Dorset County Hospital NHS Foundation Trust

IR(ME)R 2017 Employers Procedures

DCHFT EP14 THE MANAGEMENT OF INCIDENTS RELATING TO THE USE OF IONISING RADIATION

Policy Title	IR(ME)R 2017 Employers Procedures - DCHFT EP14 The Management of Incidents Relating to the Use of Ionising Radiation		
Policy Number	**2144**	**Policy Version Number**	**2**
Applicable to	All Trust staff.		
Aim of the Policy	Covers the arrangement and management of incidents relating to the use of ionising radiation as required under the Ionising Radiation (Medical Exposures) Regulations 2017 (IRMER17) and the Ionising Radiations Regulations 2017 (IRR17).		
Next Review Due Date	**01 July 2026**		
Author/ Reviewer	James Thurston, Lead Healthcare Scientist to the Trust & Head of Medical Physics & Healthcare Technology		
Policy Sponsor	Dr Rajintha Malavige, Consultant Radiologist		
Expert Group	Trust Medical Exposures Group		
Date Approved	07 July 2024		
Date First Published	22 March 2022		
Primary Specialties	Trustwide; Medical Physics		

Document Version Management

Version	Date	Reviewer	Description of Change(s)
1	Jul-2024	J Thurston	Update on procedure and Appendix 4.

IRMER17[1], Schedule 2, Regulation 6, Employer's Procedures, 1.(l):

This Employer's Procedure covers the arrangement and management of incidents relating to the use of ionising radiation as required under the Ionising Radiation (Medical Exposures) Regulations 2017 (IRMER17) and the Ionising Radiations Regulations 2017 (IRR17).

Introduction

The Ionising Radiations Regulations 2017 (IRR17)[2] and the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)[1] require the establishment of procedures for investigation and reporting and possible notification of radiation incidents involving patients, staff or members of the public. It is a duty of all staff involved in the process of the exposure of patients to ionising radiation to ensure that these exposures are no greater than intended. However, in the event of an incident, this Employer's Procedure should be followed.

This Procedure deals with situations where a known or suspected radiation incident has occurred. The incidents covered are those caused by:

- equipment malfunction:
- failure of procedure;
- failure to follow procedures;
- inappropriate professional judgement;
- human error.

Any type of radiation incident must be reported to the Radiation Protection Supervisor (RPS) and Modality Manager/Lead as soon as possible.

Guidance from the Care Quality Commission (CQC)[3] states that "When there is an accidental and unintended exposure to ionising radiation, and the employer knows or suspects that it is significant, they must investigate the incident and report it to the appropriate UK IR(ME)R enforcing authority under Regulation 8(4)." The CQC categorises Significant accidental or unintended exposures (SAUE) as:

"Accidental exposure: an individual has received an exposure in error when no exposure of any kind was intended."

"Unintended exposure: although the exposure of an individual was intended, the exposure they received was significantly greater or different to that intended. For example, an error in the dose received, or there may have been an error in either the modality or technique carried out, anatomy or timing of exposure. These can happen for many reasons including procedural, systematic or human error."

The reporting individual may also consider an imaging study to be suboptimal or incomplete, which would require the patient to be recalled for a repeat examination. These can happen for many reasons including procedural, systematic or human error.

Guidance as to what constitutes a 'clinically significant' unintended or accidental exposure has been taken from a British Journal of Radiology commentary. A **clinically significant unintended or accidental exposure** has been taken to include:

1. Any incident that has resulted in demonstrable moderate clinical harm or greater to the patient affected (e.g. a laterality error resulting in wrong side being treated).
2. A radiation incident resulting in an additional effective dose to the patient affected of 20mSv or more.
3. A radiation incident resulting in an additional skin absorbed dose of greater than 2Gy, or an eye lens absorbed dose of greater than 0.5Gy.

Examples of each type of incident are detailed in the following sections.

1. Procedural or referral errors resulting in an ionising radiation incident

There are various IRMER Operators working within the Trust including radiographers, radiologists, physicists, surgeons and cardiologists. Procedural errors will happen in healthcare organisations. It is therefore extremely important that staff recognise the importance of reporting all such incidents and that they can do so openly and transparently, and in a supportive environment. Reporting of and follow-up of errors allows the healthcare team to learn from mistakes and improve working practice.

The Royal College of Radiologists has published the report on behalf of the Clinical Imaging Board (CIB) of a working party on learning from incidents and near misses involving medical radiation, including a taxonomy and coding system for categorising all such incidents – both reportable and non-reportable. For reportable incidents, the CQC will then expect the SAUE taxonomy and coding to be used in the notification (see section on "Criteria for reporting incidents to the CQC" below).

Examples of procedural errors include:

- Imaging or performing therapy on the wrong patient
- Not checking previous history risking duplication of procedure
- Omitting pregnancy status checks
- Imaging or performing therapy on the wrong part of the body (site/side)
- Incorrect exposure set
- Incorrect detector selected
- Accidental exposure of another member of staff

Use of the Trusts IRMER Employers Procedures and justification process reduce risk of accidental patient over exposure. Local Rules should mitigate the risk of overexposing staff and members of the public. Diagnostic radiography staff are required to adhere to the Society of Radiographers pre and post examination check list, known as 'PAUSED' (Local version "Pause and Check).

Examples of errors or incorrect information occurring in the referral include:

- the wrong patient demographics
- the wrong type of imaging or therapy modality
- laterality errors (i.e. wrong side requested)
- the wrong body part

Mistakes made in the referral process are not infrequent in diagnostics. All have the potential to give a patient a radiation dose much greater than intended. It is important to keep a record of **all** errors to help determine any patterns in reporting errors.

REPORTING A PROCEDURAL OR REFERRAL INCIDENT

ANY procedural mistake that results in a patient, member of staff or member of the public receiving a radiation dose higher than intended must be reported as follows:

- Staff involved must inform the modality manager/lead and RPS as soon as possible.
- The patient or their representative should be informed as soon as possible. If staff feel unable to do this, they should ask the most senior person present to assist. If the incident is not noticed until after the patient has left the hospital, it may be more appropriate for the Referrer to speak to the patient. If moderate harm or greater has occurred, then this communication must follow the Trust's Duty of Candour Process (see the Duty of Candour guidance section).
- Staff involved must complete a DATIX (categorizing it as a radiation incident) and a Radiation Incident Report (see Appendix 2 for example of form suitable for diagnostic radiology).
- For a patient overexposure, the Trust's MPE should be informed as soon as possible, as should the Practitioner and the Referrer.
- For an overexposure of staff or a member of the public, the Trust RPA must be informed as soon as possible. The dosimeter for that member of staff can be sent back to Landauer for an emergency read, or the dose can be estimated if it is to a member of the general public or a member of staff that does not wear a dosimeter.
- The investigation is then undertaken by RPS, MPE or RPA, modality manager and /or clinical lead. Consideration should be made as to whether the incident is reportable to the CQC or HSE. The person responsible for this communication depends on the agency involved but it must be done ASAP and in any case no longer than 2 weeks after the incident occurred. The flow chart detailing the communication process that should be followed for any radiation incident can be found in Appendix 1.
- All staff directly involved in the incident should fill in a Reflective Practice Statement (Appendix 3).

The modality manager/lead is responsible for ensuring that each step in this process is followed.

2. Equipment errors resulting in an ionising radiation incident

There are many items of equipment around the Trust that use ionising radiation. Each item of equipment comes with electronic and mechanical fail-safes to prevent accidental overexposure of patients and staff. All items of equipment are also part of a quality assurance programme. Despite this, equipment errors may occur and have the potential to give both staff and patients an overexposure to ionising radiation.

Examples of equipment errors include:

- Non termination of exposure following release of exposure switch
- Image "lost" on modality causing re-imaging
- Failure to reconstruct image after exposure has been made

The CQC guidance[3] states that the term 'equipment' not only includes equipment that delivers radiation but also ancillary equipment that directly influences the dose to the individual. This can include, but is not limited to:

- contrast injectors;
- software including artificial intelligence programmes;

- picture archiving and communication systems (PACS) and radiology information systems (RIS) or similar.

REPORTING AN EQUIPMENT RELATED INCIDENT

If an Operator suspects that a piece of equipment has malfunctioned and exposed a person (patient, member of staff or member of the public) to a radiation dose greater than intended, an immediate investigation must be carried out as follows:

- The Operator must inform the modality manager/lead and RPS as soon as possible.
- The RPS or manager/lead should liaise with the MPE or RPA to determine if the equipment should be taken out of action.
- If appropriate, a notice should be placed on the piece of equipment informing other staff not to use the equipment. Any attending equipment engineer must be informed that the fault led to a radiation incident.
- The patient or their representative should be informed as soon as possible. If you feel unable to do this yourself, ask the most senior person present to assist. If the incident is not noticed until after the patient has left the hospital, it may be more appropriate for the Referrer to speak to the patient. If moderate harm or greater has occurred then this communication must follow the Trust's Duty of Candour Process (see the Duty of Candour guidance section).
- Staff involved must complete a DATIX report (online) and Radiation Incident Report (see Appendix 2 and 3**).**
- For a patient overexposure the Referrer should be notified.
- The investigation is then undertaken by the most appropriate team (e.g. RPS, MPE or RPA, modality manager/clinical lead). Consideration should be made as to whether the incident is reportable to the CQC, HSE or MHRA. The person responsible for this communication is agreed at a local level but it must be done ASAP and in any case no longer than 2 weeks after the incident occurred. The flow chart detailing the communication process that should be followed for any radiation incident can be found in Appendix 1.

The modality manager/lead is responsible for ensuring that each step in this process is followed.

3. High patient doses from interventional or cardiology procedures

Guidance from the CQC[3] on reportable ionising radiation incidents now include high patient doses from cardiology and interventional radiology procedures. The guidance states that:

- Where there is a local diagnostic reference level (DRL), a dose to the patient greater than or equal to 10 times the local DRL is now considered reportable. This applies even when there has been no procedural failure.
- Where deterministic effects are reported (excluding transient erythema), these also fall under the criteria for a reportable incident.

4. Criteria for reporting incidents to the CQC / HSE

For a patient overexposure, the Trust's MPE will need to calculate the person's effective dose and decide whether the incident needs to be reported on to the CQC. The CQC issued notification guidance[3] (see table below). Criteria for notification applies to the total exposure from the incident.

IR(ME)R incident: notification codes, categories and criteria

Use these codes when you report an IR(ME)R incident.

Notification code	Exposure category	Criteria for notification [a, b]
Accidental exposure:		
1	All modalities	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child)[c]
Unintended exposure:		
All imaging modalities		
2.1	Intended dose less than 0.3mSv	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child)[c]
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	25 mSv or above
2.4	Intended dose more than 10mSv	2.5 or more times than intended
3	Interventional or Cardiology	Where there has been **NO** procedural failure **AND** 10 or more times the Local DRL **AND/OR** observable deterministic effects excluding transient erythema
5	Foetal All modalities	Where there has been a failure in the procedure for making pregnancy enquiries **AND** the resultant foetal dose is 1mGy or more
Complementary notification codes		
M	More than one individual exposed within the same incident/theme.	All cases regardless of dose
E	Equipment fault exposure (suffix as above)	
V	Voluntary notification (suffix as above)	
C	Clinically significant event (suffix as above)	

[a] Criteria apply to the total exposure from the incident, including any intended component plus over-exposure and/or necessary repeat exposures. Where a multiplication factor is specified this is defined as **the total dose from the incident divided by the intended dose**.

[b] This column of the table defines the various notification criteria. Where the exposure is not easily estimated in mSv or the dose unit specified, an alternative recognised unit may be applied and specified in the notification.

[c] In England a child is someone who has not yet reached their 18th birthday.

IRR incident:

Where members of the public or workers receive an over-exposure to ionising radiation, the incident needs to be reported to the RPA, who may then in turn, if appropriate, report it to the HSE.

Over-exposures resulting from equipment faults before the equipment is put into clinical use, for example, for critical examination, should also be reported to the HSE.

The investigation procedure for IRR incidents is further detailed in the One Dorset Personal Dose Monitoring Procedure.

MHRA:

Where there are risks to individuals relating to medical devices, consideration should be made to reporting device and medicine-related incidents to the MHRA.

5. Reflective Practice

Following any incident involving ionising radiation, the members of staff involved should produce a statement of reflective practice, which should also be completed by the modality lead (blank format can be found in Appendix 4). This may be added to the DATIX report.

6. Following up any radiation incidents

The flow chart detailing the documentation and communication process that should be followed for any radiation incident investigations and subsequent actions, can be found in Appendix 1.

The Trust is required to keep an up-to-date record of all ionising radiation incidents. This is maintained by the Medical Physics team and should be reported to either the Medical Exposures Group (patient incidents) or Radiation Protection Group (staff and public incidents). The Trust is also required to carried out periodic trend analysis on patient radiation incidents using the CIB taxonomy coding to look for patterns requiring corrective action.

7. Duty of Candour advice

A radiation incident meets the threshold of moderate harm and requires a duty of candour disclosure if:

- It is a 'clinically significant' unintended or accidental exposure as defined under the Scope of this procedure.
- Any radiation incident that requires reporting to one of the statutory regulators (HSE, CQC or MHRA).

If this is the case the Trust's Duty of Candour processes should be followed as required by the Health & Social Care Act 2012.

8. Records

The following records which should be kept for the time stated, are required either by IRR17, or IR(ME)R17:

Record or documentation	Number of years	Regulation
Investigation of doses to staff exceeding investigation levels	at least 2 years	IRR17 9 (8)
Dosimetry assessment after an accident	to age 75 years or at least 30 years	IRR17 24 (2)
Report of immediate investigation after an overexposure	at least 2 years	IRR17 9 (8) IR(ME)R 8 (4)
Report of full investigation of a notifiable overexposure	to age 75 years or at least 30 years	IRR17 31 (5) IR(ME)R 8 (4)

References

[1] The Ionising Radiation (Medical Exposure) Regulations 2017, IRMER17

[2] The Ionising Radiation Regulations 2017, IRMER17

[3] Notifying significant accidental and unintended exposures under IR(ME)R – Guidance for employers and duty-holders, Version 3Care Quality Commission, April 2023

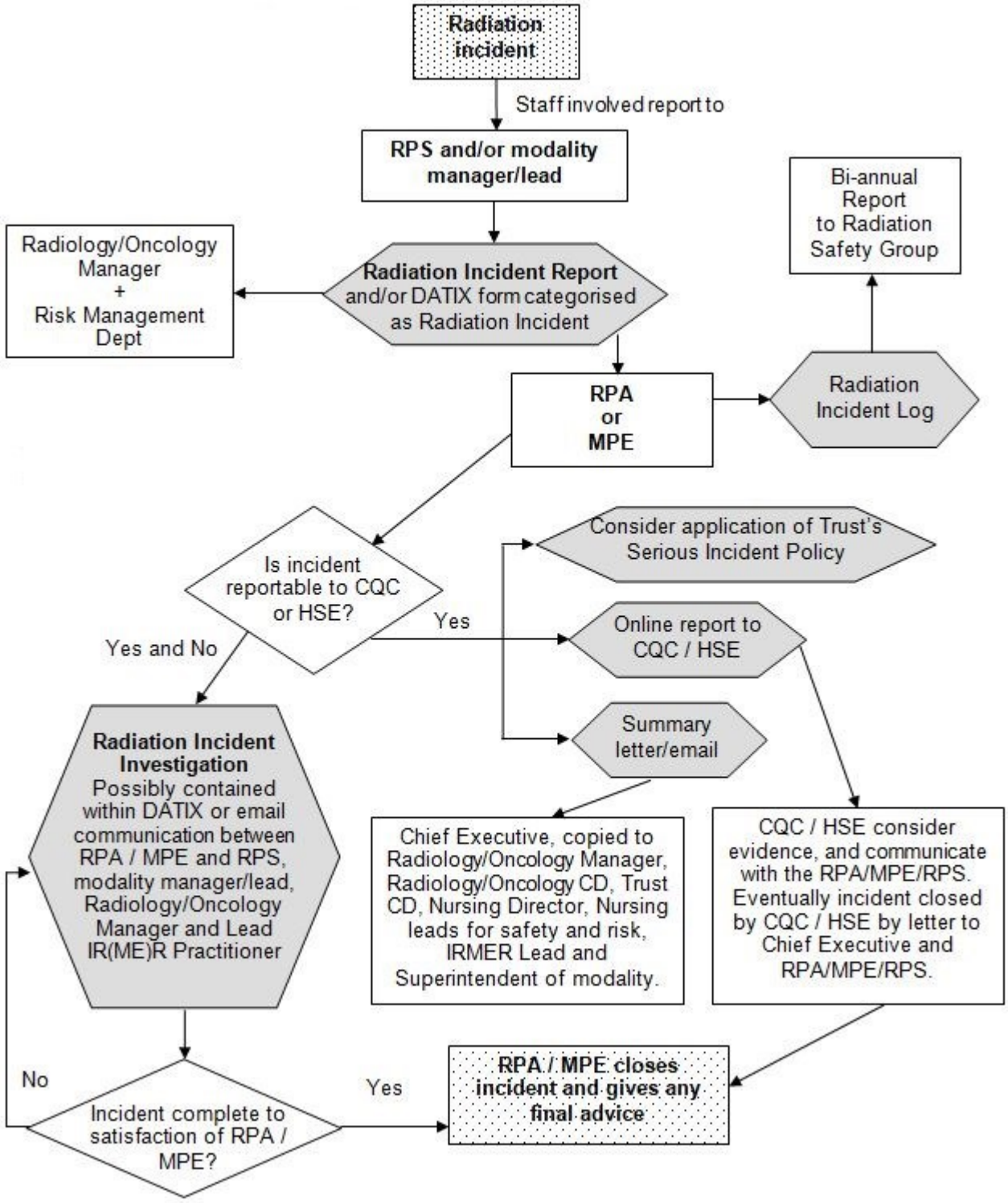
This Employers Procedure has been produced using the One Dorset Guidance Document – "Reporting Incidents Relating to the Use of Ionising Radiation".

The IR(ME)R 2017 Employers Procedures – The Management of Incidents Relating to the Use of Ionising Radiation, will be brought to the attention of all employees working with ionising radiation and will be reviewed biennially by the Medical Exposures Group (MEG).

Signed: __ _____ Date: ___07.07.2024_____

Chair of the MEG, Dorset County Hospital NHS Foundation Trust

APPENDIX 1



APPENDIX 2

Radiation Incident Report

Incident Location (room, procedure or equipment):
Name(s) of reporting individual:
Date reported:
DATIX reporting number:

Date and time of incident	
Incident description	
Persons exposed or injured (for patients include DOB, Hospital number, Gender, I/P or O/P)	
Staff present at incident	
Has the same or a similar incident occurred before (details & dates):	
Exposure parameters, e.g.: • kV • mA • mAs / time • Dose Area Product • FSD • Number of exposures	
What is the local DRL?	
Who was notified? (including patient)	
What action was taken?	
Have the local duty of candour requirements been met?	
Any further actions required to prevent reoccurrence?	

Signature: _____ **Date:** _____

Position: _____

Please return this form together with a DATIX reporting number to your MPE:

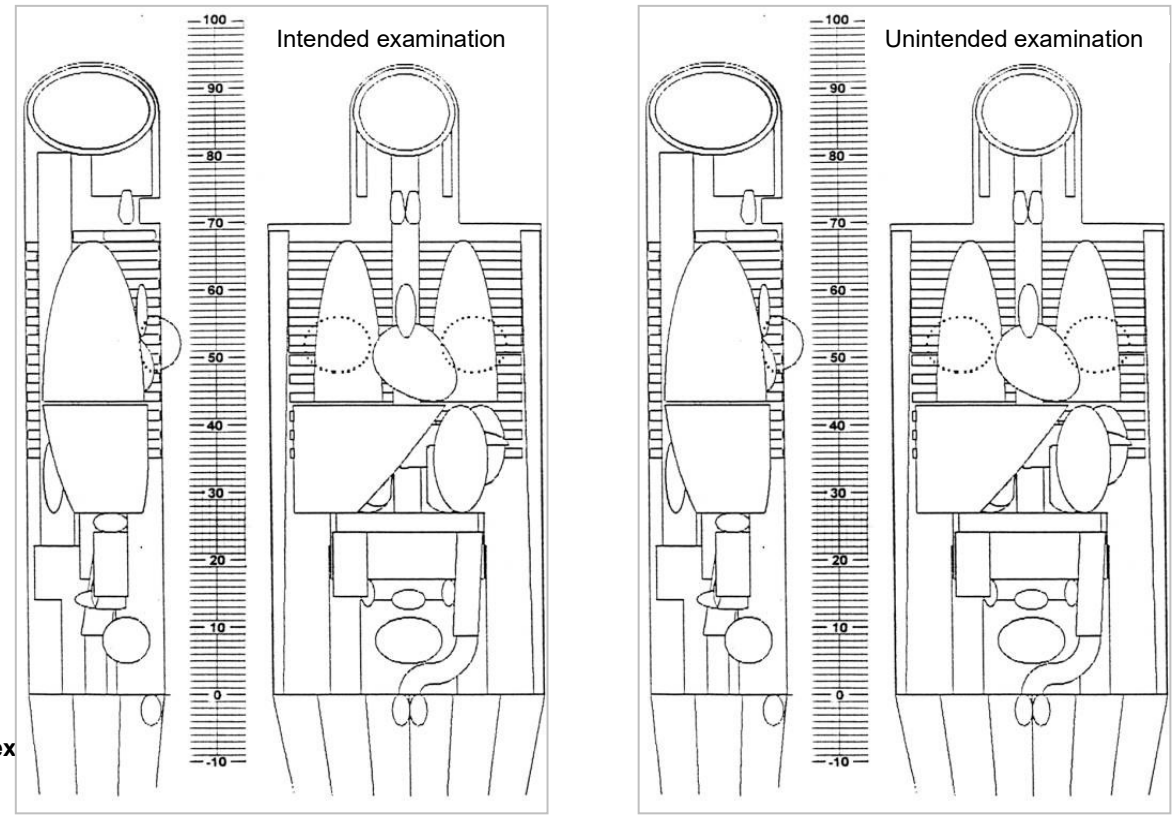
Total Effective dose:

APPENDIX 3 Radiation Incident Report (CT)

CT SCAN EXPOSURE DETAILS - REGION EXPOSED

Please highlight the approximate region of the scan on the diagram below (include critical organs if scanned e.g. testes in pelvic scan). Make further copies of this sheet if necessary.

CT ex



Details of the scanogram / scout / SPR / topogram are not required.

CT Dose Data Collection Sheet

Details		
CT scanner used		
	Intended exam	**Unintended exam**
Scan type (delete as applicable)	Helical / Axial	Helical / Axial
Sequence names e.g. Thorax Abdo/Pelvis		
DLP (dose-length product) (mGy.cm)		
$CTDI_{vol}$ (mGy)		
kV		
Pitch		
Rotation time		

APPENDIX 4 Radiation Incident Reflection and Learning Tool

Form to be completed by the operator involved in the incident.

Question	Response
Date of Incident	
Who was involved?	
One sentence description of the event:	
What happened ? (provide a succinct summary of the sequence of events and what happened from your perspective)	
What went to plan ?	
What didn't go to plan and why do you think it didn't ?	
Is there anything we could have done differently that may have avoided the incident or reduced the harm? (If yes is this only because you are thinking about it now, or do you think 'at the time' it could have been done differently)	
Contributory factors	
What do you think we (as a team) can learn from what has happened?	
Are there any immediate practice changes you think we should make?	
Are there any issues / learnings we need to take from our experience and raise as relevant for the service to learn from?	
Do you think there is anything here that requires further investigation or review? If yes what and why?	

Print Name	Signature	Date

Leads Review of Event

Question	Response
What happened ? (provide a succinct summary of the sequence of events and what happened from your perspective)	
What went to plan ?	
What didn't go to plan and why do you think it didn't ?	
Is there anything the team could have done differently that may have avoided the incident or reduced the harm?	
What are the key learnings for the team	
What local improvement actions are the team taking?	
How are these communicated to the staff?	
Are there issues that need to be forwarded for wider service consideration ?	
As the service lead do you consider further review of this case is necessary?	**Yes:** **No:**
If yes why? (What most concerns you about this case, what do you hope is achieved by further analysis and/or investigation)	
If No why not: (e.g. because all care, service and professional standards were delivered, or were mostly delivered and there are no significant gaps in care, that require further assessment).	