a modification of the standard barium swallow X-ray examination. The aims of the videofluoroscopy are to examine the anatomy and physiology of the oral cavity and pharynx during eating and drinking a radiopaque substance and to identify those disorders in speed; in movement patterns to control the bolus and in aspiration which may occur. This will enable the Speech and Language Therapist to target therapy appropriately.

2. Purpose

The purpose of the Videofluoroscopy is to provide an instrumental assessment of the oral and pharyngeal stages of the swallow with reference to the oesophageal phase.

2.1 Rationale

The most important part of the videofluoroscopy is not to ascertain whether or not the patient is aspirating, but rather to determine why they are and if there is a way to prevent it. The use of compensatory strategies and manoeuvres as well as changing consistencies are widely used to manage aspiration.

There are many studies in the literature which support the use of videofluoroscopy as an instrumental assessment to manage dysphagia effectively. Logemann (1998) has demonstrated how postural techniques are effective in eliminating aspiration of fluids. Only under videofluoroscopy can speech and language therapists identify such dramatic changes which will enable them to manage their patients appropriately. It is clearly unacceptable to sustain patients on thickened fluids which reduce intake and may lead to dehydration, infections, increase in drug management and overall increased length of stay, if by a relatively simple, minimally invasive procedure this can be remedied. Thus improving patient's quality of life and assisting the return to normal eating and drinking as much as possible.

The videofluoroscopy may also be used to prevent aspiration. The cost to the health community of mismanaging dysphagia is great. It is well documented that timely referral and management of dysphagia can dramatically reduce complications such as infections and associated treatment, delayed rehabilitation or transfer and alternative or supplementary feeding. These complications directly relate to an increase in patients' length of stay *(Carter Young et al, 1990).* Odderson (1995) stated that patients with aspiration pneumonia stayed in hospital an average 5.5 days longer than other patients. Timely use of investigative procedures i.e. videofluoroscopy/ FEES to detect aspiration which can be managed effectively to reduce the incidence of aspiration pneumonia, will give a significant cost saving. Odderson demonstrated that through effective management the incidence of aspiration pneumonia due to dysphagia can be reduced from 6.7% to 0%.

VFS is a hypothesis-driven adjunct to a full case history and clinical assessment of the patient. Referral for VFS must be clinically justified in line with IR(ME)R legislation. The purposes of VFS are detailed by many authors and may include evaluation of:

- Oropharyngeal structures (including surgical reconstruction).
- Swallowing physiology, including lip and tongue function, velopharyngeal closure, base of tongue retraction, hyolaryngeal elevation, pharyngeal contraction, upper oesophageal sphincter function, and airway protection mechanisms.
- Known or suspected oropharyngeal dysphagia.
- Swallow function using a range of food and fluid consistencies.
- Presence of and response to silent or overt aspiration.
- Impact of therapeutic interventions on swallowing physiology, safety and efficiency.
- Timing of swallow events.
- Response to biofeedback.
- Effect of fatigue on swallowing physiology.
- The risk/benefit ratio of proceeding with trial food
- Future management options
- The clarification of diagnosis
- To determine the most appropriate treatment.

2.2 Principles

The VFS SOP should be used in conjunction with the Dysphagia policy and applied when it is deemed the appropriate procedure for assessing swallow function.

2.3 Scope

The VFS SOP is intended for use by any staff member considering referral for the procedure and any staff member involved in delivering the procedure. This will guide them to identify if VFS is the most appropriate procedure to assess swallow function, whether there are any contraindications and also enable them with the knowledge to discuss the process with patients prior to referral. For staff involved in the procedure, this SOP will provide a framework for training and competency development as well as detailed information on the roles involved and a step by step guide to the process of the procedure and management of any adverse incidents.

3. Definitions

Videofluoroscopy	The technique of viewing and recording real time X-ray investigation using a video camera. This enables the moving images to be reviewed at a later time, by individual frames or in slow motion.
Contrast materials / Barium	A chemical used in certain radiological studies to enhance visualization of anatomical structures.
Oro-Pharyngeal Dysphagia	Difficulty in either the oral or pharyngeal phases of swallowing, such as in chewing, initiating the swallow, or propelling the bolus through the pharynx to the oesophagus. It is caused by multiple neurologic, structural, or other medical conditions
Aspiration	When solids or liquids that should be swallowed into the stomach are instead breathed into the respiratory system **below** the level of the vocal folds
Penetration	When solids or liquids that should be swallowed into the stomach are instead breathed into the respiratory system **above** the level of the vocal folds
Swallowing strategies/ manoeuvres	Various methods of influencing the direction and/ or flow rate of the bolus to maximise swallow function
Texture modification	Changing the consistency of diet or fluids to maximise swallow function
PACS	Picture Archiving and Communication Systems. A system based on

	the universal (Digital Imaging and Communications in Medicine) standard, which uses a server to store and allow facile access to high-quality radiologic images
CRIS	The radiology information system for reporting procedures and booking patients for procedures.
MBSimP	Modified Barium Swallow Impairment Profile

4. Accountabilities and Responsibilities

The Society and College of Radiographers in conjunction with the Royal College of Radiologists have produced guidance for team-working in clinical imaging.

A multi-disciplinary team is required including the following professionals:

- A speech and language therapist
- A radiologist (who takes overall responsibility for the procedure but may train a radiographer to have an extended scope of practice to screen)
- A radiographer
- An X-ray nurse (should be available on site to operate suction equipment if required)

The team may also include:

- OT
- Physio
- Nurse
- Dietitian
- Interpreter
- Carer/family
- ENT consultant
- Neuro-physiologist

It is not normally necessary for these members of the team to be present at all videofluoroscopies.

The RCSLT considers that the designated radiologist retains overall clinical responsibility at all times for the conduct and governance of VFS clinics. If the radiologist is not present in the VFS clinic, arrangements must be in place to ensure ready access to appropriate medical, nursing and other support in the event of an adverse incident. In paediatric VFS clinics the presence of a radiologist is considered best practice for initial assessments. In ESHT the SLT led clinic (for patients over 16 years) has access to a radiologist whenever required to support during the assessment and/or to assist in the interpretation of the assessment.

4.1 Speech and Language Therapist

The SLT has a unique role in the assessment and management of oropharyngeal dysphagia and play a key part in delivering a VFS service in a multidisciplinary context. Their role includes:

- To have a clear rationale for performing the procedure including gathering information from referral source
- To establish any ICP requirements such as PPE and to ensure this is communicated to booking staff if known prior to appointment and radiology staff
- To feedback results of bedside evaluation to the radiologist/ radiographer prior to undertaking the investigation
- To facilitate decision making re contrast type; staff required; safety equipment
- To determine the usefulness of compensatory strategies and adaptive equipment
- In conjunction with the radiologist / radiographer recommend/organise chest physiotherapy
- Vetting referrals as required through CRIS

The SLT must be aware that the following limitations apply to their role:-

- It is not the role of the SLT to make a medical diagnosis or to diagnose structural deviations
- The SLT must not undertake the procedure in the absence of the responsible radiologist or radiographer with extended scope of practice. A consultant radiologist must be on site for advice at all times

The SLT will normally take responsibility for:

- ✓ Following MBSimP protocol or deviation from this with clinical rationale
- ✓ Administration/supervision of materials – consistency, size, taste, temperature
- ✓ Patient positioning in conjunction with OT/physio, radiologist/radiographer
- ✓ Determining view – lateral or anterior
- ✓ Evaluating and interpreting function in conjunction with radiologist
- ✓ Introducing and trialing compensatory techniques
- ✓ Decision making in conjunction with the radiologist as follows:
    - No further investigations are required
    - Continue with further investigations
    - Plan further investigations
    - Whether to cease investigation if significant aspiration occurs
    - Discussion with radiologist and making recommendations
    - The SLT must clearly document in medical notes (if appropriate) and in formal report the consistencies tried and the results of each consistency. It should be clearly documented whether there was evidence of aspiration and whether this was silent using the Rosenbek Severity Scale.

4.2 Radiologist

- To have overall clinical responsibility at all times for the conduct and governance of VFS clinics
- To ensure VFS abides by IR(ME)R guidelines
- To provide support to appropriately trained with extended scope of practice (as defined by IR(ME)R
- To be available for second opinions as required
- To be available for advice and reporting on oesophageal stage difficulties encountered
- To provide support and supervision where required for the Lead SLT including peer review.

4.3 Radiographer

- Ensure the equipment is in good working order
- Have delegated responsibility to ensure the clinic meets IR(ME)R regulations
- Assist in positioning the patients
- Operate the screening equipment
- To assist in decision making and anatomical interpretation within the clinic setting
- To assist in decision making re seeking advice from the radiologist
- To check the patient ID prior to commencing the investigation
- To take delegated responsibility from Radiologist as required

4.4 Radiology nurse

The role of the Radiology nurse is to be available if required in situations where the patient becomes unwell or requires suctioning.

5. Process

5.1 Equipment / Images and sound:

The VFS images must be recorded. Recording and viewing equipment should have the facility for still-advance to enable frame-by-frame analysis. If sound recording is available it may benefit the VFS. This is not currently available at ESHT.

Some evidence suggests that VFS screened at a pulse rate of less than 15 pulses per second may not detect all features of clinical interest. Dose reference levels (DRLs) must be balanced with benefit for the individual patient and must be recorded and audited as agreed with the medical physics expert. Best-quality images should be determined in discussion with the radiologist and/or radiographer. In ESHT the lead radiologist feels that 15 PPS is adequate. This will be reviewed as evidence becomes available.

Physical equipment parameters:

The x-ray equipment must comply with IR(ME)R. It must be able to accommodate a range of patients' own seating and positioning requirements. This is crucial for obtaining optimum VFS images. Seats may need to be radiolucent to obtain AP imaging and consideration must be given to their height and position in relation to the x-ray machinery. If required support from the physiotherapy team may be sought for specialist seating requirements.

Contrast materials:

In patients at high risk of aspiration the initial test swallow should be of small volume. Water soluble contrast materials, such as non-ionic isotonic agents e.g. Omnipaque or Gastromiro, may be the preferred option. *Use of Gastrograffin is contra-indicated due to its hypertonic properties and carries an attendant risk of pulmonary oedema if aspirated.*

Consideration must be given as to how the contrast medium will affect the taste and viscosity of any food or fluid that it is added to. Standardised barium recipes have been created to meet IDDSI and MBSImP requirements. Departing from manufacturers' user instructions may invalidate licence use.

Other essential equipment:

- Utensils for mixing and presenting consistencies e.g. whisk, teaspoons, desert spoons, dysphagia cup, plastic cups, spouted beakers.
- Tissues and kidney bowls
- Suction equipment
- Hoist / frames
- Protective clothing e.g. apron and thyroid protector
- Resuscitation equipment
- Pregnancy tests

5.2 Referrals

Patients referred should always have a bedside clinical assessment by a competent SLT prior to being considered for a videofluoroscopy. The referring SLT will fill in a standard videofluoroscopy referral form (Appendix A). Since Covid – 19 the referring therapist will not routinely attend the appointment. In specific circumstances this may be allowed if deemed clinically appropriate and necessary. This should be discussed in advance and pertinent information shared. The consultant SLT, with appropriate level IR(ME)R training, will sign radiology request forms for outpatients known to ESHT SLT department. This has been decided locally following consultation with local GPs. A radiology form signed by a member of the medical team must accompany the referral form for all inpatients; both should be sent to the SLT administrator who will liaise with the lead SLT responsible for co-ordinating the clinic.

When referrals are made directly to Radiology, they will send the form to SLT department at Conquest. The lead SLT will then ensure the above process is followed, ensuring that patients receive a clinical evaluation prior to booking VFS, coordinated by the SLT administrator if required.

When referrals are made by an ESHT consultant directly to SLT for videofluoroscopy, a clinical evaluation will be required prior to booking a videofluoroscopy to ensure that the procedure is appropriate.

All referrals will be triaged in order to ascertain clinical priority where a waiting list is in effect (Appendix B). The triage system has been taken from "Videofluoroscopy in the context of COVID-19: interim guidance for speech and language therapists and service managers" July 2020, a RCSLT and ScOR joint publication Videofluoroscopy-in-the-context-of-COVID19FINAL010720.pdf (rcslt.org)

Outpatient referrals for patients under the care of external trusts will be received and triaged as above, however, due to IR(ME)R requirements regarding the justification for exposure to radiation, the X-Ray request will need to be completed by the patients GP or consultant.

5.3 Patient and carer information
An information leaflet is available on the trust internet site and a copy is sent with all outpatient appointments. The information leaflet includes the nature, risks, purpose and possible outcomes of VFS LINK

5.4 Consent
The **referring SLT** must discuss the referral with the patient, parents or carer and gain their consent in accordance with local guidelines. The client / carer must agree to the decision for radiological imaging for a swallowing assessment. Consent may be obtained either verbally or written, in either circumstance this should be documented within the SLT notes. Certain individuals may be subject to legal requirements; in the UK these are defined by The Mental Capacity Act 200520 21

Consent to the use and storage of the VFS images may be required in addition to consent to undergo the VFS. It is good practice to document consent.

5.5 The booking process
The SLT administrator will book a date for the procedure with the referring therapist. The SLT administrator will liaise with X-ray booking and send a copy of the SystmOne clinic list along with both the SLT referral and Xray referral form, if possible, one week prior to the appointment date. The SLT administrator will send out appointment letters and information leaflet.

The radiology office will ensure the patient details are recorded and available for the radiographer to add to the work list. Where porters are required for in-patients the radiology office will book these.

On arrival patients will report to the radiology reception and be directed to the waiting area. The SLT / Radiographer will greet the patient and collect them at the appropriate time.

5.6 Frequency
The clinic will be held either at the radiology department at EDGH or in the radiology department, level 3 at Conquest hospital. All patients will report to the radiology reception on arrival.

- Standard practice is one clinic per week, per site with 2 appointment slots.
- Ad-hoc sessions may be booked in liaison with radiology for inpatients if required.
- At least one SLT, a radiographer and a feeder will be needed to ensure the procedure runs smoothly.
- A radiologist or a radiographer with an extended scope of practice trained to competently screen will be available.

5.7 Duration
The assessment length varies depending upon complexity of patient, tolerance of procedure and the number of consistencies trialled. On average most assessments are completed within 20 minutes, however, with some client groups this may be longer particularly if compliance is an issue e.g. clients with a learning disability. After the assessment some clients may like to have direct feedback and view the images of their assessment. Since Covid-19 this is discouraged unless clinically necessary and time available to do so. ESHT SLTs referring into VFS have been trained to be able to go through the images with patients and explain their report at the patients next appointment if requested.

5.8 Safety
VFS is carried out in a designated radiology area with appropriate radiation protection equipment in compliance with the ionising regulations. At all times VFS is subject to the Ionising Radiation (Medical Exposure) Regulations 2000 (and subsequent amendments of 2006 and 2011). SLTs must have approval, including IR(ME)R entitlement, from their employer to undertake VFS. SLTs must adhere to these regulations.

The SLT should be instructed in and be familiar with radiological safety procedures such as:-

- Protective clothing (e.g. aprons, gloves, badges, collars, lead glasses etc.)
- Patient protection (where appropriate)
- Preparation of materials (e.g. strength of barium, which contrasts to use, etc.)
- Disposal of materials
- Universal infection control (local policies apply)
- IR(ME)R guidelines on radiation protection
- Basic life support

There must be immediate access to emergency trained personnel and equipment e.g. suction and resuscitation team, in the event of possible adverse events including:

- Reaction to aspiration (routine access to chest physiotherapy should be available in the event of a significant event).
- Deterioration in the condition of an acutely unwell patient.
- Detection of previously unsuspected tracheo-oesophageal fistula.

SLTs involved in the conduct of VFS must be aware of health and safety requirements and must adhere to local policies and procedures.

5.9 Storage Requirements
Storage of images is subject to legal requirements. Recorded material is part of the patient's record and, therefore, should be kept in accordance with Department of Health National Health Service Retention and Disposal Schedule. Radiological images are stored on PACS. Written reports are Created on CRIS and accessed via PACS or via E-Searcher. VFS reports kept in clients notes will be kept according to the patient records policy. In adults client records are required to be kept archived for 7 years. Dose-related incidents must be reported to the IR(ME)R Inspector. All clinical incidents or adverse events related to the VFS procedure must be reported as a Datix incident.

5.10 Step by Step Operating Procedure
VFS should always follow as systematic and structured a framework as possible to allow for comparison within and between patients. In ESHT the Modified Barium Swallow Impairment Profile (MBSImP), a standardized approach to instruction, assessment, and reporting of physiologic swallowing impairment based on observations obtained from the MBS study, is used. VFS is a dynamic assessment and should be flexible to allow changes to protocol or framework dependent on the patient's presentation or their response to the evaluation. VFS typically uses assessment in the lateral and anteroposterior (AP) planes. Positioning, manoeuvres and texture modifications may be trialled during the VFS to determine their impact on swallowing efficiency and safety.

Step 1	**Potential Risks if step 1 not done or done incorrectly:**
Prepare contrast materials as per MBSImP protocol. It may be necessary to prepare additions to these based on patients' needs and required outcome.	Delay in the procedure and patient fatigue may result in suboptimal assessment.
Step 2	**Potential Risks if step 2 not done or done incorrectly:**
Use checklist to ensure that all necessary checks and equipment are available prior to the clinic commencing. The VFS is viewed on a monitor/screen and recorded. Image recording enables review of the evaluation and sharing with the patient, carer and members of the multidisciplinary team (MDT). Stored images (on PACS) allow direct comparison between repeat evaluations and form part of the patient record.	Delay in the procedure and patient fatigue may result in suboptimal assessment. Failure to record the assessment will result in an inability to analyse and report on the assessment. It will also result in no images being available for direct comparison at a later date.
Step 1- Check the patient details	**Potential Risks if step 1 not done or done incorrectly**
Ensure the patient is the one requiring the procedure by checking name label, medical notes, and / or patient providing confirmation. Complete dynamic Covid – 19 risk assessment to ascertain level of PPE required.	Procedure could be carried out on incorrect patient. Risk of transmission of virus if not identified
Step 3- Gain consent	**Potential Risks if step 2 not done or done incorrectly:**
Prior to VFS being carried out, the SLT must explain the procedure and provide written information where appropriate to the patient and/or their carer. This is usually in the form of an information leaflet sent at the time of the appointment. VFS is an invasive procedure that carries some risks and hence consent should be obtained prior to the examination. Where the patient is unable to give or withhold consent e.g. dementia, it may still be appropriate to proceed with treatment if it is considered clinically necessary and in the best interest of the individual. Such decisions are governed by legislation and should be taken under advice and within the context of a multidisciplinary team. Aphasia friendly, and alternative language formats should also be available. Consent for the procedure can only be obtained by a competent SLT in VFS. Consent should be documented in the patient's records.	Patient may be anxious leading to suboptimal assessment. Patient may not fully understand the procedure and be unable to provide informed consent, and compliance may be poor.
Step 4- Positioning	**Potential Risks if step 3 not done or done incorrectly:**
Position the patient within the x-ray equipment screening area. The fluoroscopy tube should be positioned by the Radiographer to ensure the following structures are in view: • The lips anteriorly • The soft palate superiorly • The posteriorly pharyngeal wall • The seventh cervical vertebra inferiorly If all of the above cannot be viewed simultaneously it is important to look at the pharyngeal stage first and then	Inability to visualise structures may result in suboptimal imaging and may limit recommendations.

go back to the oral stage as necessary. Changing the magnification may assist in better capture of images.	
Step 5- Assessment	**Potential Risks if step 4 not done or done incorrectly:**
While positioned the patient will be given various consistencies to swallow as part of the MBSImP protocol. The protocol order will be followed by the SLT. The SLT may decide to change the order in which these materials are given from information given on the referral form and from discussions with the referring SLT and/ or patient / carer. If the patient has difficulty participating in the protocol the feeder may assist the patient. The SLT will analyse the swallow study using the MBSImP protocol assessment. These observations will form the basis of how the assessment progresses. Various techniques and strategies may be tested depending upon the presenting swallow and the co-operation of the patient.	A suboptimal assessment where appropriate textures or strategies are not assessed will limit recommendations.
Step 6- Stopping assessment	**Potential Risks if step 5 not done or done incorrectly:**
Screening should cease if: • Large amounts of aspiration occur; the patient should then be seen by the radiology nurse and physiotherapist. • The patient becomes distressed. • Any other factors which the SLT and radiologist / radiographer feel may affect the safety or wellbeing of the client.	Gross/ uncontrolled aspiration will adversely affect the client's health.
Step 6- Patient feedback	**Potential Risks if step 6 not done or done incorrectly:**
Immediately following the VFS, the SLT will discuss the initial findings and recommendations with the patient. Detailed review and discussion regarding management is for the referring SLT to discuss with the patient/ carer. The SLT will document clearly the initial findings within the medical notes for all inpatients.	Some patients / carers may benefit from this feedback which will improve adherence. Failure to follow recommendations may result in inappropriate textures or not using strategies / manoeuvres which may adversely affect the patient's health.
Step 7- Documentation	**Potential Risks if step 7 not done or done incorrectly:**
Following the clinic the SLT will review the recording of the assessment completing the MBSImP assessment template (Appendix B). The SLT will do a report of the assessment detailing the observations, providing a summary and recommendations. Techniques or strategies which are to be used to reduce risks will be documented along with any advice for therapy. The Rosenbek aspiration severity scale will also be used (Appendix C).	Failure to analyse appropriately will lead to inappropriate recommendations being made which may adversely affect the client's health. Failure to communicate recommendations may result in inappropriate textures being given which may adversely affect the client's health.
Step 8- Dosage rates	**Potential Risks if step 7 not done or done incorrectly:**
The Radiographer will record dosage rates on the PACS system in line with IR(ME)R legislation. They will also record attending clinician for reporting purposes.	Non-compliance with IR(ME)R legislation. SLT will not be able to report on to the CRIS system.

5.11 Emergency Procedures/Continuity Plan

Anticipated disruption	Impact	Outcome
Screening equipment is not available	Unable to screen assessment	Assessment to be rescheduled
Radiographer unavailable	Unable to screen assessment	Assessment to be rescheduled
Radiologist unavailable on site	Unable to obtain second opinions if required	Second opinions to be sought at earliest opportunity. Seek advice from lead SLT ay earliest opportunity.
SLT unavailable	Unable to conduct assessment	Assessment to be rescheduled
Client becomes unwell or grossly aspirates	Not appropriate to continue with assessment	Cease assessment inform radiology nurse and physiotherapist is required. If patient is unwell consideration must be made of transfer to A&E.
Client does not attend appointment due to difficulties with hospital transport	Unable to conduct assessment	Assessment to be rescheduled

5.12 Waste Disposal

Contrast consistencies not used during the assessment will be disposed of in the non-clinical bins within the X-Ray room or the sluice. Empty bottles of Gastromiro will be dispensed of in a glass bottle / sharps container. Empty and partly used bottles of EZ-HD will be disposed of in the bin.

6. Special Considerations

6.1 Pregnancy

Videofluoroscopy is a low dose procedure and as such comes under a 28 day rule for the purposes of last menstrual period (LMP date). This means that to comply with the IR(ME)R regulations IR(ME)R 17, a patient must have had a period within the last 28 days. Where patients are between the ages of 12-60 years, they will be asked, at the point of booking, when their last period was (LMP) so that the procedure can be booked within the correct timescale. It is, however, as per IR(ME)R the responsibility of the operator who will irradiate the patient to check on the patient's pregnancy status (LMP) immediately before undertaking the examination; therefore this will be checked by the radiographer on the day of the procedure as well.

6.2 Infection risk assessment

When referring for and conducting a Videofluoroscopy if is important to consider the risk of transmission of infectious diseases including COVID-19 during the procedure and the urgency of the evaluation. If the procedure is not urgent any patients with an active infection which is expected to resolve quickly should be postponed and rebooked. If the procedure is urgent then local infection, control and prevention policies should be followed.

In relation to Covid-19, a dynamic risk assessment should be carried out and ESHT guidance followed for appropriate management and PPE use. 02168_P.pdf (esht.nhs.uk)

7. Evidence Base/References

- Haruko Tohara, DDS; Eiichi Saitoh, MD; Keith A Mayes, DDS, MS; Keith Kuhlemeier, PhD and Jeffrey B Palmer, MD. Dysphagia 18:126-134 (2003)
- The Source for Dysphagia (2000) Linguisystems Inc
- Logemann, J (1998) The Evaluation and Treatment of Swallowing Disorders. Pro-ed

- Carter Young, E; Durrant Jones, L. (1990) Developing a Dysphagia Programme in an Acute Care Hospital: A Needs Assessment
- Odderson, R; Keaton, J C; McKenna, B S (1995) Swallow Management in Patients on an Acute Stroke Pathway: Quality is Cost-effective Arch.Phys.Meds.Rehabil. Vol 76 p1130-1133
- RCSLT Guidelines for Radiological Imaging 1 Dysphagia (1999)
- RCSLT Videofluroscopic evaluation of oropharyngeal swallowing function (VFS) position paper 2013
- Society of Radiographers. Team working in clinical imaging. 2012. https://www.sor.org/learning/document-library/team-working-clinical-imaging
- Department of Health. The Ionising Radiation (Medical Exposure) (Amendment) Regulations. 2011. http://www.legislation.gov.uk/uksi/2011/1567/contents/made
- Mental Capacity Act 2005(c.9), 2005.
- Rosenbek JC, et al. A penetration-aspiration scale. Dysphagia 1996; 11:2,93-98.
- Royal College of Speech and Language Therapists. Communicating Quality 3. London, 2006.
- Health Professionals Council. Managing Fitness to Practice: 2006.
- National Dysphagia Steering Group NDCS. Inter Professional Dysphagia Framework
- Department of Health. The Ionising Radiation (Medical Exposure) (Amendment) Regulations. 2011

  Videofluoroscopy in the context of COVID-19: interim guidance for speech and language therapists and service managers July 2020 RCSLT ScOR

8. Competencies and Training Requirements

8.1 Competencies

Videofluoroscopy interpretation requires the skills of a competent speech and language therapist (SLT). Professional guidelines contained in the Royal College of Speech and Language Therapists *"Guidelines for Radiological Imaging 1. Dysphagia" (1999)* state that knowledge and skills are required of the SLT in order for them to perform this procedure.

The following structure is in place to ensure a safe and professionally governed VFS service:

- Lead SLT in VFS- Consultant SLT
- Clinical specialist in VFS.
- Trainee specialist in VFS.

All SLTs working in the area of dysphagia must have background knowledge of VFS studies to inform their clinical assessment and management. Service managers must ensure that adequate resources are in place to monitor and support the maintenance of competencies in VFS for appropriate grades of staff.

The speech and language therapy services at ESHT have adopted the RCSLT recommended competency programme as a part of the professional governance structure. An individual SLT's level of competence should be maintained and reviewed at annual appraisal. Competencies are signed off by the lead SLT.

SLTs responsible for conducting VFS independently will have MBSimP certification.

SLTs undertaking VFS do participate in peer-review activities in order to maintain, develop and share knowledge and expertise with colleagues within the service and throughout local/regional networks. SLTs are also encouraged to participate in national Clinical Excellence Networks (CENs) with a specific focus on VFS.

SLTs undertaking the lead role in the SLT led VFS will be Band 8 and above and will have been identified as Lead SLT for VFS in ESHT. As a minimum, the Level 4 VFS SLT will be recognised as an extended scope practitioner.

8.2 Medico-legal implications

The SLT must ensure that approval has been given by the employing authority, with recognition of competence to perform the procedure written into job descriptions, adherence to local health and safety policy and adequate professional liability insurance cover either through the Trust, the Professional Body or Professional Union. The RCSLT provides an insurance policy that indemnifies all its practising members in the UK, Channel Islands and the Isle of Man where their actions meet the professional and clinical practice expectations laid out in RCSLT guidance. This covers proven liability arising from alleged professional negligence, breach of professional conduct and damage to property.

The SLT must abide by HCPC professional code of practice and only perform duties for which they are appropriately trained and experienced.

8.3 Location of training records

It is the professional responsibility of the SLT to maintain accurate and timely records of CPD. A record of external training events will be held on the health roster system (ESR) and in the member of staff's personal file. Supervision records will also record training events attended. Record of signed competencies will be held by the therapist and recorded as completed in supervision records.

9. Monitoring Arrangements

VFS services should be audited on a regular basis within an IR(ME)R and local clinical governance framework. SLTs specialising in VFS are encouraged to pursue the development of an evidence base in VFS.

This SOP has been discussed with NATSSIPS and LOCSSIPS lead and SOP complaint with requirements

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Competency framework	Anita Smith	Literature search, updated RCSLT position papers	2 years	VFS/ FEES Peer review	VFS/ FEES Peer review	VFS/ FEES Peer review
Evidence base	Anita Smith	Literature search, updated RCSLT position papers	2 years	VFS/ FEES Peer review	VFS/ FEES Peer review	VFS/ FEES Peer review
Adverse incidents	Anita Smith	NHSI updated RCSLT position papers	2 years	VFS/ FEES Peer review	VFS/ FEES Peer review	VFS/ FEES Peer review

10. Equality and Human Rights Statement

Specific guidance around empowering and supporting people to make decisions for themselves or considering the best interests of an individual in relation to dysphagia are provided within this SOP. Broader guidance on the Mental Capacity Act and Best Interests Decision Making can be found in The Trust's Mental Capacity Act Policy.

Equality Impact Assessment Form

1. Cover Sheet

Please refer to the accompanying guidance document when completing this form.

Strategy, policy or service name	Standard Operating Procedure Videofluoroscopy
Date of completion	Oct 2022
Name of the person(s) completing this form	Anita Smith
Brief description of the aims of the Strategy/ Policy/ Service	Procedural document for the use of Videofluoroscopy in ESHT
Which Department owns the strategy/ policy/ function	Speech and Language Therapy
Version number	V2
Pre Equality analysis considerations	All ESHT staff who refer to or work with SLTs conducting Videofluoroscopy
Who will be affected by this work? **E.g. staff, patients, service users, partner organisations etc.**	All ESHT staff who refer to or complete Videofluoroscopy and patients
Review date	Oct 2025
If negative impacts have been identified that you need support mitigating please escalate to the appropriate leader in your directorate and contact the EDHR team for further discussion.	N/A
Have you sent the final copy to the EDHR Team?	Yes

2. EIA Analysis

<table>
<tr><td></td><td>☺ 😐 ☹</td><td>Evidence:</td></tr>
<tr><td>Will the proposal impact the safety of patients', carers' visitors and/or staff?

Safe: Protected from abuse and avoidable harm.</td><td>Choose: Positive</td><td>This SOP is designed to improve patient safety by setting out the processes and remedial action required in the event of an adverse incident. All guidance contained in this SOP is drawn from evidenced based literature and fully referenced.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
<tr><td>Gender reassignment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr>
<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
</table>

None, this SOP applies equality to all population groups and is unlikely to result in different outcomes between those who share a protected characteristic and those that don't share a protected characteristic, or experience other challenges which may lead to a difference in health outcomes.</td></tr>
</table>

<table>
<tr><td>Is the proposal of change effective?

Effective: Peoples care, treatment and support achieves good outcomes, That staff are enabled to work in an inclusive environment. That the changes are made on the best available evidence for all involved with due regards across all 9 protected Characteristics</td><td>Choose:
Positive
Neutral
Negative</td><td>This SOP is designed to achieve good outcomes for. All guidance contained in this SOP is drawn from evidenced based literature and fully referenced. This SOP applies equality to all population groups and is unlikely to result in different outcomes between those who share a protected characteristic and those that don’t share a protected characteristic.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
</table>

None, this SOP applies equality to all population groups and is unlikely to result in different outcomes between those who share a protected characteristic and those that don’t share a protected characteristic, or experience other challenges which may lead to a difference in health outcomes.</td></tr>
<tr><td>What impact will this have on people receiving a positive experience of care?</td><td>Choose:
Positive
Neutral
Negative</td><td>This SOP is designed to improve patient experience of care by setting out the processes for the procedure including those which make the procedure more acceptable / comfortable for patients. All guidance contained in this SOP is drawn from evidenced based literature and fully referenced.</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr>
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</table>

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</table>

<table>
<tr><td>Does the proposal impact on the responsiveness to people's needs?</td><td>Choose:
Positive
Neutral
Negative</td><td></td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><th>Race</th><th>Gender</th><th>Sexual orientation</th><th>Age</th><th>Disability & carers</th></tr>
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<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>What considerations have been put in place to consider the organisations approach on improving equality and diversity in the workforce and leadership?</td><td>Choose:
Positive
Neutral
Negative</td><td>We expect that all staff groups be equally enabled to develop the skills and competence required to utilise this SOP</td></tr>
<tr><td>Equality Consideration
Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td><td></td><td>
<table>
<tr><th>Race</th><th>Gender</th><th>Sexual orientation</th><th>Age</th><th>Disability & carers</th></tr>
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<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
</table>

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</td></tr>
<tr><td colspan="3">Access
Could the proposal impact positively or negatively on any of the following:</td></tr>
<tr><td>• Patient Choice</td><td>Choose:
Neutral</td><td>The patients are provided information on the procedure via the patient leaflet which identifies alternative procedures available</td></tr>
<tr><td>• Access</td><td>Choose:
Neutral</td><td>None</td></tr>
<tr><td>• Integration</td><td>Choose:
Neutral</td><td>None</td></tr>
</table>

Equality Consideration *Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)*		<table><tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>Gender reassignment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr></table> VFS clinics run from both acute hospital sites. In respect of the operating procedure specifically we do not anticipate any equality considerations. However, we recognise that there may be equality considerations regarding service locations but these are beyond the scope of this review of the operating procedure itself.
Engagement and Involvement How have you made sure that the views of stakeholders, including people likely to face exclusion have been influential in the development of the strategy / policy / service:	Choose: Neutral	Range of clinical staff have been engaged in the development of this SOP identified within the SOP. Wider stakeholder engagement was not undertaken due to the fact that this is a very specific clinical procedure. The evidence on which the SOP is developed will have included acceptability for this kind of intervention to patients.
Equality Consideration Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)		<table><tr><td>Race</td><td>Gender</td><td>Sexual orientation</td><td>Age</td><td>Disability & carers</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>Gender reassignment</td><td>Marriage & Civil Partnership</td><td>Religion and faith</td><td>Maternity & Pregnancy</td><td>Social economic</td></tr><tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr></table> N/A As above
Duty of Equality Use the space below to provide more detail where you have identified how your proposal of change will impact.	Choose: Neutral	
Characteristic	**Rating** ☺ ☹ 😐	**Description**
Race	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.
Age	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.

Disability and Carers	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category. If a patient is in a wide wheelchair and cannot transfer they will be required to have the procedure at EDGH as the equipment is not restricted to seating width. The same procedure and protocol is followed.
Religion or belief	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.
Sex	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.
Sexual orientation	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.
Gender re-assignment	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.
Pregnancy and maternity	Choose: Negative	Although this is a low risk procedure, it is not advisable for pregnant patients. A individual risk / benefit assessment would be required if instrumental assessment was required and no other options were appropriate
Marriage and civil partnership	Choose: Neutral	As described above we do not anticipate the procedure described in this SOP to impact on this protected characteristic group category differently to those who don't share the same characteristics within this category.

Human Rights

Please look at the table below to consider if your proposal of change may potentially conflict with the Human Right Act 1998

Articles		Y/N
A2	Right to life	**N**
A3	Prohibition of torture, inhuman or degrading treatment	**N**
A4	Prohibition of slavery and forced labour	**N**
A5	Right to liberty and security	**N**
A6 &7	Rights to a fair trial; and no punishment without law	**N**
A8	Right to respect for private and family life, home and correspondence	**N**
A9	Freedom of thought, conscience and religion	**N**
A10	Freedom of expression	**N**
A11	Freedom of assembly and association	**N**
A12	Right to marry and found a family	**N**
Protocols		
P1.A1	Protection of property	**N**
P1.A2	Right to education	**N**
P1.A3	Right to free elections	**N**

APPENDIX B – Referral Form

East Sussex Healthcare NHS Trust

East Sussex Speech and Language Therapy Service for Adults

Videofluoroscopy/ FEES Referral

Name: Address:	Hospital Number: I/P or O/P Ward:	NHS Number:
D.O.B:	Time since onset of Dysphagia:	
If female client is still menstruating, VF should be within 28 days of period commencing. * Please tick to show whether this needs to be taken into account or not.	Appointment date will depend on cycle ☐ Not applicable ☐ **If a pt lacks capacity we will need a signed form from the NOK stating to the best of their knowledge the patient is not pregnant and sign and print their name with the relationship to the patient and the date.**	
Referring Consultant/GP:	**Infection information (Covid, MRSA etc.):**	
Primary Diagnosis (if known):		
Known Allergies:		
Ambulance required: No **** if yes, please ensure Radiology form states type of ambulance***		

Transfer information ****please provide as much information as possible.***	Independent	With one	With two
	Special technique	Special equipment	

Summary of SALT bedside assessment:	
Current SALT recommendations:	What do you hope to find out?
Can client follow instructions?	Has the patient had any recent chest infections?
Has the patient lost weight recently / how much?	Please note any gastroenterology / ENT involvement (e.g. OGD, Barium swallow, FNE)

Has the patient a history of:

Base of skull fractures	Yes / No
Hereditary haemorrhagic telangiectasia *(Bleeding disorders)*	Yes / No
Life threatening nose bleeds (Epistaxis) *within last 6 weeks*	Yes / No
Nasopharyngeal stenosis	Yes / No
Craniofacial anomalies	Yes / No
Sino-nasal and anterior skull base tumours/surgery	Yes / No
Trauma to nasal cavity secondary to surgery or injury within the last six weeks	Yes / No

Please note: *Due to restricted seating arrangements in the clinic your patients must be able to sit in a standard chair or their own wheelchair and therefore have reasonable sitting balance. We are not able to accommodate beds in the FEES clinic. You must also be able to attend with your client for a VFS. Please consider this before referring to the clinic.*

Preferred investigation *(please tick)* Videofluoroscopy EDGH

Videofluoroscopy Conquest ☐

FEES EDGH ☐

FEES Conquest ☐

Signed Date

Please print name Contact

Return this form to SALT Dept, Level 1, Conquest Hospital, The Ridge, St

*** Client or SLT should contact the department at Conquest to advise of first day of period so that appointment can be made ASAP. All paper work should be done in advance by referring therapist**

Referring SLT use only: P1 ☐ **P2** ☐ **P3** ☐ **P4** ☐ **P5** ☐
(RCR Priority)

APPENDIX C: Triage system

Priority	Definition/description	Videofluoroscopy
P1	High probability of potentially life threatening condition	Aspiration risk unmanaged or physiology unknown with known respiratory and/or nutrition compromise
P2	High probability of condition potentially causing significant long term harm	Aspiration risk unmanaged and/or physiology unknown with no known respiratory or nutrition compromise
P3	Possibility of potentially life threatening condition	Aspiration risk managed or physiology known, change anticipated
P4	Possibility of condition potentially causing significant long term harm	Aspiration risk managed or physiology known, change not anticipated
P5	Unlikely to be life threatening or cause significant long-term harm	During COVID-19, bedside assessment/management of swallowing

Adapted from the table to support service prioritisation in the RCR's COVID-19 interim guidance on restarting elective work

APPENDIX D: Scoring form

MBSImP Scoring Sheet

Patient Name								Hospital Number														
Clinician								Date														
	LATERAL VIEW													***A-P VIEW***								
COMPONENT	**L0 (Thin)**				**L2 (S1)**			**L3 (S2)**	**L4 (S3)**	**Solid**			**L2 (S1)**	**L4 (S3)**	**Overall Impression**		**Strategies / Extra Trials****				
	5 ml**	5 ml	Sip	Sqtl	5 ml	Sip	Sqtl	5 ml	5 ml	L5**	L6**	Biscuit	5 ml	5 ml							
1. Lip Closure* (0 - 4)																					
2. Tongue Control during Bolus Hold (0 - 3)																					
3. Bolus Prep/Mastication (0 - 3)																					
4. Bolus Transport/Lingual Motion (0 - 4)																					
5. Oral Residue* (0 - 4)																					
6. Initiation of Pharyngeal Swallow (0 - 4)															+						
7. Soft Palate Elevation (0 - 4)																*Tot Oral*					
8. Laryngeal Elevation (0-3)																					
9. Anterior Hyoid Movement (0 - 2)																					
10. Epiglottic Movement (0-2)																					
11. Laryngeal Vestibular Closure (0 - 2)																					
12. Pharyngeal Stripping Wave (0-2)																					
13. Pharyngeal Contraction (0 - 3)																					
14. PES Opening (0 - 3)																					
15. Tongue Base Retraction* (0 - 4)																					
16. Pharyngeal Residue* (0 - 4)															+						
17. Esophageal Clearance Upright Position (0 - 4)																*Tot Phgl*					
Penetration-Aspiration Scale (1 - 8)															*Total Esophageal*						
Spontaneous Cough / Throat Clear?																					
Feeling of Sticking?																					
Comments																					

**For these components a score of 1 is not counted in the Total Oral or Pharyngeal Scores. **Not counted in the Overall Impression Score.*

Appendix E: Rosenbek Aspiration Severity Scale

Rosenbek 8-Point Penetration-Aspiration Scale

1 – Material does not enter airway

Penetration

2 – Material enters the airway, remains above the vocal folds, and is ejected from the airway (no residue).

3 – Material enters the airwy, remains above the vocal folds, and is not ejected from the airway (visible residue remains).

4 – Material enters the airway, contacts the vocal folds, and is ejected from the airway (no residue).

5 - Material enters the airway, contacts the vocal folds, and is not ejected from the airway (visible residue remains).

Aspiration

6 – Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway (no subglottic residue visible).

7 - Material enters the airway, passes below the vocal folds, and is not ejected into the larynx or out of the airway (visible subglottic residue despite patient response).

8 – Material enters the airway, passes below the vocal folds, and no effort is made to eject (visible subglottic residue, no patient response).

Rosenbek, J., Robbins, J., Roecker, E., Coyle, J., & Woods, J. (1996) A penetration-aspiration scale. Dysphagia, 11-2; 93-98.

East Sussex Healthcare NHS Trust

Standard Operational Procedure Booking process for Fetal Anomaly scans

Document ID:	2023
Version:	V1.0
Ratified by:	Radiology, K Howe-Bush
Date ratified:	04th March 2020
Name of author and title:	Kerry Howe-Bush, Ultrasound Manager; [redacted], Radiology Divisional Administrator; [redacted], Radiology office Manager, [redacted], Obstetric Ultrasound Appointments Clerk
Date originally written:	10th January 2020
Date current version was completed:	03rd March 2020
Name of responsible committee/individual:	K Howe-Bush
Date issued:	05th March 2020
Review date:	March 2021
Target audience:	Obstetric appointments clerks, Sonographers
CQC Fundamental Standard:	Safety, Good Governance
Compliance with any other external requirements (e.g. Information Governance):	PHE
Associated Documents:	Information Governance Policy First Trimester Ultrasound Guidelines Second Trimester Guidelines Chaperone Procedure Suspected or identified fetal abnormality Multiple Pregnancy Deprivation of Liberty Safeguards Mental Capacity Act Patient Documentation and Record Keeping Policy and Procedure for Service User Information Policy for Identification of Patients Safeguarding Adults at risk Recording, Investigation and Management of Complaints Equality, Diversity and Human Rights Policy Risk Management Incident Management and Reporting Duty of Candour (Being Open) Policy

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1.0	29/01/2020	Kerry Howe-Bush et al	New Document	-

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Kerry Howe-Bush	Ultrasound Manager	29/01/2020
[redacted]	Divisional Administrator	29/01/2020
[redacted]	Appointments Manager	29/01/2020

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

2. Purpose

Standardisation of process to book anomaly scan for obstetric patients.

2.1. Rationale

Prevention of missed screening opportunities for obstetric patients and compliance with Public Health England guidelines.

2.2. Scope:

This procedure applies to all Radiology Administrative staff, Sonographers and obstetricians working in the Obstetric Ultrasound department and includes permanent, temporary and bank staff.

3. Definitions

CQ – Conquest Hospital
CRIS – Computerised Radiology Information System
DNA – Did not attend
EDGH – Eastbourne District General Hospital
FASP – Fetal Anomaly Screening Programme (Public Health England).
PHE – Public Health England
IR(ME)R – Ionising Radiation (Medical Exposure) Regulations
PACS – Picture Archiving Computer System
QA – Quality Assurance
EDD – Estimated Delivery Date
CMW – Community Midwives

4. Computer Programmes

CRIS and Viewpoint software.

5. Accountabilities and Responsibilities

Title or Group	Duties/Responsibilities
Sonographer Trainee Sonographers Obstetricians	• Justification of requests using obstetric protocols • Confirmation of patient identity and obtain consent prior to booking of examination • Advise type and urgency of examination in accordance with local protocol • Obtain high quality images whilst maintaining a high standard of patient care • Ensure procedures for safety of staff and patients are followed • Ensure local rules are adhered to

	• Ensure dignity of patients are maintained at all times
Radiology Administrative Staff	• Book Anomaly scan as per guidelines provided by Ultrasound Manager and/or Sonographer according to FASP standards • Accurately communicate appointment information to patients. • Ensure information Governance policy is followed • Follow standard procedure for attending and booking examinations using CRIS system • Ensure procedures for safety of staff and patients are followed • Ensure local rules are adhered to • Ensure dignity of patients are maintained at all times

6. Procedures and Actions to Follow

6.1. Overview of process for arranging Anomaly scans

- When the woman arrives for her first trimester scan, attend on CRIS system and place the anomaly scan on the request list (see 6.6)
- Once the Sonographer has completed the scan, they will escort the woman to the desk and provide a copy of the report showing the future scan(s) required which are to be scanned into CRIS as evidence of the request
- If a repeat first trimester scan is required book the scan as per the written instructions provided by the sonographer. Amend the Anomaly scan to "waiting/planned" ready to book when the repeat first trimester scan is completed. (See 6.7)
- If an anomaly scan is required, use the obstetric gestation calculator wheel to calculate scan window (18+0 weeks to 20+6 weeks gestation) from the EDD (See 6.5). If there are capacity issues, escalate this (See 6.10)
- Book the Anomaly scan using the 'UANOM' entry on the request list (see 6.9)
- Write the Anomaly scan appointment details in the woman's hand-held pregnancy notes.
- Print appointment letter and give to patient
- Take money for scan images (if required)
- Advise women to go for blood test (if required). The Sonographer will have already advised the patient to this and will tell you if a blood test is required.
- Monitor the request list daily and amend/book as necessary. If there is uncertainty about whether these scans are still required, seek Sonographer guidance; they will investigate examinations already performed.

6.2. Incomplete Anomaly scans

- If the Sonographer is unable to complete the Anomaly scan at the first attempt, they will ask that you book a second attempt. A copy of the report should be provided to evidence this request. This scan should be completed before 23+0 weeks gestation. This can be calculated using EDD (see 6.5)

- The Sonographer will have placed a sticker on the inside of the front cover of the woman's hand-held notes. Add the date and time of the next appointment in the relevant box. Print appointment letter and give to patient. If sticker is not present then speak to the sonographer to obtain in order to proceed.
- If there are capacity issues, escalate this (See 6.10)

6.3. Where appointments Clerk is not present

- The Sonographer will leave a copy of the scan report with instructions in a dedicated folder to be securely stored at the reception desk. Check this daily.
- Book the appointment within the required timeframe
- If the appointment is within 7 days or less, please contact the woman via telephone to ensure that she is aware of the booking. Print appointment letter as confirmation and post. Two attempts at contact at different times (within 24 hours) must be made before sending appointment letter.

6.4. Scan durations

- 30 minutes for a singleton pregnancy
- 60 minutes for a twin pregnancy – Sonographer to confirm pregnancy is a twin when requesting scan
- Seek Sonographer guidance for triplets or more – Sonographer to confirm pregnancy is triplets when requesting scan
- 30 minutes for completion of Anomaly scan unless the Sonographer asks for a shorter examination time because very limited anatomy checks are required. On these occasions, please document this on the CRIS system (See 6.12)

6.5. Using the Obstetric Gestation Calculator Wheel to calculate EDD:

- Place the 'probable day of delivery' arrow to the EDD.
- Find the number of weeks of gestation you require on the inner wheel (18-20+6).
- Use the dates on the outer wheel to identify the scan window.

6.6. DNA process (CRIS)

- CRIS will automatically DNA the patient overnight. Check for DNAs on a daily basis
- Select appointment tab
- Using the information boxes at the bottom of the screen:
- Enter site
- Select previous day's date
- Enter examination code (UANOM)
- Select "list" to the right of the screen
- This will list all the patients from the previous day who did not attend
- Double click patient examination to take you to the "event details" screen
- Select cancel tab
- Select "patient DNA card returned"
- Select "print letter"
- Select DNA card returned button to save change
- Send letter to the CMW (See 6.11)

6.7. Adding to the request list

- Search for the patient
- Select "new"
- Complete referrer information, exam code(s), date received and urgency

- Select “request”
- Select “accepted”
- Scan first trimester (12 week) scan report if available
- Select “save”

6.8. Changing Request to Waiting/Planned:

- Search for the patient
- Select correctly dated and coded exam
- Select “request”
- Click on “waiting / planned”
- Enter date required by
- Enter reason for entry
- Select “Save”

6.9. Booking from the request list

- Search for the patient
- Select correctly dated and coded exam – UANOM
- Select “request”
- Highlight scan new image and accept boxes
- Add first trimester (12 week) scan report into scanner
- Save
- Enter patient hospital X number and select correctly dated and coded exam
- Right click – select add to diary
- Bring up the CRIS diary page
- Use the calculator (See 6.5) and calculate when scan is required by EDD details or by instructions given by sonographer in first trimester (12 week) scan report
- Find appropriate appointment slot within diary. If unable to find appointment slot (see 6.10)
- Drag patient name from the “scratch pad” and drop into correct day and time slot agreed with patient
- Follow process within 6.1 about confirmation to patient

6.10. Capacity Issues

- If you are unable to appoint the woman within the specified timeframe escalate this to a Sonographer.
- If no Sonographers are available or, they are unable to provide a solution, please escalate the issue to the Ultrasound Manager emailing volume and exams needing appointment.

6.11. Women who do not attend (DNA)

- Do not call the patient.
- DNA the entry on CRIS (See 6.6), print letter and send to the Community Midwives
- so that they are aware the patient did not attend
- Add note to say that the CMW have been informed if they are informed by phone but ensure that letter is still printed and sent.
- The CMW will re-request the anomaly scan (If required), follow the booking process
- and aim to appoint within the required timeframe.

6.12. Making notes on CRIS (Include notes about patient choice, later dates etc.

- Enter patient hospital X number
- Select correctly dated and coded exam and click “change”
- Click on the history tab and write comments under “event details” including information about patient choice, reasons for UTA, any offered appointments that are declined and reasons, sonographer instructions
- Click save

7. Equality and Human Rights Statement

See Appendix A.

8. Training

- Staff should receive CRIS training and booking processes
- Staff should be trained in guidelines for booking scans according to FASP standards.

9. Monitoring Compliance with the Document

Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Compliance of SOP	K Howe-Bush	Meeting	Annual	[redacted]	[redacted] K Howe-Bush	[redacted] K Howe-Bush

10. References

Fetal Anomaly Screening Programme handbook 2018

Appendix A – EHRA Form

A Due Regard, Equality & Human Rights Analysis form must be completed for all procedural documents used by East Sussex Healthcare NHS Trust. Guidance for the form can be found here on the Equality and Diversity Extranet page.

East Sussex Healthcare NHS Trust

Due Regard, Equality & Human Rights Analysis

Title of document: **Standard Operational Procedure. Booking process for Fetal Anomaly scans.**
Who will be affected by this work? E.g. staff, patients, service users, partner organisations etc. Appointments Staff, Sonographers.
Please include a brief summary of intended outcome: Standardise booking process for fetal anomaly scans

		Yes/No	Comments, Evidence & Link to main content
1.	**Does the work affect one group less or more favourably than another on the basis of:** (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)		
	• Age	No	
	• Disability (including carers)	No	
	• Race	No	
	• Religion & Belief	No	
	• Gender	No	
	• Sexual Orientation (LGBT)	No	
	• Pregnancy & Maternity	No	
	• Marriage & Civil Partnership	No	
	• Gender Reassignment	No	
	• Other Identified Groups	No	
2.	**Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?**	No	(Ensure you comment and link to main policy with page/paragraph number)
3.	**What are the impacts and alternatives of implementing / not implementing the work / policy?**	Missed screening opportunities for obstetric women, non-compliance with PHE guidelines.	
4.	**Please evidence how this work / policy seeks to "eliminate unlawful discrimination, harassment and victimisation" as per the Equality Act 2010?**	Standardises process for all staff	
5.	**Please evidence how this work / policy seeks to "advance equality of opportunity between people sharing a**	Standardises process for all staff	

	protected characteristic and those who do not" as per the Equality Act 2010?	
6.	**Please evidence how this work / policy will "Foster good relations between people sharing a protected characteristic and those who do not" as per the Equality Act 2010?**	Standardises process for all staff
7.	**Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)**	Yes
8.	**Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?**	Contribution to document.
9.	**Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).**	No.

East Sussex Healthcare NHS Trust

Application and Acceptance Process for Radiology Non-Medical Referrers

Document ID Number	2090
Version:	V3
Ratified by:	Radiation Protection Committee CSD Quality and Safety Group
Date ratified:	January 2024
Name of author and title:	Ian Diton
Date originally written:	20 March 2020
Date current version was completed	28 December 2023
Name of responsible committee/individual:	Radiation Protection Committee
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Review date:	January 2026
Target audience:	ESHT and community non-medical healthcare professionals
Compliance with CQC Fundamental Standard:	Safe Care and Treatment (regulation 12)
Compliance with any other external requirements (e.g. Information Governance):	The ionising radiation (Medical Exposure) Regulations 2017 and IR(ME)R 2018 Amendment
Associated Documents:	IR(ME)R Diagnostic Reference Level (DRL) Strategy. IR(ME)R Medical Exposures Manual. Policy for the Safe Use of Ionising and Non-Ionising Radiations. Applicable referral protocol.

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1.0	20/03/2020	Ian Diton	New document	First issue
V2.0	19/07/2022	Ian Diton	Document reviewed and updated	Minor changes to contact details, process flow and NMR application form. Appendix D- List of approved protocols added
V.3.0	15/12/2023	Ian Diton	Document reviewed and updated	New EIA form added. Update to the non-medical referrer application form. General updates.

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Dr Neil Barlow	IRMER Lead	July 2022
[redacted]	Non-medical referrer coordinator	July 2022
[redacted]	Non-medical referrer coordinator	July 2022
Ian Diton	Radiology Quality Manager	July 2022
Dr Justin Harris	IRMER Lead (pre Nov 2021)	August 2020
Radiation Protection Committee	Radiation Protection Committee	July 2022
Radiation Protection Committee	Radiation Protection Committee	January 2024

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Background and Purpose

The requesting of imaging examinations such as X-rays and ultrasounds does not form part of the standard training for non-medically qualified healthcare professionals. One aspect of the modernisation of the NHS has been the increase of extended roles for non-medical healthcare professionals such as nurses and allied health professionals, including requesting diagnostic procedures such as imaging examinations.

Non-medical Healthcare professionals (e.g Nurse and Paramedic Practitioners) form an important element of the primary and secondary care service development across the county. The ability to order diagnostic imaging not only enhances the ability of a healthcare professional to manage patient care but allows true collaborative working to be achieved.

This document describes the process of non-medical healthcare professionals to submit an application. This procedure also includes the necessary steps to be taken to gain approval to request imaging examinations, for patients presenting with undifferentiated and undiagnosed conditions, where X-Ray or ultrasound is needed as part of the patient's clinical management.

2. Scope

The Referrer must be a formally recognised:

ESHT Nurse Practitioner who has completed either a BSc (Hons)/ MSc programme in Nurse Practitioner Studies or equivalent examination as agreed with the IRMER Lead Practitioner for ESHT radiology and Lead Consultant for the area of work.

Community Nurse Practitioner who has completed either a BS BSc (Hons)/ MSc programme in Nurse Practitioner Studies or equivalent examination as agreed with the IRMER Lead Practitioner for ESHT radiology and Lead ANP for the CCH prior to application.

Paramedic Practitioner who has completed a Specialist Paramedic Practitioner Programme or equivalent examination as agreed with the IRMER Lead Practitioner for ESHT radiology and Lead ANP for the CCH prior to application.

Advanced Practitioner registered with a professional body such as the Health and Care Professionals Council (HCPC), Chartered Society of Physiotherapists (CSP) or British Chiropody and Podiatry Association (BCPA).

ESHT Radiographer appropriately trained who has completed BSc (Hons) programme in diagnostic radiology or equivalent.

3. Roles and Responsibilities

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 and the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018, require employers to provide a framework for radiation protection for medical exposures. The regulations provide clarity on the responsibilities of the referrer, practitioner, and operator, as well as the employer.

Within the context of IR(ME)R 2017:

- the **referrer** has responsibility for providing sufficient medical data relevant to the exposure.
- the **practitioner** (normally a radiographer or radiologist) is responsible for "justifying" the exposure using the clinical information provided by the referrer. Radiographers justify the exposure using the practitioner's guidelines. The practitioner (radiologist) will decide the most appropriate clinical imaging procedure. In some cases this may involve a procedure which uses non-ionising radiation, or a decision may be taken that a clinical imaging will provide no additional clinical information. It is therefore essential that the referrer provided the practitioner with sufficient information to carry out the justification process.

Eligibility criteria for a referrer- IR(ME)R requirements

- *The Ionising Radiation (Medical Exposure) (Amendment) Regulations (IR(ME)R) 2017* define the **referrer** as a registered health care professional who profession is regulated by a body as detailed within Sections 25(3) of the *National Health Service Reform and Health Care Professionals Act 2002.*
- The **referrer** must be entitled to act in this capacity by the employer. The scope of entitlement should also be specified, that is, which examinations the individual can refer for. Under IR(ME)R 2017 the term "employer" is used to mean clinical imaging service provider, and not necessarily the employer who holds the contract of employment of the referrer.
- The **referrer** must be aware of their responsibilities under the regulations as a duty holder.
- Under IR(ME)R 2017, Healthcare professionals will become a **referrer** and will then be clinically responsible for the imaging request.

The **Radiology IRMER Lead Practitioner** approves new referral protocols and is responsible for the acceptance status of applications.

The **Radiology Quality Manager** overseas the application and approval process and associated records.

The **Radiology Non-medical referrer (NMR) coordinators** receive, check and process referrer requests, answer clinical and user set up enquiries and maintain the associated records.

The **Radiology Quality Administrator** processes referrer requests and maintains the associated records.

4. Definitions

IR(ME)R- Ionising Radiation (Medical Exposure) Regulations 2017 and IR(ME)R 2018 Amendment.
NMR- Non-medical referrer.

5. Key Contacts

The Radiology NMR Coordinators are the main point of contact for all applications. Contact details are as follows:

Radiology Non-Medical Referrer Coordinator contact emails:-

Generic E-mail account: Esht.radiologyreferrers@nhs.net

General guidance for locations local to Eastbourne DGH: [redacted]

General guidance for locations local to the Conquest Hospital: [redacted]

ICE and PACS assistance:-
For both sites use: esh-tr.ICE@nhs.net, esht-PACSHELP@nhs.net, esht.ocs@nhs.net

6. Process description

Any Healthcare professional wishing to apply as a non-medical referrer must have approval from their department line manager. This is to ensure that applicants are considered to be suitable to refer and are supported clinically within their area of work. Once agreed the non-medical referrer applicant will then follow the Trust application process as shown in the flowchart on pages 8 & 9 using the application form (Appendix 2) on pages 17-20

1. The referring location must have an approved referrer protocol specific to their area of work. If one of the existing protocols cannot be used, then a protocol must be created by the referring location and sent to the Radiology IRMER Lead Practitioner for approval. A list of current approved referral protocols is available in Appendix D of this document.

2. Qualifying candidates must attend the IRMER ½ day training course provided by the Radiology department at either the Eastbourne or Conquest hospital sites. Contact esht.radiologyreferrers@nhs.net for the date of training sessions and any enquiries about the training process.

3. Each attendee will receive a certificate on completion of the IRMER ½ day training course. Please note: This training course provides detailed training and the online IRMER refresher course (e-learning/ e-LfH) **will not** be accepted for **new** applicants.

4. Once the NMR applicant has completed the training, a non-medical referrer application form (appendix B) must be completed and e-mailed to the generic e-mail address: esht.radiologyreferrers@nhs.net.
   Please note that a separate application is required for each different location of work (except in the case of GP surgery networks as long as the same supervising clinician is assigned for all locations). On receipt of the completed application form, the information provided is checked by the Radiology NMR coordinator and if correct passed to the Radiology IRMER Lead Practitioner for review of the application.

5. If the application is approved the referrer is added to the pending authorisation tab on the non-medical referrer database by the Radiology NMR Coordinator / Radiology Quality Administrator. If rejected the application form is e-mailed back to the applicant by the radiology NMR coordinator with an explanation of the reason why.

6. When approved, the applicant is then assigned permissions for the IT systems as follows:-

   The NMR coordinator / Radiology Quality Administrator sends an email to the ICE (esh-tr.Ice@nhs.net), PACS (esht.pacshelp@nhs.net) &/ Ordercomms

OCS (esht.ocs@nhs.net) teams to instruct them to set up permissions for the newly approved referrers. Confirmation is received by the NMR coordinator / Radiology Quality Administrator from the ICE & PACS teams/ Ordercomms (OCS) team when completed.

Please note that ESHT employees will require their department line manager to approve NMR's to obtain access the required Trust IT system programs.

7. The Radiology NMR Coordinator / Radiology Quality Administrator updates the excel database with the system set up information for the applicant in the appropriate columns.

8. When all the stages stated above have been completed the Radiology NMR coordinator / Radiology Quality Administrator will then email confirmation (appendix 3) to the successful applicant and a copy of the signed approved application form (Appendix 2), together with an electronic copy or link of the approved protocol for that referrer type. The clinical supervisor and radiology referrers are copied into the email for information only. The applicable Radiology modality leads are also informed to ensure any necessary preparations are in place before referrals commence. The referring area lead will also be notified when applicable (e.g. A&E).

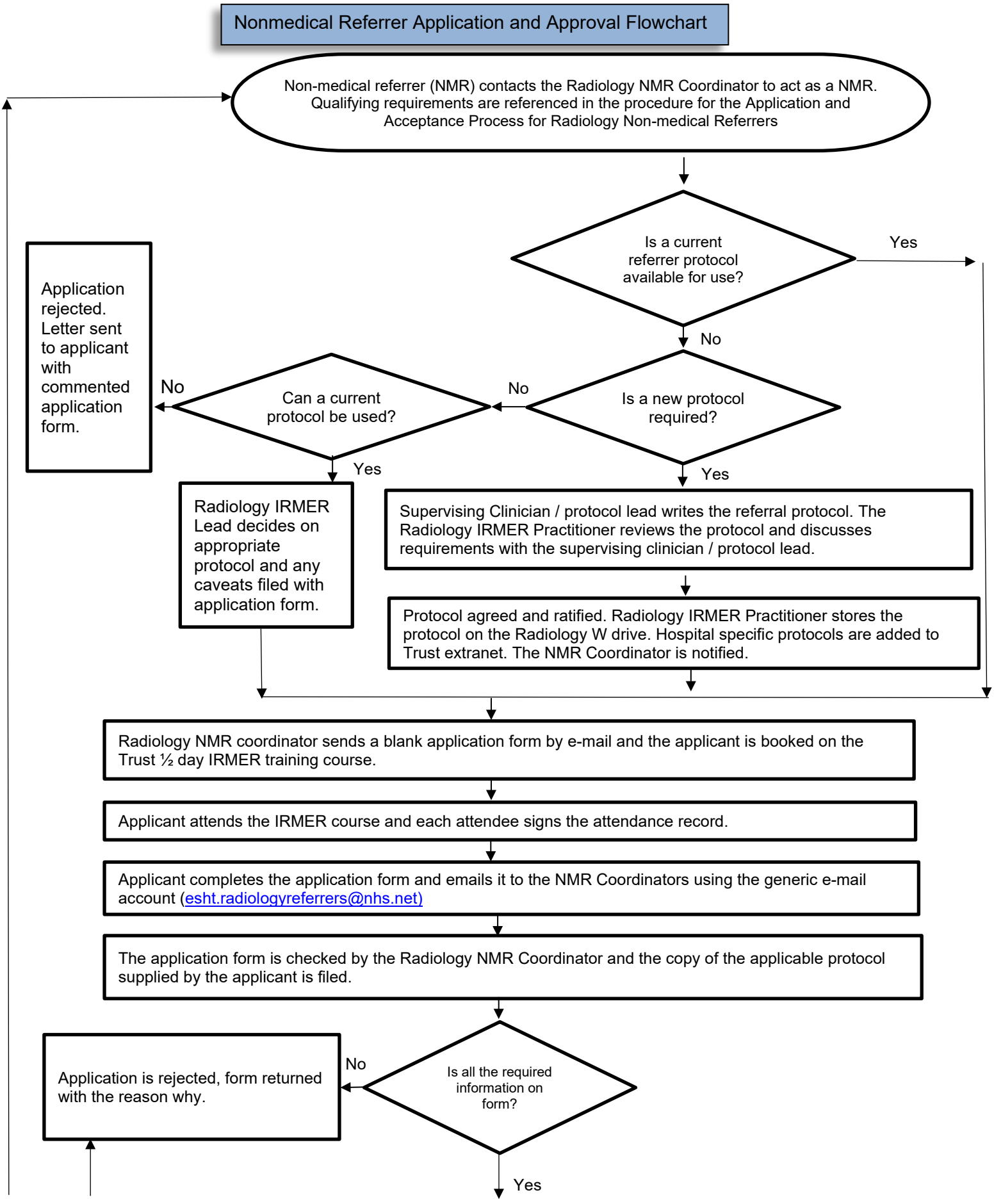
9. The Radiology Quality Administrator moves the approved referrer record in the NMR spreadsheet from the pending authorisation tab to the approved personnel list tab and ensures a copy of the IRMER certificate and approved application form are stored on the radiology shared drive and hyperlinked to the entry.

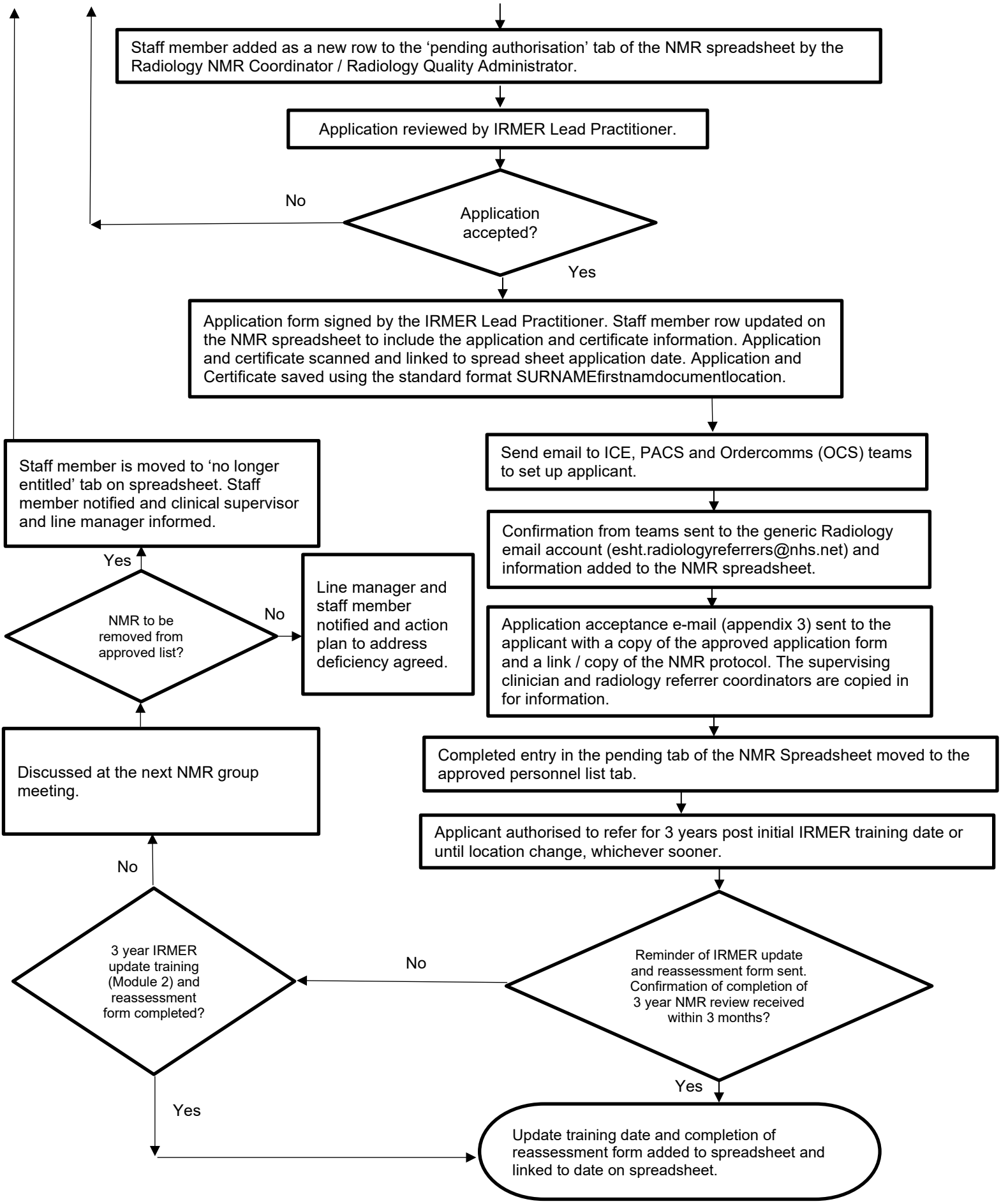
10. The NMR is subject to competency assessment and Audit in accordance with the ESHT Policy for the Requesting of Imaging Examinations by Non-medically Qualified Professionals as overseen by the supervising Clinician.

11. After the initial IRMER training is completed, an IRMER update is expected for the NMR to remain compliant. This is performed every 3 years online (via MyLearn or e-lfh). This consists of the module 2 of the IRMER e-learning program (000 e-IRMER Module 02- Management and Radiation Protection of the Patient). The course certificate is then sent to the Radiology NMR Coordinator using the generic e-mail address (esht.radiologyreferrers@nhs.net e-mail address).

12. NMR's must notify the radiology NMR coordinators of all status changes such as:-
    - The referral location changes
    - They retire or leave their role
    - No longer require referral rights

The following flowchart provides information on each stage of the process.


Nonmedical Referrer Application and Approval Flowchart
Non-medical referrer (NMR) contacts the Radiology NMR Coordinator to act as a NMR. Qualifying requirements are referenced in the procedure for the Application and Acceptance Process for Radiology Non-medical Referrers
Is a current referrer protocol available for use?
Yes
No
Is a new protocol required?
No
Yes
Can a current protocol be used?
No
Yes
Application rejected. Letter sent to applicant with commented application form.
Radiology IRMER Lead decides on appropriate protocol and any caveats filed with application form.
Supervising Clinician / protocol lead writes the referral protocol. The Radiology IRMER Practitioner reviews the protocol and discusses requirements with the supervising clinician / protocol lead.
Protocol agreed and ratified. Radiology IRMER Practitioner stores the protocol on the Radiology W drive. Hospital specific protocols are added to Trust extranet. The NMR Coordinator is notified.
Radiology NMR coordinator sends a blank application form by e-mail and the applicant is booked on the Trust ½ day IRMER training course.
Applicant attends the IRMER course and each attendee signs the attendance record.
Applicant completes the application form and emails it to the NMR Coordinators using the generic e-mail account (esht.radiologyreferrers@nhs.net)
The application form is checked by the Radiology NMR Coordinator and the copy of the applicable protocol supplied by the applicant is filed.
Is all the required information on form?
No
Application is rejected, form returned with the reason why.
Yes


Staff member added as a new row to the 'pending authorisation' tab of the NMR spreadsheet by the Radiology NMR Coordinator / Radiology Quality Administrator.
Application reviewed by IRMER Lead Practitioner.
Application accepted?
No
Yes
Application form signed by the IRMER Lead Practitioner. Staff member row updated on the NMR spreadsheet to include the application and certificate information. Application and certificate scanned and linked to spread sheet application date. Application and Certificate saved using the standard format SURNAMEfirstnamdocumentlocation.
Send email to ICE, PACS and Ordercomms (OCS) teams to set up applicant.
Confirmation from teams sent to the generic Radiology email account (esht.radiologyreferrers@nhs.net) and information added to the NMR spreadsheet.
Application acceptance e-mail (appendix 3) sent to the applicant with a copy of the approved application form and a link / copy of the NMR protocol. The supervising clinician and radiology referrer coordinators are copied in for information.
Completed entry in the pending tab of the NMR Spreadsheet moved to the approved personnel list tab.
Applicant authorised to refer for 3 years post initial IRMER training date or until location change, whichever sooner.
Reminder of IRMER update and reassessment form sent. Confirmation of completion of 3 year NMR review received within 3 months?
No
Yes
3 year IRMER update training (Module 2) and reassessment form completed?
No
Yes
Update training date and completion of reassessment form added to spreadsheet and linked to date on spreadsheet.
Discussed at the next NMR group meeting.
NMR to be removed from approved list?
Yes
No
Line manager and staff member notified and action plan to address deficiency agreed.
Staff member is moved to 'no longer entitled' tab on spreadsheet. Staff member notified and clinical supervisor and line manager informed.

7. Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
IRMER Compliance	Radiology Quality Manager	Q-Pulse	Annual	Radiation Protection Committee	Radiation Protection Committee	Radiation Protection Committee. Radiology Clinical Services Manager. Health and Safety Steering Group.

Appendix 1: Equality and Health Inequalities Impact Assessment (EHIA) Form

Equality and Health Inequalities Impact Assessment (EHIA) template

Undertaking EHIA helps us to make sure that our services and polices do not inadvertently benefit some groups more than others, ensuring that we meet everyone's needs, and our legal and professional duties.

This is important because:

- Assessing the potential for services and policies to impact differently on some groups compared with others is a legal requirement.
- People who find it harder to access healthcare services are more likely to present later when their disease may be more progressed, have poorer outcomes from treatment, and need more services than other groups who have better access.

The Equality Act 2010 legally protects people from discrimination in the workplace and in wider society. It is against the law to discriminate against anyone because of:

- age
- gender reassignment
- being married or in a civil partnership
- being pregnant or on maternity leave
- disability
- race including colour, nationality, ethnic or national origin
- religion or belief
- sex
- sexual orientation.

These are called 'protected characteristics'. The Act requires that public sector organisations meet specific equality duties in respect of these protected characteristics. This is known as the public sector equality duty.

Public Sector Equality Duty

Public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees.

Public bodies must have due regard to the need to:

- eliminate discrimination
- advance equality of opportunity
- foster good relations.

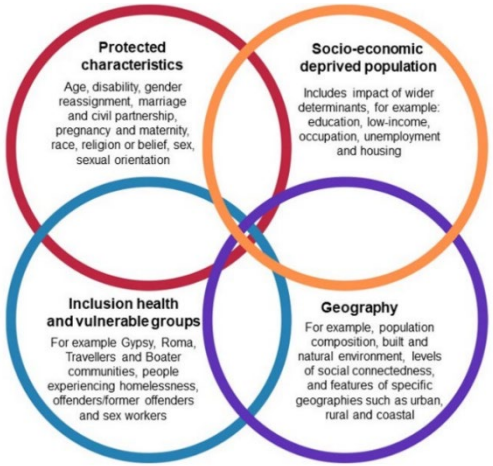
Armed Forces Covenant Duty
The new Covenant Duty raises awareness of how Service life can impact on the Armed Forces community, and how disadvantages can arise due to Service when members of that community seek to access key local services. The Duty requires organisations to pay due regard to the Covenant principles when exercising functions in healthcare. “Due regard” means that we need to consciously consider the unique obligations and sacrifices made by the Armed Forces; that it is desirable to remove disadvantages faced by the Armed Forces community; and that special provision may be justified in some circumstances.

Health Inequalities Duties- Equity for all
In addition to our legal duties in relation to Protected Characteristics, the Health and Social Care Act and other legislation, NHS Planning Guidance and sector specific recommendations require the NHS to have regard to the need to address health inequalities (or differences in access to or outcomes from healthcare) and take specific action to address them.

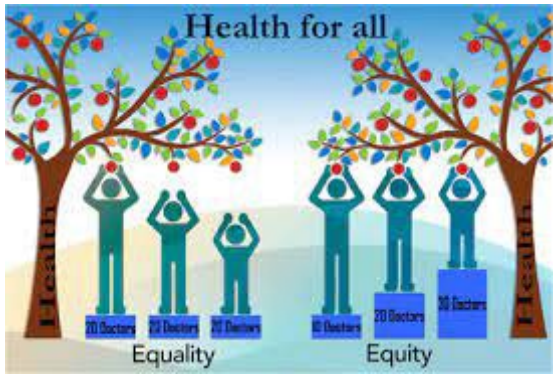
Figure 1 shows the different population groups, factors associated with where we live, or our individual circumstances, which separately, or when combined, influence access to and outcomes from health care.

Getting equal outcomes may require different inputs (or services). In completing an EHIA its important to think about whether a one size fits all approach will generate the same good outcomes for everyone, or whether we might need to make some tweaks or adjustments to enable everyone to benefit equally. The health tree diagram shows that unless we think about the needs of different people, equal services might generate unequal outcomes.

Factors associated with poorer health outcomes (PHE 2021)[1]



The Health Tree[1]



The following principles, drawn from case law, explain what we must do to fulfil our duties under the Equality Act:

- **Knowledge:** everyone working for the Trust must be aware of our equality duties and apply them appropriately in their work.
- **Timeliness:** the duty applies at the time of considering policy options and/or before a final decision is taken – not afterwards.
- **Real Consideration:** the duty must be an integral and rigorous part of your decision-making and influence the process.
- **Sufficient Information:** you must assess what information you have and what is needed to give proper consideration.
- **No delegation:** the Trust is responsible for ensuring that any contracted services which provide services on our behalf can comply with the duty, are required in contracts to comply with it, and do comply in practice. It is a duty that cannot be delegated.
- **Review:** the equality duty is a continuing duty. It applies when a policy/process is developed/agreed, and when it is implemented/reviewed.
- **Proper Record Keeping:** to show that we have fulfilled our duties we must keep records of the process and the impacts identified.
  NB: Filling out this EHIA in itself does not meet the requirements of the equality and health inequalities duties. All the requirements above must be fulfilled or the EHIA (and any decision based on it) may be open to challenge. Properly used, an EHIA can be a tool to help us comply with our equality and health inequalities duty and as a record that to demonstrate that we have done so. It is advised that you complete the short EHIA training session on MyLearn before completing this EHIA.

[1] https://www.researchgate.net/figure/Equality-and-equity-of-medical-resources-distribution_fig2_323266914

SECTION A ADMINISTRATIVE INFORMATION

This form is a central part of how the Trust makes sure and can demonstrate to others that we are meeting our legal duties; and how we can assure ourselves that all patients will get the best outcome for them from our services.

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal. **Function/policy/service name and number:**	Application and Acceptance Process for Radiology Non-Medical Referrers		
Main aims and intended outcomes of the function/policy/service and summary of the changes you are making (if existing policy/service):	The policy will achieve our general equality duty where we will have to demonstrate due regard for advancing equality by: • Removing or minimising disadvantages suffered by people due to their protected characteristics. • Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. • Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low		
How will the function/policy/service change be put into practice?	Ratified document will be available on QPulse document management system and trust intranet		
Who will be affected/benefit from the policy?	The policy will support an equitable and inclusive workplace for our workforce		
State type of policy/service	**Policy √**	Service ☐	
	Business Case ☐	Function ☐	Existing
Is an EHIA required? NB :Most policies/functions will require an EA with few exceptions such as routine procedures	**Yes** √		
	No ☐ (If no state reasons)		
Accountable Director: (Job Title)	Equality Diversity and Inclusion Lead		
Assessment Carried out by:	Name: Ian Diton		
Contact Details:	[redacted]		
Date Completed:	30/01/2024		

SECTION B ANALYSIS AND EVIDENCE

Analysis of the potential impact – Equality and Health Inequalities Duties

For this section you will need to think about all the different groups of people who are more likely to experience poorer access or have poorer outcomes from health and care services. For each group please describe in the first column the potential impact you have identified, in the second column explain how you have arrived at this conclusion and what information you used to identify the potential impact, and in the third column say what you are going to do to prevent it from happening, or which elements of a service or policy specifically address the potential impact. Key things to remember.

- Everyone has protected characteristics but some groups who share one or more protected characteristics may be more likely to have poorer outcomes or access compared with others – and it is this potential that the EHIA process seeks to identify and address.
- The information included here should be proportionate to the type and size of the policy/service/change.
- An update to a policy should demonstrate that you have considered the potential for the policy to impact differently on different groups and taken steps to address that.
- A minor policy update is likely to need to be much less comprehensive than an EHIA for a major service change.
- You will need to know information about who uses or could use your service/policy will apply to (the population). You can use information about current patients or staff, and about the general population the Trust serves.

3. PROTECTED CHARACTERISTICS - Main potential positive or negative impact of the proposal for protected characteristic groups summarised

Please write in the box below a brief summary of the main potential impact (positive or negative)
Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below, but make sure you include information on how you now there will be no impact.**

This policy address our legal specific Public Sector Equality Duty (PSED) where we must, in the exercise of our functions, have due regard to the need to:
• Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
• Advance equality of opportunity between people who share a protected characteristic and those who do not.
• Foster good relations between people who share a protected characteristic and those who do not.

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Age: older people; middle years; early years; children and young people.	This policy protects staff from all age groups no matter what age they are as outlined in the Equality Act 2010	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS	N/A
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	This policy has a positive impact on all staff that have a disability or long term health condition. It links into the (Dis)Ability & Health Passport to enable adequate adjustment to take place and the Carers Passport to achieve a work life balance	The Workforce Disability Equality Standard, set out by NHS England details the positive association between increased disability equality and workplace experience for disabled individuals	N/A
Gender Reassignment and/or people who identify as Transgender	This policy has a positive impact on those that are transitioning from their gender assigned at birth to another gender. This policy links into the Gender Recognition Act 2004	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS	N/A
Marriage & Civil Partnership: people married	This policy does not have a negative impact on a member of staffs marital or	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging –	N/A

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
or in a civil partnership.	civil partnership status	detailed in the NHS People Plan NHS England » Belonging in the NHS	
Pregnancy and Maternity: before and after childbirth and who are breastfeeding.	This policy has a positive impact on pregnancy, maternity and also including paternity rights with, The Employment Rights Act 1996 which sets out rights to health and safety, time off for antenatal care, maternity leave and unfair dismissal	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS	N/A
Race:	This policy has a positive impact for all staff regardless of their race or ethnicity	The Workforce Race Equality Standard, set out by NHS England details how the positive association between increased race equality and workplace experience for disabled individuals	N/A
Religion and belief: people with different religions/faiths or beliefs, or none.	This policy has a positive impact on all staff the wish to observe religious practices and those that don't	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS	N/A
Sex:	This policy has a positive impact on gender and looks at statutory duties under the Gender pay Gap	The Gender Pay Gap Report details the positive association with gender equality and workplace experience	N/A

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Sexual orientation	This policy has a positive impact on staff no matter what their sexual orientation is	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS	N/A
Veterans/Armed Forces Communities	This policy ensures 'due regard' is considered for veterans and the armed forces community	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS	N/A

4. HEALTH INEQUALITIES -Potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). **If the policy/procedure is unrelated to patients, this sections does not require completion.**

Please state none if you have assessed that there is not an impact, but please make sure you complete the 'how do you know this' column to demonstrate that you have considered the potential for impact**. If you identify the potential for impact for one or more of these groups please complete the full assessment in Appendix**

Groups who face health inequalities[2]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
This includes all groups of people who may have poorer access to or outcomes from healthcare services. It includes: People who have experienced the care system; carers; homeless people; people involved in the criminal justice system; people who experience substance misuse or addiction; people who experience income or other deprivation; people with poor health literacy; people living in rural areas with limited access to services; refugees or asylum seekers; people in or who have been in the armed force; other groups who you identify as potentially having poorer access and outcomes.	There is strong evidence that where an NHS workforce is representative of the community that it serves, patient care and the overall patient experience is more personalised and improves	NHS England » Belonging in the NHS	N/A

SECTION C ENGAGEMENT

5. Engagement and consultation

a. Talking to patients, families and local communities can be a rich source of information to inform health care services. If you are making substantial changes it's likely that you'll have to undertake specific engagement with patients. For smaller changes and policies your may have undertaken some engagement with patient groups, gained insight from routine sources e.g. patient surveys, PALS or Complaints information or information from Healthwatch, you may also have looked at relevant engagement that others have undertaken in the Trust, or locally
Have any engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	No X

b. If yes, please ensure all stakeholders are listed in the consultation table at the beginning of the policy.

SECTION D SUMMARY OF FINDINGS

Reflecting on all of the information included in your review-

6. EQUALITY DUTIES: Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please **add an x** to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?	X	X	X
The proposal may support?			
Uncertain whether the proposal will support?			

7. HEALTH INEQUALITIES: Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	*X*	*X*
The proposal may support?		
Uncertain if the proposal will support?		

8. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1	N/A	
2	N/A	
3	N/A	

9. EHIA sign-off: (this section must be signed)

Person completing the EHIA:	[redacted] **Ian Diton**	**Date:30/01/2024**
Line Manager of person completing:	[redacted]	**Date: 30/01/2024**

Breakdown of Groups who are more likely to experience health inequalities:

Groups who face health inequalities[3]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Looked after children and young people	N/A		
Carers of patients	N/A		
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	N/A		
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	N/A		
People with addictions and/or substance misuse issues	N/A		
People or families on a low income	N/A		
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	N/A		
People living in deprived areas	N/A		

Groups who face health inequalities[3]	Summary explanation of the potential positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
People living in remote, rural and island locations	N/A		
Refugees, asylum seekers or those experiencing modern slavery	N/A		
People who have served in the Armed Forces	N/A		
Other groups experiencing health inequalities (please describe)	N/A		

Appendix – EHIA Resources
Sources of Information on the East Sussex population and sources of community or patient insight.

Population Data
State of the County 2021 Focus on East Sussex

East Sussex JSNA

Community Insight

Further Reading on Equality and Health Inequalities

Training

Appendix 2: Non-Medical Referrer Application Form

The Ionising Radiations (Medical Exposure) Regulations, 2017 require that all patients x-rayed or administered with radioactive substances at East Sussex Healthcare NHS Trust are referred by a registered medical practitioner, dental practitioner or other health care professional that have been granted entitlement by the Trust. Application is made to the Radiation Protection Committee, and the following information is required.

Full Name inc. Title:	
Staff payroll number (ESHT staff):	
Signature:	
Employer:	
Work Address (Including Department):	
Contact Phone Number:	
Work Email Address:	
Profession:	
Clinical Qualifications:	
Registration Body & Number:	
***Intended Protocol(s):**	
Protocol Lead:	
Reason for Application:	
Date of Application:	
Name of Supervising Clinician:	
Signature of Supervising Clinician:	
Contact Details of Supervising Clinician if different to work address above:	

*I agree that I have read, understood, and will practice within the scope of the protocol listed above.
I understand that if I have any clinical queries regarding the scope or practice within the protocol, I will raise them with my Supervising Consultant or protocol lead.
(Signature) …….
(Date) ……

You will only be entitled to refer once this application has been received with its supporting documentation, signed and approved by the lead IR(ME)R Practitioner and you have received an e-mail confirming entitlement.

On completion, please either scan or photograph all the pages of the application and send to the following email address:-

esht.radiologyreferrers@nhs.net

If you have any queries about this form, or what information to include to support your application, please contact the non-medical radiological imaging team on esht.radiologyreferrers@nhs.net

Notes for Applicants

- Referral Criteria MUST be clearly stipulated as part of the agreed Protocol for Referral.
- The purpose of Referral Criteria is to ensure the Practitioner at the Hospital has sufficient information to justify the requested procedure.
- Referral Criteria must be complied with, otherwise the request form will be returned to you to be completed correctly.
- Staff returning a request form will be acting under Procedures laid down by the Trust.
- Repeated failure to comply with Referral Criteria will result in the entitlement to refer to this Trust for imaging being removed.

Applications from Outside ESHT

Please write to the Radiology Quality Manager who will present your case to the Radiation Protection Committee with:

- Stipulate the examinations, modalities you wish to refer for and for what clinical indications
- Ensure you have clearly outlined who will be medically responsible for the patient's care
- Provide details of Registered Practice Address
- Please complete the attached documentation to the best of your knowledge and provide all certificates of training.

Application to become a Referrer – Additional Supporting Information

1. **Have you undertaken the ½ day inhouse IR(ME)R 2017 training provided by the ESHT Radiology department?**

   YES / NO
   If **yes,** please supply evidence of that training with dates and location below.

   If **no,** contact radiology for dates of forthcoming training

2. **Are you applying to act as a referrer under an existing agreed referral protocol?**

   YES / NO

   If **yes,** please state the full title of the protocol and revision level below.

   ……

   If **no,** please contact the Radiology Quality Manager for further advice

3. **Who is the Supervising Clinician (Medically Qualified) for this agreed protocol?**

   Name: …….

   Post:…….

   Signature:……

The Supervising Clinician must ensure that the Clinical protocol under which you are applying to become a referrer is up to date and reflects best practice.
They must also sign your application.

Application to become a Referrer – Outcome of Application

Name of applicant……

Application **agreed** by East Sussex Healthcare NHS Trust Radiation Protection Committee

DATE:……

SIGNED:……..

POSITION:……..

REFERRAL CRITERIA SENT TO APPLICANT:……..

Application **refused** by East Sussex Healthcare NHS Trust Radiation Protection Committee

DATE:……

SIGNED:……..

POSITION:……..

REASONS FOR REFUSAL:

Appendix 3: Application acceptance e-mail

To: Non-medical referrer applicant
CC: Supervising Clinician;
esht.radiologyreferrers@nhs.net

Subject: Non-medical radiology referrer application approval

Dear Non-medical referrer applicant,

The IRMER radiology non-medical referrer application that you submitted has been approved by the Radiology IRMER Lead and the access to the IT systems completed. Please find attached the approved IRMER application form and the link / attachment of the applicable referral protocol (ref: ????).

Please ensure you do not commence radiology imaging referrals until after _____.

Kind Regards,

Non-Medical Referrer Coordinator

Appendix 4: List of approved protocols

Please click on the following links to view.

1957 Non-Medical Referral for Acute Oncology Clinical Nurse Specialists

1958 Non-Medical Referral for Qualified Advanced Clinical Practitioners Working in Urology

1960 was 1959 Non-Medical Referral for Qualified Advanced Clinical Practitioners Working in Acute Medicine & Amb Care

1961 Non-Medical Referral for Qualified Advanced Clinical Practitioners Working as Adv & Cancer Nurse Specialists, & Pt Pathway matrons in Colorectal Cancer

1962 Non-Medical Referral for Qualified Advanced Clinical Practitioners Working in iMSK Services

1963 Non-Medical Referral for Senior ED Nursing Staff & ENPs working in the Emergency Department

1964 Non-Medical Referral for Tuberculosis Specialist Nurses
1737 Procedure for Services led by Practitioners with Delegated Authority Undertaking Surveillance Cystoscopy
1744 Procedure for the Services led by Practitioners with Delegated Authority Undertaking One Stop Haematuria Clinic

2086 Non-Medical Referral for Surgical Care Practitioners Working in ESHT Orthopaedic Services

2087 Non-Medical Referral for Qualified Advanced Clinical Practitioners Working in Paediatric Musculoskeletal Services (iMSK)

2088 Non-Medical Referral for Macmillan Consultant Nurse - Breast Unit

2089 Non-Medical Referral for Gastroenterology Specialist Nurses & Nurse Endoscopists

2100 Non-Medical Referral for Advanced Paediatric Nurse Practitioners (APNP) Requesting Radiological Investigations

2101 Non-Medical Referral for Gastrointestinal Clinical Nurse Specialists

2104 Non-Medical Referral for Radiological Imaging Advanced Clinical Practitioners Working within Acute Gynaecology and Obstetrics Care

2148 Non-Medical Referral Protocol for Radiological Imaging Qualified Specialist Podiatrists

2149 Non-Medical Referral Protocol for Radiological Imaging Breast Clinical Nurse Specialist

2150 Non-Medical Referral Protocol for Radiological Imaging Systemic Anti-Cancer Treatment Nurses

2240 Non-Medical Referral for Radiological Imaging for SLT videofluoroscopy

2241 Non-Medical Referral for Radiological Imaging for Macmillan Advanced Nurse Practitioner And Clinical Nurse Specialist Skin Cancer

2250 Non-Medical Referral Protocol for Radiological Imaging Emergency Department Authorised Nurses - Patient Triage

2251 Non-Medical Referral for MRI - Paediatric Audiology Specialist Nurses

2361 Non-Medical Referral Protocol for Radiological Imaging for Gastroenterology Specialist Nurses Nurse Endoscopists
2520 Non-Medical Referral Protocol for Radiological Imaging Advanced Clinical Practitioners (ACPs) and Trainee Advanced Clinical Practitioners (tACPs) working in the Emergency Department (ED) and Urgent Treatment Centre (UTC)
2521 Non-Medical Referral Protocol for Radiological Imaging Bowel Dysfunction Nurse Specialists acting as an operator under guidance for Defecatory Proctograms
2532 Non-Medical Referral Protocol for Radiological Imaging Bowel Dysfunction Nurse Specialists
2536 Non-Medical Referral Protocol for Radiological Imaging First Contact Practitioners Working in General Practice
2576 Non-Medical Referral Protocol for Advanced Critical Care Practitioners (ACCPs) working in Critical Care
2579 Non-Medical Referral Protocol for Radiological Imaging For Cardiac Nurse in Acute Medicine Cardiology Care
2580 Non-Medical Referral Protocol for Stroke Specialist Nurses employed by ESHT
2581 Non-Medical Referral for Radiological Imaging Radiographers requesting plain films prior to an MRI scan or following a CT guided biopsy
2582 Non-Medical Referral Protocol for Radiological Imaging Vascular Access Specialist Nurse Practitioners Vascular Access Team
2583 Non-Medical Referral Protocol for Radiological Imaging Clinical Nurse Specialists for Hepatology and Viral Hepatitis Nurses

Please contact the non-medical referrer coordinator (esht.radiologyreferrers@nhs.net) for an electronic copy of the following protocol:-

- Non-Medical Referral for Qualified Advanced Clinical Practitioners Working in General Practice

East Sussex Healthcare NHS Trust

Policy for the Requesting of Imaging Examinations by Non-medically Qualified Professionals

Document ID Number	2613
Version:	V1
Ratified by:	Clinical Documentation and Policy Ratification Group
Date ratified:	12 March 2024
Name of author and title:	Ian Diton
Date originally written:	December 2023
Date current version was completed	December 2023
Name of responsible committee/individual:	Dr Neil Barlow (ESHT IRMER Lead Practitioner)
Division/Speciality:	Core Services, Radiology
Date issued:	20 March 2024
Review date:	March 2027
Target audience:	All Trust and primary care non-medical referrers and NMR Clinical supervisors.
Compliance with CQC Fundamental Standard	Safe Care and Treatment (Regulation 12)
Compliance with any other external requirements (e.g. Information Governance)	IR(ME)R – Ionising Radiation (Medical Exposure) Regulations 2017 and IR(ME)R 2018 Amendment.
Associated Documents:	IR(ME)R Medical Exposures Manual. Policy for the Safe Use of Ionising and Non-Ionising Radiations. IR(ME)R Diagnostic Reference Level (DRL) Strategy.

Did you print this yourself? Please be advised the Trust discourages retention of hard copies of the procedural document and can only guarantee that the procedural document on the Trust website is the most up to date version.

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
V1.0	December 2023	Ian Diton	New Document	New Document

Consultation Table

Name of Individual or group	Title	Date
Dr Neil Barlow	ESHT IRMER Lead Practitioner	January 2024
Simon Merritt	ESHT Medical Director	January 2024
Radiology NMR Coordinators	Radiology NMR Coordinators	January 2024

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

This document sets out the policy of the Imaging Service within East Sussex Healthcare NHS Trust (ESHT) for the requesting of imaging examinations by non-medically registered professionals.

This policy specifies the framework of acceptable practice for non-medical referrers requesting imaging examinations. In addition, it reflects the responsibilities of the individual referrers and ESHT in accordance with the Ionising Radiation (Medical Exposure) Regulations 2017.

The number and scope of extended roles continues to increase. In order to ensure a consistent and objective approach to the evaluation of the future need, a specific evaluation process has been developed and is documented within this policy.

2. Rationale

All non-medical referrers must hold current professional registration with either the Nursing and Midwifery Council (NMC) or Health and Care Professions Council (HCPC).

All non-medical referrers should have at least 6 months post-registration experience and have undertaken a recognised post registration course which includes clinical assessment.

In addition to the professional registration requirements, those undertaking this role will need to attend non-medical referrers training and undergo supervised practice as detailed in section 9.

The IR(ME)R Regulations 2017 state that the Trust must have a procedure to identify individuals entitled to act as authorised referrers for imaging procedures utilising ionising radiation. Under IR(ME)R:

- The referrer has prime responsibility for, and must be competent to provide, sufficient and necessary patient identification and clinical information for the practitioner.
- The imaging practitioner has the responsibility for justifying the procedure based on the clinical information provided. The practitioner is therefore responsible professionally and legally for the justification of each individual medical radiation exposure.

The framework provided by IR(ME)R 2017 also provides a best practice model for imaging modalities which do not involve ionising radiation (such as US and MRI) and the need for appropriate training and clarification of roles and responsibilities is relevant to all the imaging modalities.

3. Principles

Changes in the delivery of healthcare brought about by the NHS and Community Care Act, Care Act 2014 – Community Care and the NHS Long Term Plan have resulted in the delegation of some traditionally led tasks to non-medical, but professionally registered professionals. This development has brought with it new opportunities for Nurses, Allied Health Professions (AHP's) and other health and care professionals and builds further on extending practise.

One of the elements of these roles affected by this change has been the need for non-medically qualified referrers (NMR) to be suitably authorised to request appropriate imaging examinations. It is essential that to optimise the benefit of such a development, the associated risks are identified and appropriately managed. As some examinations involve an exposure to ionising radiation ESHT must accept the delegation of such tasks as appropriate and justified in accordance with the Ionising Radiation (Medical Exposure) Regulations 2017.

NMR referring maybe part of a clinical team where they will be acting on a radiology report as opposed to evaluating the image itself, such as in a GP practice. The NMR may also be referring

as an autonomous practitioner who will be reviewing the images (clinical evaluation) and making a decision on patient treatment prior to the radiology report being issued, for example in the Emergency Department. When applicable this will be referenced in the non-medical referrer protocol.

4. Scope

This policy applies to non-medical referrers such as Nurses and Allied Health Professionals working within ESHT and the GP practices within the East Sussex CCG wishing to refer patients for imaging examinations undertaken within ESHT facilities.

Any staff groups such as Physicians Assistants that do not hold professional registration with either the NMC or HCPC cannot be recognised as an NMR and are excluded from this policy.

Individual local agreements with services will be agreed by the Radiology General Manager and authorised by the Radiology Clinical Lead / nominated representative and the Medical Lead or nominated representative for the referring service.

The local agreements will cover:

- Who can request
- How they can request
- What they can request
- In what circumstances (presentation and justification)

5. Definitions/Glossary

APP – Advanced Practice Physiotherapist
CMG – Clinical Management Group
IRMER - Ionising Radiation (Medical Exposure) Regulations 2017
EPR – Electronic patient record
ESHT – East Sussex Healthcare NHS Trust
GP – General practitioner
ICE – Integrated Clinical Environment – order communications software
ICS - Integrated Care Systems
MR scan – magnetic resonance scan
Imaging examinations – referrals for x-rays, CT scan, MR scan, US scan, fluoroscopy procedures
NMR – non-medical referrer
Operator – Radiographer, Sonographer or Radiologist who is responsible for the practical aspects of an imaging examination
Practitioner – Radiologist, Reporting Radiographer or Sonographer who justifies the examination
Protocol – established clinical guideline which states the examination/s authorised
RIS – Radiology Information System
US scan – ultrasound scan
XR – X-ray examination

6. Accountabilities and Responsibilities

The Executive Lead responsible for this policy is the ESHT Chief Executive Officer.

The Radiology General manager is designated as having overall responsibility for ensuring that:

a) all relevant staff are aware of this policy.
b) there are mechanisms in place for providing assurance that the policy is followed.
c) there are written local agreements with the relevant parties and the Imaging Service.
d) non-medical referrer training is available.
e) the record of training and update training is kept centrally within the Imaging Service.

The Modality Leads or Senior Radiographers are responsible for ensuring that radiographic staff in the clinical areas follow this policy.

The Radiographic staff (radiographers and radiologists) have a duty to follow this policy and report any concerns where referrers are referring outside of the agreed scope or are not on the list of approved referrers.

Senior Clinical Managers are responsible for:

a) ensuring that any new or existing requests to refer for imaging examinations are within the scope of the policy and local agreements.
b) the clinical staff referring remain up to date with their non-medical referrers training.

Non-medical referrers are responsible for:

a) referring imaging examinations within the local agreement (applicable NMR protocol).
b) ensuring their non-medical referrer training is up to date.
c) Ensuring the initial four-week period of referring x-rays or first 10 x-rays referred are reviewed by the supervising clinician to ensure that all of the radiological examinations requested by them is appropriate.
d) Perform regular Self-Audit and share the results with the supervising clinician in accordance with section 10 of this policy.

The Imaging Radiation Protection Committee oversees all matters relating to compliance with radiation regulations and will support this policy.

7. Process

Requests for a new agreement to Refer.

a) Any staff requesting to refer must have the support of their CMG, Service or GP practice including approval from a Consultant/GP and Head of Nursing/Head of Service for AHP staff (where appropriate).
b) The referring service must have an NMR protocol for the specific staff group involved or if possible, utilise an existing NMR protocol. If a protocol is not available, the referring service clinical leads must draft one. Once completed the protocol must be approved by the Radiology Radiation Protection Committee before any applications to refer to the protocol can be received.
c) When an approved protocol is in place, an application form (available by sending a request to the radiology referrer generic e-mail account as follows) must be completed and forwarded to the Radiology Referrer generic e-mail account (esht.radiologyreferrers@nhs.net) together with any relevant supporting information e.g. national guidelines, clinical pathways.
d) The request will be discussed with the IRMER Lead practitioner and NMR referral team who will confirm whether the request to refer is accepted.
e) If accepted the Radiology Quality Manager will draw up the local agreement between the Imaging Service and the local service/CMG/GP practice. This agreement will be held with

the Imaging Department policy record and a copy sent to the relevant CMG or ICS Learning hub (for Primary care).

f) If not already completed, the individual(s) will need to undertake non-medical referrers training as detailed in Section 9.
g) Approved referrers will be listed on the approved Non-Medical Referrer register maintained by the Radiology Department.
h) The full process is described in the procedure entitled 'Application and Acceptance Process for Radiology Non-Medical Referrers'.

5.2 Referrer Responsibilities

a) Every request must be fully completed in line with the Imaging Service standards, including the patients' full name, date of birth, address, NHS number, full clinical details and written or electronic signature (where applicable).
b) The imaging examination must only be requested when the results, either positive or negative, will alter patient management.
c) The patient must be given a full explanation of the need for an examination including providing where possible the individual or their representative to be exposed adequate information relating to the benefits and risks associated with the radiation dose from the exposure. Relatives/carers must be involved, especially for some children and patients with capacity issues.
d) The referrer must also consider and disclose to the Radiographer if the patient is known to be, or there is a high risk of pregnancy.
e) The referrer should adhere to the published departmental guidelines regarding appropriate indications for x-ray and ultrasound.
f) High radiation dose examinations such as CT should only be made as part of a multi-disciplinary team or consultant led care. The consultant acting as authorising provider must, as a minimum, be named in the referral.
g) To minimise the risk to our patients and the Trust, the Imaging Service will not accept requests received from non-medically registered staff whom are not on the list of approved referrers or for examinations outside of the local agreement (NMR Protocol). Referrers will be cross-checked against the authorised NMR database.

5.3 Radiology Responsibilities

a) All imaging examinations will be justified by the practitioner or authorised according to protocol by the radiographic staff prior to the examination being performed.
b) If the request does not have sufficient clinical information for the radiographic staff to justify the request according to guidelines, the radiographic staff may contact the referrer to seek clarification (if appropriate) and gain further information. They may also (if applicable) seek the advice of a consultant radiologist prior to carrying out the procedure.
c) Any request that is not justified will be rejected. Primary care - a rejection letter is sent to the surgery by post. Within the hospital - all rejections are rejected by the Radiographer contacting the referrer by phone number or bleep. Any rejection that was rejected through CRIS by the Radiographer should also have a rejection letter sent to the referrer via the internal post.
d) The radiographic staff will ensure that the patient has been correctly identified before proceeding with the examination.
e) For X-rays, the Radiographer will take standard projections in accordance with the Departmental Plain Film Imaging protocols, and additional projections if they believe them to be necessary and appropriate.

5.4 Accountability

The extended role of the non-medically registered referrer requesting imaging examinations is undertaken by the individual on the understanding that:

- Each referrer must work within the scope of practice of their assigned protocol and is personally accountable for his or her own practice.
- Electronic referrals must be made in the name of the Non-Medical Referrer who has assessed the patient. It is not permitted for staff to refer using another colleague's system login.
- Referrers and the Imaging Service adhere to the local agreement (NMR Protocol) that specifies the requesting of appropriate imaging examinations by a non-medically qualified professional.
- A named Consultant or GP (i.e. referrers delegating the task) remain medically responsible for the patients who are examined under this process. The radiology result will be returned to the named responsible consultant (provided an authorising consultant has been listed) or GP.
- Each Non-Medical Referrer undertakes annual audits of their own practice; these audits may be requested periodically for review under IR(ME)R by the Radiology department. If not forthcoming the NMR privilege may be revoked. See section 10.
- To inform the Radiology department of any change of name in order to be compliant with IR(ME)R regulations.
- If the NMR's clinical supervisor changes, it is the responsibility of the NMR referrer to send in a new application form with the name and signature of the new supervising clinician (doctor or consultant). Only once this application is approved can referrals commence under the new supervising clinician.
- A new application form is required for each referring location and must be submitted to radiology for approval. This is to ensure that the supervising clinician is assigned for each location.
- If an existing approved non-medical referrer leaves their approved location of work or job role, the radiology department must be notified using the generic radiology referrer e-mail address (esht.radiologyreferrers@nhs.net).

5.5 Reporting

a) The examination will be reported by a Radiologist/Reporting Radiographer/Sonographer according to departmental procedure unless there is a written agreement to the contrary.
b) It is the responsibility of the health care professional responsible for the patient to ensure that an evaluation of the images/report obtained is recorded in the patient notes.
c) Results acknowledgement: It is the responsibility of the referrer and employing practice to have systems in place to ensure ALL results when returned to a referrer are read, acknowledged, and acted upon. The referring clinician is responsible for informing the patient of their results, positive or negative, and documenting that this has been done in line with NPSA Safer Practice Notice 16 – Early identification of failure to act on radiological imaging reports.

5.6 NMR scope of practice

Each individual NMR protocol contains the referral scope of practice. Additions or changes to the NMR referral scope must be approved by the Trust IRMER Lead Practitioner and the Radiation Protection Committee. If approved the applicable NMR protocol/s must be updated and approved before implementation.

8. Evidence Base/References

IR(ME)R – Ionising Radiation (Medical Exposure) Regulations 2017 and IR(ME)R 2018 Amendment.
NMR protocols (via ESHT Extranet document search, or for community referrers the NMR approval email).

Position Statement on Non-Medical Referrers - British Institute of Radiology (bir.org.uk)

9. Competencies and Training Requirements

6.1 Management and Administration of the Education and Training

a) In order to comply with the requirements under IRMER, all new and existing staff who wish to practice under this policy will be required to undertake a programme of education. This is to ensure that each individual has an appropriate knowledge base to understand the legal and professional responsibility they hold in relation to the IRMER regulations and this document.

b) The Imaging Service will take the lead role in the co-ordination of the radiation protection training programme and will ensure that a rolling programme is maintained.

c) All non-medically registered staff undertaking the extended role of the requesting of imaging examinations must complete a programme of education as specified and a period of training in their workplace appropriate to the role.

d) ESHT requires all non-medical Referrers must have completed the appropriate IR(ME)R training. This consists of initial ½ day training session and then subsequent refresher training 'e-learning for Health' modules every three years thereafter. This training must completed prior to any non-medical referrer requests imaging; these can be found by searching the MyLearn catalogue or e-learning for healthcare for the 'Ionising Radiation (Medical Exposure) Regulations (e-IRMER)'.

IRMER module 02
Management and Radiation Protection of the Patient
Patient Selection
- The Justification of Patient Exposure
- General Radiation Protection

e) e) Following attendance on the ½ day non-medical referrers training course, the non-medical referrer must complete an application form (with the applicants and supervising clinicians signature) which must be forwarded by e-mail to Radiology Referrer team generic e-mail address (esht.radiologyreferrers@nhs.net). Paper copies of the application form will not be accepted.

f) Once the non-medical referrer has been approved by the IRMER Lead Practitioner, access to the electronic referring system will be added to their profile for listed locations enabling them to refer for the locally agreed imaging examinations.

g) All referrers must be assessed and documented as suitable to carry out the tasks described prior to receiving authorisation to practice under this policy.

10. NMR Assessment / Audit

NMR Assessment

The process of assessment will have two parts:
a) Underpinning Knowledge of IR(ME)R, radiation protection and local governance. This knowledge is acquired through the attendance on the initial ½ day NMR training programme which is demonstrated through successful attendance of the session, and thereafter the completion of the My Learn IRMER e-module 2.
b) Supervised Practice after completion of the relevant education. NMR's will be required to undertake clinical practice under supervision. The duration and manner in which this is managed will be specific to the speciality in which the referrer is practising. It is therefore the individual Supervising Clinician / CMG's responsibility to formalise the details of acceptable clinical supervision. The nominated supervising GP or hospital consultant will be recorded against the NMR in the registers held within radiology department.

Assessment of NMR practice competence

- The named GP or consultant currently registered with the GMC with employer status will be responsible for ensuring the NMR is competent.
- An audit will be undertaken by the NMR over an initial four-week period or first 10 imaging examinations to ensure that all of the radiological examinations requested by them is appropriate and encourage reflection on practice under clinical supervision
- The NMR will request a minimum of 10 imaging studies and write in the patient notes which GP/consultant supervised the requests. The NMR will document in the patient's medical notes why and when the x-ray investigation has been ordered will ensure the x-ray result is reviewed by a GP / consultant.
- The named GP/consultant will sign off the NMR as competent if all the requests have been appropriate and indicate this to the Radiology Quality manager who holds the register of approved NMR.
- Random audits will be performed by the Radiology department to ensure competency assessment is maintained. NMR's will be requested to provide evidence of competency in order to maintain approval status.
- Each NMR is responsible for remaining updated on changes in practice and their own clinical knowledge.
- Documentation and evidence will be required and made available if necessary.

Audit

The audit cycle is a vital part of healthcare.
Ongoing audits will be performed to ensure that referred examinations are appropriate to the referrers' scope of practice and the suitability and impact of referrals assessed and actions taken to address any issues that could compromise the overall quality of patient care.
Below are the main two methodologies by which this will be achieved:

1. *Global Data Extraction*
   There will be a periodical overall audit of rejected NMR referrals. The extraction of RIS information will give the trust a view of overall performance. More granularity is accessible where necessary, for instance if there are concerns over a referrer or a protocol. A benchmark of 95% percent will be the initial setting for this approach, in line with other diagnostic benchmarks.
2. *Self-Audit*
   NMRs will carry out self-audit. At its most basic, this will be a pen and paper exercise. In a given session/week, the referrer records a minimum of ten referrals. The number of and reason(s) for rejections are recorded with any data and reflective learning documented as appropriate.

Beyond the above approaches, there may be other exercises, initiated by either radiology or the clinical management of the NMR team.

Based on any findings, radiology will reserve the right to address any concerns. These may range from extra training, through to the withdrawal of referral rights, in accordance with radiation protection legislation and good HR practise.

Re-assessment

NMR will need to undergo reassessment every 3 years if they wish to continue to practice this extended role. An NMR reassessment form (appendix B) must be completed and submitted to the Radiology generic e-mail address (esht.radiologyreferrers@nhs.net) for evaluation within 3 months of the 3 year anniversary of your last approval.

Non-medical referrers who fail to complete the reassessment form and/or training within the designated time frame will be removed from the register and access to the electronic referring system will be removed from the individual's profile.

In the event of a major change in appropriate legislation, it may be necessary for additional training to be carried out within the time limit. In this event, all appropriate parties will be advised of the scope of further training required.

11. Monitoring Arrangements

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Procedure, NMR register, Audit evidence	IRMER Lead Practitioner	Audit tool, document review.	NMR reassessment every 3 years, document control (annual review)	Radiation Protection Committee	Radiation Protection Committee meeting members	Radiation Protection Committee

Appendix A: Equality and Health Inequalities Impact Assessment (EHIA) Form

Public Sector Equality Duty
Public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees.

Public bodies must have due regard to the need to:

- eliminate discrimination
- advance equality of opportunity
- foster good relations.

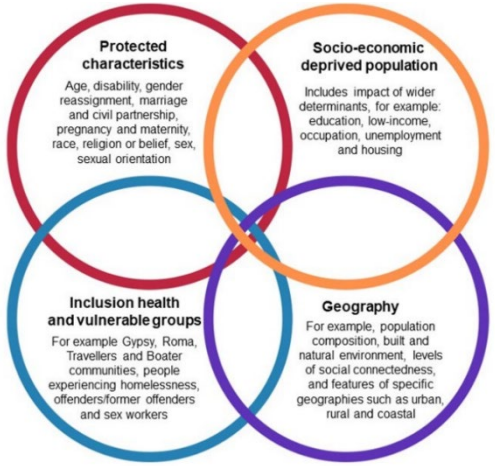
Armed Forces Covenant Duty
The new Covenant Duty raises awareness of how Service life can impact on the Armed Forces community, and how disadvantages can arise due to Service when members of that community seek to access key local services. The Duty requires organisations to pay due regard to the Covenant principles when exercising functions in healthcare. "Due regard" means that we need to consciously consider the unique obligations and sacrifices made by the Armed Forces; that it is desirable to remove disadvantages faced by the Armed Forces community; and that special provision may be justified in some circumstances.

Health Inequalities Duties- Equity for all
In addition to our legal duties in relation to Protected Characteristics, the Health and Social Care Act and other legislation, NHS Planning Guidance and sector specific recommendations require the NHS to have regard to the need to address health inequalities (or differences in access to or outcomes from healthcare) and take specific action to address them.

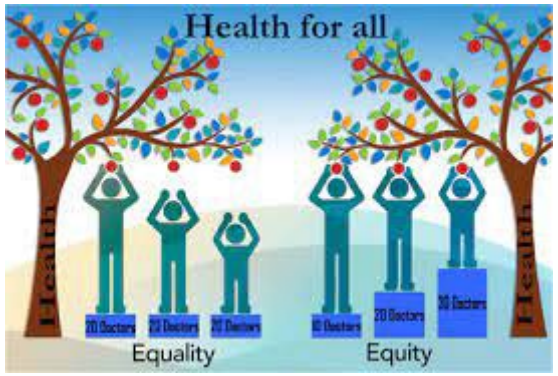
Figure 1 shows the different population groups, factors associated with where we live, or our individual circumstances, which separately, or when combined, influence access to and outcomes from health care.

Getting equal outcomes may require different inputs (or services). In completing an EHIA its important to think about whether a one size fits all approach will generate the same good outcomes for everyone, or whether we might need to make some tweaks or adjustments to enable everyone to benefit equally. The health tree diagram shows that unless we think about the needs of different people, equal services might generate unequal outcomes.

Factors associated with poorer health outcomes (PHE 2021)[1]



The Health Tree[1]



The following principles, drawn from case law, explain what we must do to fulfil our duties under the Equality Act:

- **Knowledge:** everyone working for the Trust must be aware of our equality duties and apply them appropriately in their work.
- **Timeliness:** the duty applies at the time of considering policy options and/or before a final decision is taken – not afterwards.
- **Real Consideration:** the duty must be an integral and rigorous part of your decision-making and influence the process.
- **Sufficient Information:** you must assess what information you have and what is needed to give proper consideration.
- **No delegation:** the Trust is responsible for ensuring that any contracted services which provide services on our behalf can comply with the duty, are required in contracts to comply with it, and do comply in practice. It is a duty that cannot be delegated.
- **Review:** the equality duty is a continuing duty. It applies when a policy/process is developed/agreed, and when it is implemented/reviewed.
- **Proper Record Keeping:** to show that we have fulfilled our duties we must keep records of the process and the impacts identified.

NB: Filling out this EHIA in itself does not meet the requirements of the equality and health inequalities duties. All the requirements above must be fulfilled or the EHIA (and any decision based on it) may be open to challenge. Properly used, an EHIA can be a tool to help us comply with our equality and health inequalities duty and as a record that to demonstrate that we have done so. It is advised that you complete the short EHIA training session on MyLearn before completing this EHIA.

[1] https://www.researchgate.net/figure/Equality-and-equity-of-medical-resources-distribution_fig2_323266914

SECTION A ADMINISTRATIVE INFORMATION

This form is a central part of how the Trust makes sure and can demonstrate to others that we are meeting our legal duties; and how we can assure ourselves that all patients will get the best outcome for them from our services.

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal. **Function/policy/service name and number:**	Policy for the Requesting of Imaging Examinations by Non-medically Qualified Professionals		
Main aims and intended outcomes of the function/policy/service and summary of the changes you are making (if existing policy/service):	The policy will achieve our general equality duty where we will have to demonstrate due regard for advancing equality by: • Removing or minimising disadvantages suffered by people due to their protected characteristics. • Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. • Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low		
How will the function/policy/service change be put into practice?	Ratified document will be available on the Radiology Q-Pulse document management system and Trust intranet		
Who will be affected/benefit from the policy?	The policy will support an equitable and inclusive workplace for our workforce		
State type of policy/service	**Policy √**	Service ☐	
	Business Case ☐	Function ☐	Existing
Is an EHIA required? NB :Most policies/functions will require an EA with few exceptions such as routine procedures	**Yes** √		
	No ☐ (If no state reasons)		
Accountable Director: (Job Title)	Equality Diversity and Inclusion Lead		
Assessment Carried out by:	Name: Ian Diton		
Contact Details:	[redacted]		
Date Completed:	30/01/2024		

SECTION B ANALYSIS AND EVIDENCE

Analysis of the potential impact – Equality and Health Inequalities Duties

For this section you will need to think about all the different groups of people who are more likely to experience poorer access or have poorer outcomes from health and care services. For each group please describe in the first column the potential impact you have identified, in the second column explain how you have arrived at this conclusion and what information you used to identify the potential impact, and in the third column say what you are going to do to prevent it from happening, or which elements of a service or policy specifically address the potential impact. Key things to remember.

- Everyone has protected characteristics but some groups who share one or more protected characteristics may be more likely to have poorer outcomes or access compared with others – and it is this potential that the EHIA process seeks to identify and address.
- The information included here should be proportionate to the type and size of the policy/service/change.
- An update to a policy should demonstrate that you have considered the potential for the policy to impact differently on different groups and taken steps to address that.
- A minor policy update is likely to need to be much less comprehensive than an EHIA for a major service change.
- You will need to know information about who uses or could use your service/policy will apply to (the population). You can use information about current patients or staff, and about the general population the Trust serves.

3. PROTECTED CHARACTERISTICS - Main potential positive or negative impact of the proposal for protected characteristic groups summarised

Please write in the box below a brief summary of the main potential impact (positive or negative) Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below, but make sure you include information on how you know there will be no impact.**

This policy address our legal specific Public Sector Equality Duty (PSED) where we must, in the exercise of our functions, have due regard to the need to: • Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act. • Advance equality of opportunity between people who share a protected characteristic and those who do not. • Foster good relations between people who share a protected characteristic and those who do not.

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Age: older people; middle years; early years; children and young people.	This policy protects staff from all age groups no matter what age they are as outlined in the Equality Act 2010.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	This policy has a positive impact on all staff that have a disability or long term health condition. It links into the (Dis)Ability & Health Passport to enable adequate adjustment to take place and the Carers Passport to achieve a work life balance.	The Workforce Disability Equality Standard, set out by NHS England details the positive association between increased disability equality and workplace experience for disabled individuals.	N/A
Gender Reassignment and/or people who identify as Transgender	This policy has a positive impact on those that are transitioning from their gender assigned at birth to another gender. This policy links into the Gender Recognition Act 2004.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	This policy does not have a negative impact on a member of staffs marital or civil partnership status.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A
Pregnancy and Maternity: before and after childbirth and who are breastfeeding.	This policy has a positive impact on pregnancy, maternity and also including paternity rights with, The Employment Rights Act 1996 which sets out rights to health and safety, time off for antenatal care, maternity leave and unfair dismissal.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A

Protected characteristic groups	Summary explanation of the *potential* positive or adverse impact of your proposal	How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback	Action that will be taken to address the potential for negative impact.
Race:	This policy has a positive impact for all staff regardless of their race or ethnicity.	The Workforce Race Equality Standard, set out by NHS England details how the positive association between increased race equality and workplace experience for disabled individuals.	N/A
Religion and belief: people with different religions/faiths or beliefs, or none.	This policy has a positive impact on all staff the wish to observe religious practices and those that don't.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A
Sex:	This policy has a positive impact on gender and looks at statutory duties under the Gender pay Gap.	The Gender Pay Gap Report details the positive association with gender equality and workplace experience.	N/A
Sexual orientation	This policy has a positive impact on staff no matter what their sexual orientation is.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A
Veterans/Armed Forces Communities	This policy ensures 'due regard' is considered for veterans and the armed forces community.	There is strong evidence that where an NHS workforce is representative of all protected characteristics it fosters a sense of belonging – detailed in the NHS People Plan NHS England » Belonging in the NHS.	N/A

4. HEALTH INEQUALITIES -Potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). **If the policy/procedure is unrelated to patients, this sections does not require completion.**

Please state none if you have assessed that there is not an impact, but please make sure you complete the 'how do you know this' column to demonstrate that you have considered the potential for impact**. If you identify the potential for impact for one or more of these groups please complete the full assessment in Appendix**

Groups who face health inequalities[2]	**Summary explanation of the potential positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
This includes all groups of people who may have poorer access to or outcomes from healthcare services. It includes: People who have experienced the care system; carers; homeless people; people involved in the criminal justice system; people who experience substance misuse or addiction; people who experience income or other deprivation; people with poor health literacy; people living in rural areas with limited access to services; refugees or asylum seekers; people in or who have been in the armed force; other groups who you identify as potentially having poorer access and outcomes.	There is strong evidence that where an NHS workforce is representative of the community that it serves, patient care and the overall patient experience is more personalised and improves.	NHS England » Belonging in the NHS.	N/A

SECTION C ENGAGEMENT

5. Engagement and consultation

a. Talking to patients, families and local communities can be a rich source of information to inform health care services. If you are making substantial changes it's likely that you'll have to undertake specific engagement with patients. For smaller changes and policies your may have undertaken some engagement with patient groups, gained insight from routine sources e.g. patient surveys, PALS or Complaints information or information from Healthwatch, you may also have looked at relevant engagement that others have undertaken in the Trust, or locally
Have any engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	**No X**

b. If yes, please ensure all stakeholders are listed in the consultation table at the beginning of the policy.

SECTION D SUMMARY OF FINDINGS

Reflecting on all of the information included in your review-

6. EQUALITY DUTIES: Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please **add an x** to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?	X	X	X
The proposal may support?			
Uncertain whether the proposal will support?			

7. HEALTH INEQUALITIES: Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	*X*	*X*
The proposal may support?		
Uncertain if the proposal will support?		

8. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1	N/A	
2	N/A	
3	N/A	

9. EHIA sign-off: (this section must be signed)

Person completing the EHIA:	[redacted] **Ian Diton**	**Date:30/01/2024**
Line Manager of person completing:	[redacted] **Melissa Brotherwood**	**Date: 30/01/2024**

Appendix

Breakdown of Groups who are more likely to experience health inequalities:

Groups who face health inequalities[3]	**Summary explanation of the potential positive or adverse impact of your proposal**	**How do you know this? (include here a brief explanation of what information you have used to identify potential adverse impact e.g. NICE guidance, local data, evidence reviews, stakeholder or patient feedback**	**Action that will be taken to address the potential for negative impact.**
Looked after children and young people	N/A		
Carers of patients	N/A		
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	N/A		
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	N/A		
People with addictions and/or substance misuse issues	N/A		
People or families on a low income	N/A		

People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	N/A		
People living in deprived areas	N/A		
People living in remote, rural and island locations	N/A		
Refugees, asylum seekers or those experiencing modern slavery	N/A		
People who have served in the Armed Forces	N/A		
Other groups experiencing health inequalities (please describe)	N/A		

Appendix – EHIA Resources
Sources of Information on the East Sussex population and sources of community or patient insight.

Population Data
State of the County 2021 Focus on East Sussex

East Sussex JSNA

Community Insight

Further Reading on Equality and Health Inequalities

Training

Appendix B: Non-Medical Referrer Reassessment Form

Non-Medical Referrer Reassessment form

As stated in the ESHT Policy for the requesting of imaging examinations by non-medically qualified professionals, please complete and return this form to esht.radiologyreferrers@nhs.net

1	Name of referrer	
2	Registration Body & Number	
3	Name of current supervising clinician (note: if this has changed since your previous application then a new application form is to be completed)	
4	List the applicable protocols to refer radiology examinations.	
5	Location referring from.	
6	Date IRMER refresher training completed and certificate sent to esht.radiologyreferrers@nhs.net	
7	Date self-audit completed.	
	Date completed audit evidence form (included in the NMR protocol) was e-mailed to the Radiology Department (using the following e-mail address esht.radiologyreferrers@nhs.net)	
	Date audit evidence discussed with your supervising clinician	
	Was any corrective action or retraining recommended?	
8	Any changes to your personal details provided on your previous application (e.g. Name change, job role change, etc)?	
9	Any changes that may impact your NMR referrals that the radiology Department may need to be aware of?	
10	Comments	

NMR Signature: _____

Date: _____