East Sussex Healthcare
NHS Trust

Eastbourne District General Hospital
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East Sussex
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FOI REF: 25/661

12th November 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:

Under the Freedom of Information Act 2000, I would like to request the following information relating to the provision of diagnostic imaging services (e.g., MRI, CT, ultrasound) at weekends by [East Sussex Healthcare NHS Trust].

1. Service Provision

a. Please provide details of the Trust's policy and/or operational practice regarding diagnostic imaging services at weekends, specifically:

Mammography - The Trust's policy is that there is no routine breast service at weekends or evenings.

MRI – InHealth MRI at Eastbourne District General Hospital (EDGH) operate 7am-7pm on Saturdays and Sundays. Conquest Hospital run lists on a voluntary bank basis that run to help meet waiting list initiatives.

Ultrasound- USC Head and Neck and Breast patients are booked on an ad hoc basis. Outpatient and General Practitioner lists booked at Bexhill Community Diagnostic Centre (CDC) on Saturdays and Sundays.

General Xray and Interventional Radiology (EDGH) - Weekend diagnostic imaging services are limited to A&E and inpatient cases only. Two diagnostic radiographers are scheduled to work in shifts from 8 am to 8 pm and two from 8 pm to 8 am. Additionally, patient escorts from Temporary Workforce Services are available from 9:00 am to midnight to assist the radiographers.

General Xray, Fluoroscopy, and Interventional Radiology (Conquest Hospital) - Xray imaging out of hours including weekends are provided for urgent imaging of A&E and Inpatients by 2 Radiographers (8 am to 8 pm / 8

pm to 8 am). A support from 1 Radiology Department Assistant is also provided from 9 am to midnight Saturday and Sunday.

Fluoroscopy service cover for Trauma imaging are also provided in Theatres or any other medical emergency (Saturday/Sunday 9 am to 5 pm). Outside of these hours, 1 of the A&E radiographer will cover Theatre emergency imaging.

1 Interventional Radiographer on call (8 am to 8 pm / 8 pm to 8 am) cover is provided for any Urgent IR procedures.

CT imaging out of hours including weekends are provided for urgent imaging of A&E and Inpatients by 2 Radiographers (8 am to 8 pm / 8 pm to 8 am) and 1 RDA. Not all staff are substantively funded. CT access for emergency scans is provided 365 days per year

b. Whether routine or urgent scans are performed on Saturdays and Sundays.

Mammography - The Trust run additional lists on some Saturday mornings, these are for two week waits ad urgent patients.

MRI - USC, urgent and routine patients are booked on Saturdays and Sundays at EDGH. If a Conquest list runs, these cohort of patients are booked.

Ultrasound - USC, urgent and routine patients are booked at Bexhill CDC on Saturdays and Sundays.

CT Scanning - For CT routine booked lists are carried out in line with staffing levels available. Emergency scans are carried out from AE and IP referral sources. Some more routine wards may be scanned at the weekend as 'catch up' if staffing allows when their clinical information does not justify an urgent scan

General X Ray - As above, we X-ray patients from A+E, as well as the wards (urgent/post op etc) irrespective of urgency so as to help with the Trusts bed status.

Eastbourne General Xray and Interventional Radiology - During weekends, one on-call radiographer is available from 8:00 am to 8:00 pm for urgent interventional radiology procedures. Additionally, one cardiac radiographer is on call to cover the cath lab, (8 am to 8 am (24 hours)) In the event of emergency theatre cases, the general radiographer on duty handles the imaging requirements. IR consultant makes final decision if procedure is appropriate.

c. Which departments (e.g., Radiology, Emergency, Oncology) have weekend imaging access.

Mammography The Trust run additional lists on some Saturday mornings, these are for two week waits ad urgent patients.

MRI - InHealth MRI (EDGH) operate 7am to 7pm on Saturdays and Sundays. CQ run lists on a voluntary bank basis that run to help meet waiting list initiatives.

Ultrasound- USC, urgent and routine patients are booked at Bexhill CDC on Saturdays and Sundays.

CT Scanning - CT IP/AE including SDEC. Emergency Oncology patients would usually come through gateway areas that can request for CT.

CT imaging out of hours including weekends are provided for urgent imaging of A&E and Inpatients by 2 Radiographers (8 am to 8 pm / 8 pm to 8 am) and 1 RDA.

General X Ray - As above

Eastbourne General Xray and Interventional Radiology - Radiology, Emergency, all inpatient areas

Interventional Radiology - 24hr on call emergency service, referrals to IR Consultant

d. Staffing levels allocated for imaging at weekends compared to weekdays.

Mammography does not routinely work weekends, we only cover any adhoc clinics, which the Ultrasound department need to run. This is dependent on the size of the list but always 1 Mammographer sometimes 2 are needed.

MRI – EDGH InHealth 2 radiographers and 1 RDA per scanner, 2 scanners running 7 am to 7 pm

Ultrasound- 1 sonographer and 1 RDA per room, 2 rooms operating at Bexhill CDC

Eastbourne General Xray and Interventional Radiology -

2 long day Diagnostic Radiographers
2-night shift Diagnostic Radiographers
1 on-call Interventional Radiographer (8 am to 8 pm)
2 on-call Cardiac Radiographers (8 am to 8 am)
So, a total of 7 each weekend day over 24-hour period
On weekdays – There 15 Radiographers covering the general, interventional department and cath lab during the day with 2 radiographers for general and 1 Radiographer for cath lab overnight in the week.

Conquest General Xray, Fluoroscopy, and Interventional Radiology - Xray imaging out of hours including weekends are provided for urgent imaging of A&E and Inpatients by 2 Radiographers (8 am to 8 pm / 8 pm to 8 am). A support from 1 Radiology Department Assistant is also provided from 9 am to midnight Saturday and Sunday.

Fluoroscopy service cover for Trauma imaging are also provided in Theatres or any other medical emergency (Saturday/Sunday 9 am to 5 pm). Outside of these hours, 1 of the A&E radiographer will cover Theatre emergency imaging.

1 Interventional Radiographer on call (8 am to 8 pm, 8 pm to 8 am) cover is provided for any Urgent IR procedures.

Conquest General Xray staffing: - Weekdays

2 staff covering Emergency services from 8 am to 8 pm.
2 staff covering Theatre Imaging from 8.30 am to 5 pm.
1 staff covering Theatre Imaging out of hours from 11 am to 7 pm.
1 staff covering Portable imaging from 8.30 am to 5 pm.
6 staff covering Inpatient and Outpatient Xray imaging from 8.30 am to 5 pm.
1 staff covering Vetting responsibilities of all requests

Conquest Interventional and Fluoroscopy staffing: - Weekdays

2 staff covering from 8.30 am to 5 pm.

Nuclear Medicine do not have access to 99mTc Radiopharmaceuticals at weekends.

Routine non 99mTc imaging is undertaken on Saturdays 8 am to 5 pm.

DAT scans are scanned 1st Saturday each month. This is the only Saturday they can be delivered by supplier.

SeHcats are scanned over 2 Saturdays per month.

2 Radiographers cover each duty. Only walk in patients that require no additional support are booked.

Weekday shifts require 3 Radiographers as workload is much greater.
Duties are voluntary.

CT Scanning. CT at both sites only has funding for emergency service cover at weekends, but staff work on Bank so that as full lists as staffing allows are run. Essentially staffing for emergency scans is no different to the weekdays. Any voluntary staff will make up staffing to scan additional routine Outpatient scans (2nd staffing expansion plan is being put together now, to aim for full substantive staffing of all scanners for full 8-8 hours all weekend)

General X Ray - 2 Radiographers are rostered to each 12-hour shift, day and night. RDA support is available from 8.30 am to midnight each day.

2. Refusals and Limitations

a. Has the Trust refused or limited weekend scanning for non-emergency/Urgent patients in the past 12 months?

Mammography-none

MRI – Conquest, due to staffing challenges

Eastbourne General Xray and Interventional Radiology - None.

Conquest General Xray, Fluoroscopy, and Interventional Radiology - None.

Nuclear Medicine - No.

General X Ray - As long as each request is justified, and equipment uptime is maintained then we have not introduced any additional rules to limit imaging at weekends for A+E or In-Patients.

CT Scanning - IRMER states all radiation exposures need to be clinically justified in accordance with departmental protocols most of which follow RCR and NICE guidance. Audits are performed to ensure compliance with relevant NICE guidance, but we do not have the ability to track all non-justified requests at present.

b. If so, please provide the rationale or policy documents related to this decision.

CT Scanning and General X Ray - Please see the attached policy and note the following exemptions have been applied.

The Trust also follows The Royal College of Radiologists (RCR), NICE Guidelines, as per the attached list, Care Quality Commission 'Ionising Radiation Regulations' and guidelines from our insourcing provider.

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 documents.

Section 40(2) has been applied to the names of individuals that do not work for the Trust and contact details, and these have therefore been reacted from the attached documents.

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 this information may allow the identification of

individuals and disclosure 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.

Section 31(1)(a) has also been applied to the names of the Trust IT systems within this document; therefore, these have also been redacted.

Under Section 1(1)(a) of the Freedom of Information Act (FOIA), the Trust can confirm that it holds information relevant to your request, however, we are unable to disclose it for the reasons explained below.
Historically, we would disclose information relevant to the Trust's IT systems, infrastructure and software as part of our transparency agenda under the terms of the Freedom of Information Act (FOIA). However, in light of the recent cyber-attacks on NHS hospitals and the serious impact these have had on patient services and the loss of patient data, we are having to reconsider this approach. Please see several links to news articles about these recent cyber incidents provided below for your information.

- *NHS England — London » Synnovis Ransomware Cyber-Attack*
- *NHS England confirm patient data stolen in cyber attack - BBC News*
- *Merseyside: Three more hospitals hit by cyber attack - BBC News*

As a result of these attacks, thousands of hospital and GP appointments were disrupted, operations were cancelled, and confidential patient data was stolen which included patient names, dates of birth, NHS numbers and descriptions of blood tests.

When we respond to a Freedom of Information request, we are unable to establish the intent behind the request. Disclosure under the FOIA involves the release of information to the world at large, free from any duty of confidence. Providing information about our systems or security measures to one person is the same as publishing it for everyone. While most people are honest and have no intention of misusing information to cause damage, there are criminals who look for opportunities to exploit system weaknesses for financial gain or to cause disruption.

In the context of the FOIA, the term ''public interest'' does not refer to the private or commercial interests of a requestor; its meaning is for the "public good". The Trust receives a significant number of requests each year regarding our IT systems, infrastructure and cyber security measures. Most of these requests are commercially driven and serve no direct public interest. Information relevant to our IT portfolio is often requested by consultancy companies who then pass on this information to their client base. Many of these requests are submitted through the FOI portal whatdotheyknow.com who publish our responses, making this information available to an even wider audience.

As a large NHS Trust we hold extensive personal data relevant to our patients and staff, much of which is considered very sensitive. A lot of this information is held electronically on various administration and clinical systems. We have a duty under the Data Protection Act 2018 and the UK GDPR to protect this personal information and take all necessary steps to ensure this data is kept safe. This means not disclosing information that could allow criminals to gain unlawful access to our systems and infrastructure. The Trust can be heavily fined should it be found to have acted in a negligent way which results in a personal data breach. We need to demonstrate that we comply with our legal obligations under data protection and freedom of information legislation, but we must be careful that too much transparency does not result in harm to our patients or staff, or cause disruption to our services.

Moreover, under the Network and Information Systems (NIS) Regulations Act 2018, operators of essential services such as NHS organisations like ours have a legal obligation to protect the security of our networks and information systems in order to safeguard our essential services. By releasing information that could increase the likelihood or severity of a cyber-attack, the Trust would fail to meet its security duties as stated in section 10 of the Network and Information Systems Regulations 2018. Should we not comply with these requirements regulatory action can be taken against the Trust. Further information about the Network and Information Systems (NIS) Regulations Act 2018 can be found here – The Network and Information Systems Regulations 2018: guide for the health sector in England - GOV.UK

Your request asks for policy documents related to radiology which unfortunately mention specific details regarding our IT Systems which, for the reasons explained above, would be inappropriate to release into the public domain. If disclosed, it is possible that patient data as well as other confidential information would be put at risk. Such disclosure could also impact on the security of our systems and result in serious disruption to the health services we deliver to the local community. Section 31(1)(a) of FOIA provides that information is exempt if its disclosure would, or would be likely to, prejudice (a) the prevention or detection of crime. In this case, disclosure would be likely to prejudice the prevention of crime by enabling or encouraging malicious acts which could compromise the Trust's IT systems and infrastructure. The Trust's capacity to defend itself from such acts relates to the purposes of crime prevention and therefore section 31(a) exemption is applicable in these circumstances. For these reasons, the Trust considers disclosure of the information you are seeking to be exempt under section 31(1)(a) [*law enforcement*] of the FOIA and the names of the systems within the policies, procedures, or guidance documents is being withheld. The full wording of section 31 can be found here: Freedom of Information Act 2000

Section 31 is a *qualified* exemption and therefore we must consider the prejudice or harm that may be caused by disclosure of the information you have requested, as well as apply a public interest test that weighs up the factors in maintaining the exemption against those in favour of disclosure.

In considering the prejudice or harm that disclosure may cause, as explained should the Trust release information into the public domain which draws attention to any weaknesses relevant to the security of our systems or those of a supplier, this information could be exploited by individuals with criminal intent. Increasing the likelihood of criminal activity in this way would be irresponsible and could encourage malicious acts which could compromise our IT systems or infrastructure, result in the loss of personal data and/or impact on the delivery of our patient services. We consider these concerns particularly relevant and valid considering the increasing number of cyber incidents affecting NHS systems in recent years and the view by government, the ICO and NHS leaders that the threat of cyber incidents to the public sector is real and increasing.

- Organisations must do more to combat the growing threat of cyber attacks | ICO

In the Government's Cyber Security Strategy 2022-2030, the Chancellor of the Duchy of Lancaster and Minister for the Cabinet Office states on page 7: *"Government organisations - and the functions and services they deliver - are the cornerstone of our society. It is their significance, however, that makes them an attractive target for an ever-expanding army of adversaries, often with the kind of powerful cyber capabilities which, not so long ago, would have been the sole preserve of nation states. Whether in the pursuit of government data for strategic advantage or in seeking the disruption of public services for financial or political gain, the threat faced by government is very real and present.*

Government organisations are routinely and relentlessly targeted: of the 777 incidents managed by the National Cyber Security Centre between September 2020 and August 2021, around 40% were aimed at the public sector. This upward trend shows no signs of abating."

With this in mind, we then considered the public interest test for and against disclosure. It should be noted that the public interest in this context refers to the public good, not what is 'of interest' to the public or the private or commercial interests of the requester. In this case we consider the public interest factors in favour of disclosure are:

- Evidences the Trust's transparency and accountability
- Provides information relevant to the IT systems and applications the Trust uses
- Reassures the public and partners that the Trust procures these systems in line with Procurement legislation
- Reassures the public and partners that the Trust's IT infrastructure and systems are secure

Factors in favour of withholding this information are:

- Public interest in crime prevention
- Public interest in avoiding disruption to our health services
- Public interest in maintaining the integrity and security of the Trust's systems
- Public interest in the Trust avoiding the costs associated with any malicious acts (e.g. recovery, revenue, regulatory fines)
- Public interest in complying with our legal obligations to safeguard the sensitive confidential information we hold

In considering all of these factors, we have concluded that the balance of public interest lies in upholding the exemption and not releasing the information requested. Although disclosure would provide transparency about our software systems and IT infrastructure, this is outweighed by the harm that could be caused by people who wish to use this information to assess any vulnerabilities in our security measures and consequently use this information for unlawful purposes. Cybercrime can not only lead to major service disruption but can also result in significant financial losses. As a publicly funded organisation, we have a duty for ensuring our public funding is protected and spent responsibly. Moreover, as a public body the Trust must demonstrate that it keeps its confidential data and IT infrastructure safe and complies with relevant legislation, but at the same time we must be vigilant that transparency does not provide an opportunity for individuals to act against the Trust. In considering the impact that recent cyber-attacks have had on NHS services, including the cancellation of thousands of patient appointments and procedures as well as the loss of confidential patient data, we consider the overriding public interest lies in withholding this information. The private or commercial interests of a requester should not outweigh the public interest in protecting the integrity of our systems and continuity of our essential patient services. Although we appreciate there may be legitimate intentions behind requesting this information, we must take a cautious approach to requests of this nature and appreciate your understanding in this matter.

It is important to note that the Trust and its commissioning partners are required to follow very specific rules when procuring equipment or services. Information about procurement and tendering can be found on our website – Governing documents, incorporating: Standing Orders, Standing Financial Instructions, Scheme of Delegation.

To contact the Procurement Service, please email - esht.procurement@nhs.net

3. Impact on Patients

Any internal reports, assessments, or audits (from the last 2 years) evaluating the impact of limited/no weekend scanning on:

a. Patient waiting times.

Nuclear Medicine - 4 - 6 weeks.

General X Ray - We image all patients that are justified from within the Trust (A+E/In-patients)

b. Diagnosis delays.

Mammography - Not applicable.

General X Ray - Patient waiting times fluctuate depending on demand (increasing the number of referrals in a short space of time will increase short term waits), availability of Porters to transfer patients, and equipment uptime (currently well over 95%).

CT Scanning - Patient waiting times fluctuate depending on demand (increasing the number of referrals in a short space of time will increase short term waits), availability of Porters to transfer patients, and equipment uptime (currently well over 95%)

c. Treatment outcomes.

Not applicable.

d. Patient complaints or incidents related to scanning delays.

Clarification was sought asking you to confirm the timeframe and confirmation was received that you require the following:

Please can I have the request for the 2 Financial year's 2023/24 and 24/25.

We received no complaints during the period requested.

Please see the table below for the number of incidents reported for each of the requested years, by the level of harm assessed by the reporter:

Level of Harm	2023/24	2024/25
Severity 1 – None/Near Miss	5	12
Severity 2 – Minor	1	3
Severity 3 – Moderate	1	0
TOTALS	**7**	**15**

All 22 incidents were reviewed by an appropriate manager and where necessary, learning was identified for implementation.

4. Exceptions and Escalation

a. Circumstances in which weekend scans can be performed outside the usual schedule.

CT Scanning and General X Ray - If a referral is not accepted by a Radiology Registrar or Medica then referrers can go to the Interventional Radiologist on call to discuss

b. Escalation processes for clinicians seeking urgent imaging at weekends.

Mammography - Not applicable.

MRI – Referral to be discussed with Radiologist and MRI dept

Eastbourne General Xray and Interventional Radiology - Not applicable as out-of-hours services are already covered by existing staffing arrangements.

Conquest General Xray, Fluoroscopy, and Interventional Radiology- Not applicable as out of hours service for Xray and Fluoroscopy are provided.

Nuclear Medicine - Not applicable

CT Scanning - If a referral is not accepted by a Radiology Registrar or Medica then referrers can go to the Interventional Radiologist on call to discuss

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

Document ID Number	502
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:	13 November 2023
Review date:	September 2024
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	Lynne Bradford, 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 [redacted] 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	[redacted] Chris Salt Victoria Rowse	Update	EP-09 Pregnancy and Breastfeeding Protocol. Updated to reflect latest guidance. 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 [redacted]	ESHT IRMER Practitioner Consultant Radiologist Radiology Clinical Lead SMSKPE Clinical Director	February 2023 (July 2022 & February 2023 Radiation Protection Committee Meeting)
[redacted] Neil Barlow [redacted] Chris Salt Victoria Rowse	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.

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 courses 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 [redacted].)

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 [redacted], 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	[redacted] 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 [redacted])	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 - [redacted]	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 [redacted] 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 [redacted] 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 [redacted] 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 [redacted].
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 [redacted] 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 [redacted] 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 [redacted] 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 [redacted] entry. The Operators will also be required to confirm completion of the procedure on [redacted].

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

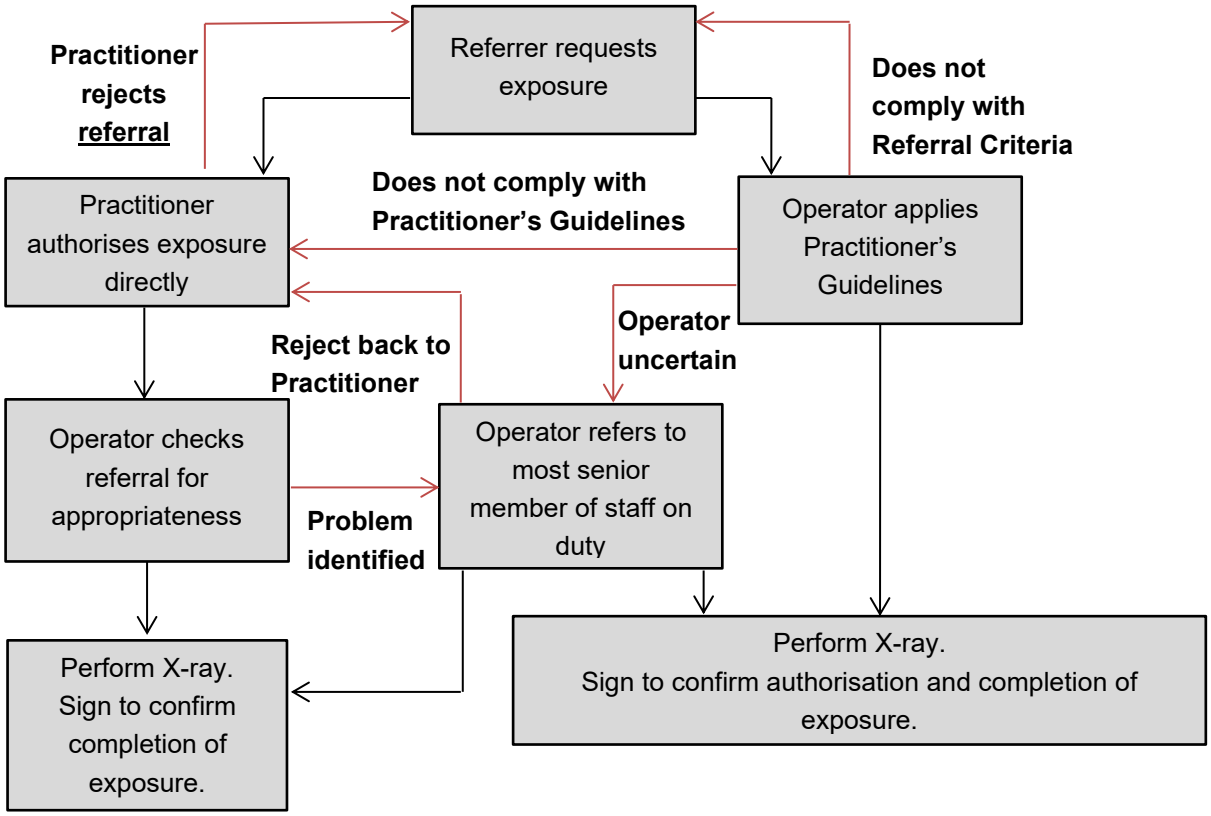
After the exposure has been completed, all relevant information must be recorded on the [redacted], on the patient request form, in the imaging logbook, or in the patient's notes, including information relevant to the calculation of a patient dose (see *EP-14 Estimation of Patient Dose and Population 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 [redacted]
- Enter these details on [redacted] 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 [redacted] 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 are 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 [redacted] 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 [redacted])
- 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 [redacted] for imaging history)
- If so, when and what?

The patient will then be registered on HIS[redacted] 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 [redacted] 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 ([redacted]) 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 may be, 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

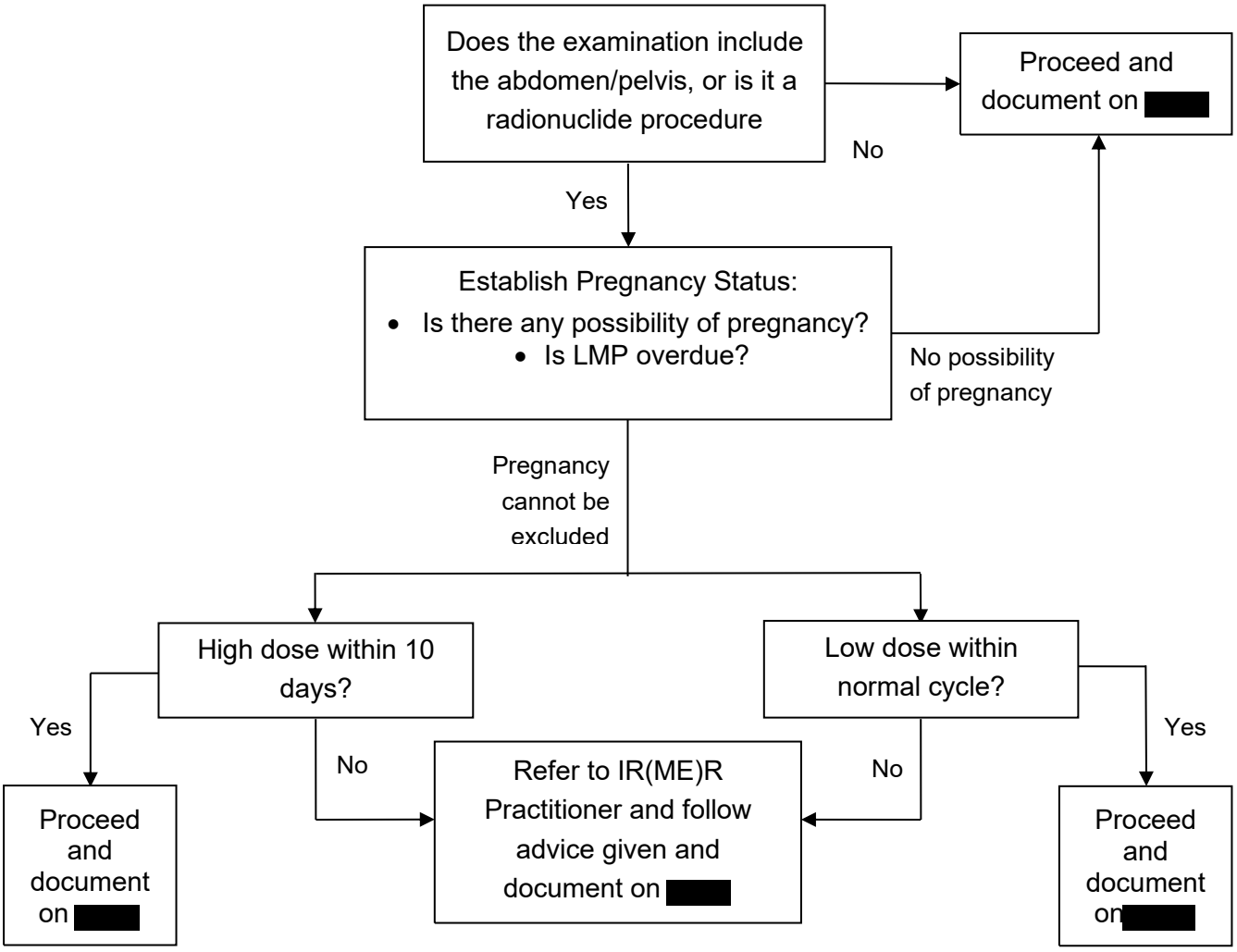
Where relevant, it is the Radiographer's responsibility to confirm that an individual of childbearing potential in theatre who requires imaging, is not pregnant (The result of the pre-op pregnancy test is available in the patient's pre-op checklist document).

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 [redacted] 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 [redacted]. 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

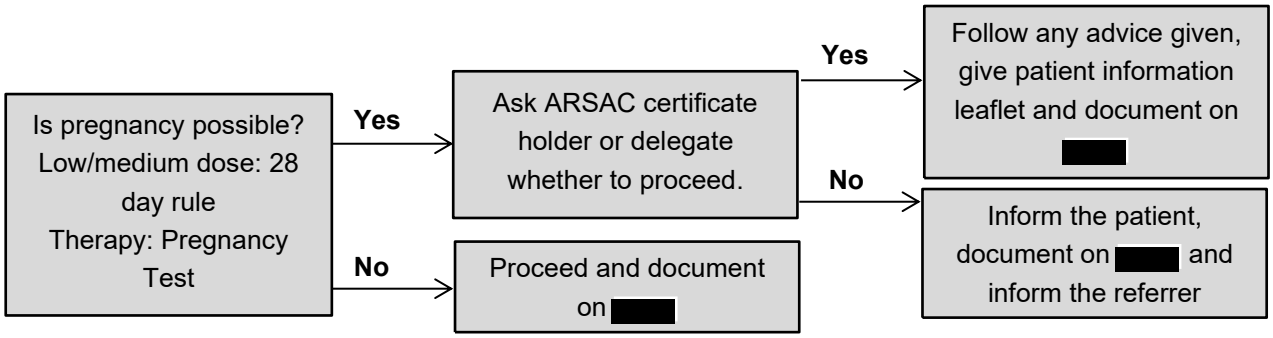
- Imaging of patients outside the 10/28 day rule will only proceed if the need for diagnostic information outweighs the clinical risk of ionising radiation to a potential foetus.
- This will be a clinical decision made by a suitable IRMER practitioner.
- The decision to proceed will be documented on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

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 [redacted]

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 [redacted] 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 [redacted] (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 [redacted] 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 [redacted] 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 [redacted]). 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 [redacted] 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 [redacted]) 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 [redacted] 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 [redacted] 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 [redacted] 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 ([redacted]) 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 [redacted] 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 [redacted] 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 [redacted] 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. 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

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<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
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Negative</td><td>
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<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>
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<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>
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Neutral
Negative</td><td></td></tr>
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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>
What considerations have been put in place to consider the organisations approach on improving equality and diversity in the workforce and leadership?	Choose: Positive Neutral Negative	Click here to enter text.
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>
Access Could the proposal impact positively or negatively on any of the following:		
• Patient Choice	Choose: Positive Neutral Negative	

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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>
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Neutral
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<td>Equality Consideration Highlight the protected characteristic impact or social economic impact (e.g. homelessness, poverty, income or education)</td>
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<tr><th>Race</th><th>Gender</th><th>Sexual orientation</th><th>Age</th><th>Disability & carers</th></tr>
<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
<tr><th>Gender reassignment</th><th>Marriage & Civil Partnership</th><th>Religion and faith</th><th>Maternity & Pregnancy</th><th>Social economic</th></tr>
<tr><td>☐</td><td>☐</td><td>☐</td><td>☐</td><td>☐</td></tr>
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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

4. 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	[redacted]	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[redacted]	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

5. 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 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:-

[redacted]

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 [redacted]

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

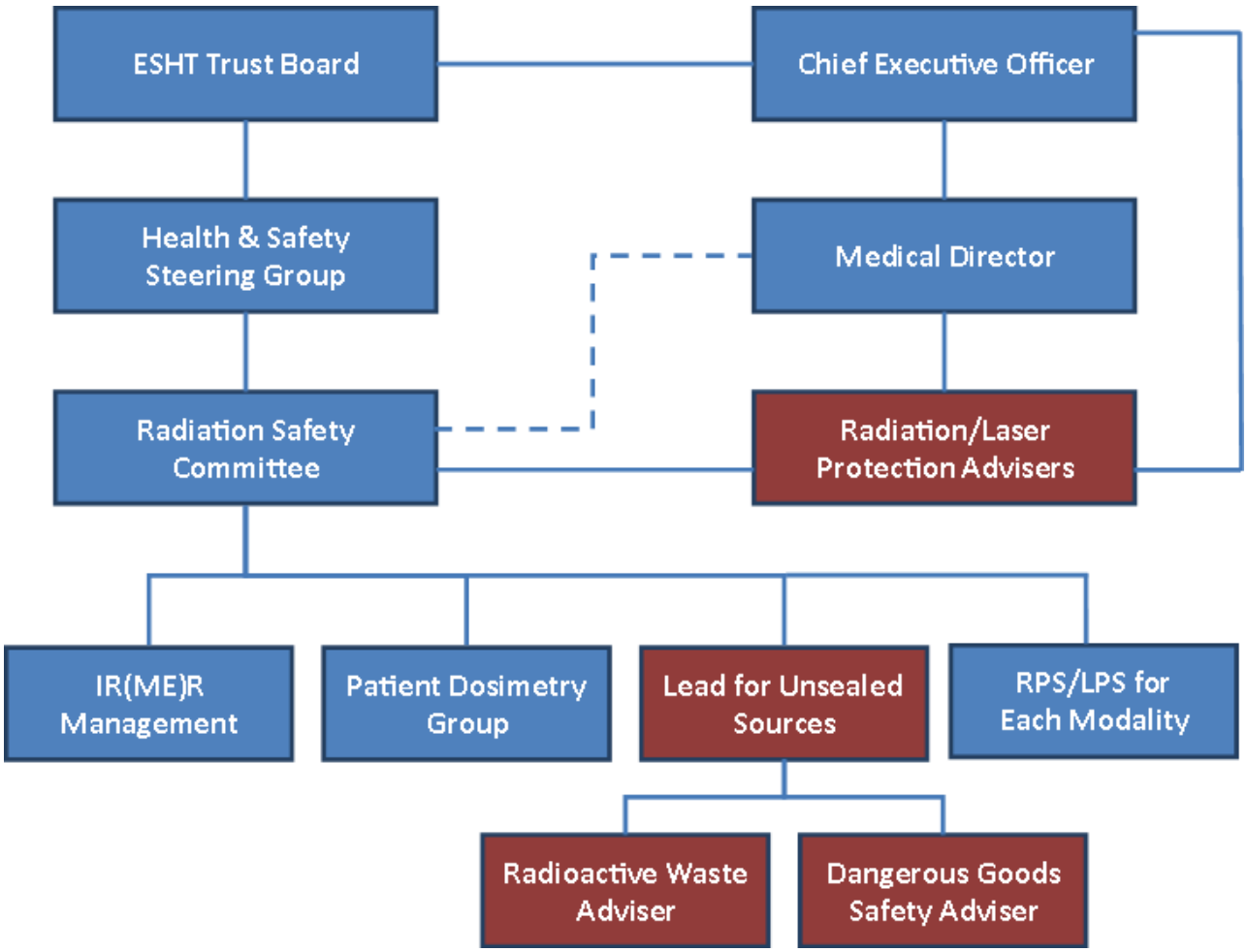
DATE:……

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 [redacted]

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

Radiography/Fluoroscopy:

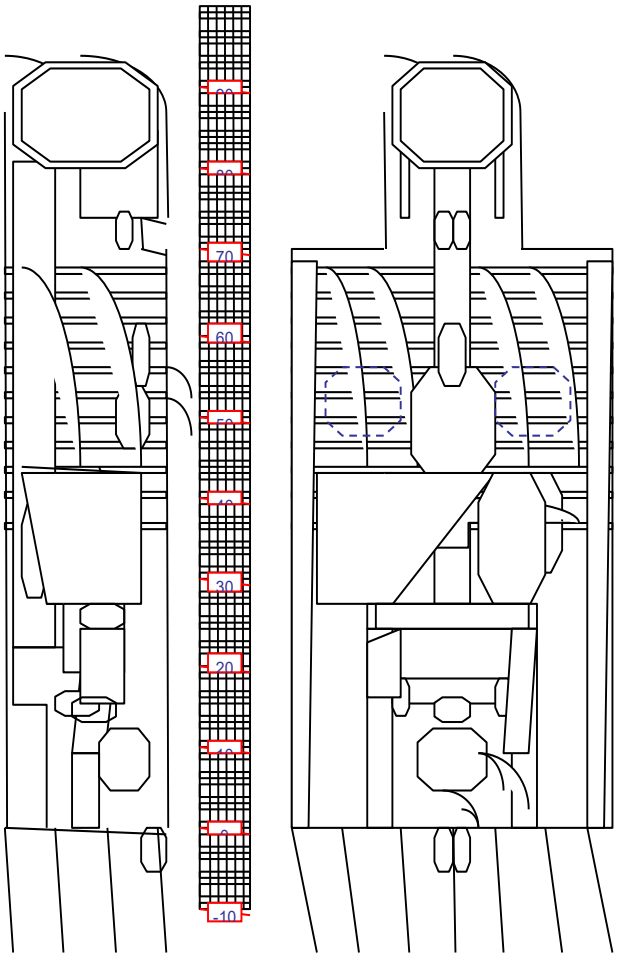
Examination (include view as well as L or R)	Tick if *non* standard coverage	kV	mAs	Time	Post Exposure mAs	AEC or Manual Exposure?	EI	Intended Exp Yes/No	Plate Size	Focus to *Skin* dist cm (estimate)	Actual DAP Number	DAP units	Shielding? Where?

* 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 [redacted]
Dose Constraint	Applies only to subjects ***not*** receiving any benefit from the exposure.(i.e. additional care exposures). If the constraint is exceeded a [redacted] 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 [redacted]

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.

Applicable NICE Guidelines CT MRI (not all apply to both modalities. May not be complete!)

NG12 Suspected cancer: recognition and referral
NG158 Venous thromboembolic diseases: diagnosis, management and thrombophilia testing
NG41 Spinal injury: assessment and initial management
NG232 Head injury: assessment and early management
NG122 Lung cancer: diagnosis and management
NG2 Bladder cancer: diagnosis and management
NG101 Early and locally advanced breast cancer: diagnosis and management
NG131 Prostate cancer: diagnosis and management
NG85 Pancreatic cancer in adults: diagnosis and management
NG35 Myeloma: diagnosis and management
CG75 Metastatic spinal cord compression in adults: risk assessment, diagnosis and management
CG81 Advanced breast cancer: diagnosis and treatment
NG115 Chronic obstructive pulmonary disease in over 16s: diagnosis and management
NG147 Diverticular disease: diagnosis and management
CG104 Metastatic malignant disease of unknown primary origin in adults: diagnosis and management
NG52 Non-Hodgkin's lymphoma: diagnosis and management
CG122 Ovarian cancer: recognition and initial management
NG83 Oesophago-gastric cancer: assessment and management in adults
NG230 Thyroid cancer: assessment and management
NG36 Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over
NG51 Sepsis: recognition, diagnosis and early management
NG14 Melanoma: assessment and management
NG47 Haematological cancers: improving outcomes
NG151 Colorectal cancer
NG104 Pancreatitis
NG99 Brain tumours (primary) and brain metastases in over 16s
DC3 New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners

CG147 Peripheral arterial disease: diagnosis and management
NG128 Stroke and transient ischaemic attack in over 16s: diagnosis and initial management
NG39 Major trauma: assessment and initial management
NG156 Abdominal aortic aneurysm: diagnosis and management
NG148 Acute kidney injury: prevention, detection and management
NG37 Fractures (complex): assessment and management
NG118 Renal and ureteric stones: assessment and management
NG127 Suspected neurological conditions: recognition and referral
NG19 Diabetic foot problems: prevention and management
NG65 Spondyloarthritis in over 16s: diagnosis and management
NG38 Fractures (non-complex): assessment and management
NG59 Low back pain and sciatica in over 16s: assessment and management
NG73 Endometriosis: diagnosis and management