Title of Document:	IR(ME)R Procedure (L) Procedure to ensure that the referrer, practitioner, and the individual exposed or their representative, are informed of occurrence of any relevant clinically significant accidental or unintended exposure, and of the outcome of the analysis of the exposure.
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Update and place into new template	16.06.2021
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Updated with latest CQC SAUE guidance	11.03.2025
Nuclear Medicine extravasation considered a SAUE. Informing patients of incidents (DoC).	08.04.2026
Individuals involved in developing / reviewing / amending this document: (titles only)	
Radiology Clinical Services Manager	
Medical Physics Expert	
Quality Governance Lead	
Key staff responsibilities	Post:
Report any incidents that have resulted in accidental / unintended exposure as laid out in procedure (K)	Practitioner /Operator
In the case of incorrect referral and exposure to pregnancy it is the responsibility of the referrer to ensure that the patient or their representative are informed of the occurrence and the outcome of the analysis of this exposure including root causes and corrective actions implemented that are designed to minimise the risk of a recurrence.	Referrer
Ensure that the incident is recorded in a manner consistent with the hospital procedure for recording such incidents. (All incidents will be raised via the DATIX system). Ensure that the outcome of the analysis of this exposure including root causes and corrective actions implemented that are designed to minimise the risk of a recurrence are shared so that wider learning is made.	Quality Governance Lead / Incident Handler

In-line with regulation 6 schedule 2 requirements within IR(Me)R 2017, the purpose of this procedure is to identify the steps to be followed to ensure that relevant persons are informed following accidental or unintended exposures within Diagnostic X-ray, Nuclear Medicine, Cardiology and Interventional Radiology.

Definitions:

- **Significant accidental or unintended exposure (SAUE) –** These exposures are defined 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, in the dose received, the modality or technique carried out, anatomy, radiopharmaceutical or timing of exposure. These can happen for many reasons including procedural, systematic or human error.

Incidents that do not meet the SAUE notification criteria:

You do not need to make a statutory notification for:

- Repeat exposures involving no procedural, human, systematic or equipment errors. These are not included in the definition of SAUE. For example, where original images are undiagnostic and need a technical repeat or are not diagnostic due to contrast extravasation (excluding Nuclear Medicine, where extravasation must still be considered as a SAUE) or movement.
- Foetal exposures where the dose is above 10mGy and there has been no procedural failure or doses above 1mSv where there has been a procedural failure. However, these may be notifiable as a clinically significant event. Professional bodies have published guidance on what constitutes a 'clinically significant event': Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine and Implications in clinical practice in radiotherapy: Guidance from the Radiotherapy Board.

- **Clinically significant accidental or unintended exposure (CSAUE) –** A CSAUE is defined as the above with the addition of either:
  - Stochastic effects resulting from accidental or unintended exposure to ionising radiation that results in a 0.1% (1 in 1,000) or greater lifetime cancer risk or 0.1% or greater risk of childhood cancer in the case of fetal exposures.
  - For deterministic effects, unjustified exposure resulting in greater than:
    - 0.5 Gy to the lens of the eye
    - 0.5 Gy to the heart or brain
    - 5 Gy dose to skin including backscatter for skin reactions
    - 50 mGy to the thyroid following the administration of a radiopharmaceutical where there has been a failure in the thyroid blocking procedure
  - An exposure regardless of the dose received by the patient that affects the individual's quality of life to a level that requires intervention or treatment

Practice

If either a SAUE or CSAUE has occurred or is suspected, Radiographers must ensure this is reported on DATIX following IR(ME)R procedure K radiation incident flowchart as seen in *appendix 2*.

A preliminary investigation must be carried out by an appropriate investigation handler. It is expected that Medical Physics Expert (MPE) are contacted for support where they can undertake an assessment of the dose and risk associated with the exposure according to the relevant employer's procedure.

If the MPE's assessment and advice concludes that the accidental or unintended exposure is 'reportable' (*appendix 1*) then the Radiology Governance Team must be informed, and site superintendent or modality lead must report this to the CQC in line with expected requirements within 2 weeks from the date of exposure.

The assigned investigation handler will initiate an investigation to determine the root causes of the incident, implement corrective or preventative actions to minimise the risk of a recurrence and provide a formal report to the CQC within 12 weeks.

The investigation handler will provide a written notification to the Referrer and Practitioner of the occurrence of the incident, the analysis and the outcomes. All related documentation inclusive of emails trails, learning opportunities will be attached to the Datix.

In addition, the investigation handler will follow Trust policy for Duty of Candour and document this on Datix. This is where in case of a CSAUE (see definition on previous page) the patient must be informed of the incident.

Trust - Being Open (Duty of Candour) Policy

Appendix 1:

Notification Code	EXPOSURE CATEGORY	CRITERIA FOR NOTIFICATION
	ACCIDENTAL EXPOSURE	
1	All modalities	>/= 3mSv effective dose (adult) >/= 1 mSv effective dose (child) (England)
	UNINTENDED EXPOSURE (ALL RADIOLOGY MODALITIES)	
2.1	Intended dose <0.3mSv	>/= 3mSv (adult) >/= 1mSv (child)
2.2	Intended dose 0.3mSv - 2.5mSv	10 or more times than the intended dose
2.3	Intended dose 2.5 – 10mSv	>/= 25mSv
2.4	Intended dose >/= 10mSv	2.5 or more times than the intended
3	Interventional/Cardiology	Any unintended exposure resulting in observable tissue reactions, including but not limited to procedural failures or equipment malfunctions
5	Foetal exposure	Where there is an unintended foetal exposure AND the resultant foetal dose is 10mGy or more.
6	Breastfeeding infant (NM ONLY)	Where there has been a failure in the department procedure and infant dose IS >/= 1 mSv
7	Incorrect radiopharmaceutical	Any administration of the incorrect radiopharmaceutical to a patient, regardless of dose.
10.1	Selective internal radiation therapy	Delivered activity is outside +/- 20% of the prescribed activity
10.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity

[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.

Complementary notification codes

As well as notification codes 1-9, the table includes complementary codes that help to identify specific types of incident:

- **Voluntary:** incidents that do not necessarily meet the criteria for statutory notification but, because of other significant or unusual circumstances, may be submitted for wider learning. These may include near misses, such as wrong treatment plans in radiotherapy or brachytherapy that are identified before delivering an exposure, or where a wrong treatment plan is used but the outcome was not clinically significant.
- **Clinically significant:** incidents involving 'clinically significant' exposure(s). The criteria for these are developed and published by professional bodies.

- **Multiple individuals (more than one):** where a theme has been identified over a number of incidents, where a single incident has involved multiple individuals, or where a separate but similar incident has been identified that affects more than one individual. These are notifiable regardless of the doses received by each individual person.
- **Equipment:** refers to incidents where equipment failures are the direct cause.

Where a notification specifies a complementary notification code as the basis for an incident, you **must** also provide a notification code 1-9, to indicate the most relevant exposure category for the incident. More than one complementary code may be relevant.

Appendix 2:

Radiation Incident Flowchart

M:\Acute\Radiology\Radiology Team Share Point\RADIATION PROTECTION inc LOCAL RULES\RADIATION INCIDENT FLOW.pdf

Reference

CQC "Notifying significant accidental and unintended exposures under IR(ME)R - Guidance for employers and duty-holders Version 21 August 2024