

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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amending this document: (titles only)	
Chair of the radiation protection committee	
WAHT MPE	
Quality Governance Lead Radiographer	
Key staff responsibilities	Post:
Report any incidents that have resulted in	Practitioner /Operator
accidental / unintended exposure as laid out in	
procedure (K)	
In the case of incorrect referral and exposure to	Referrer
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.	
Ensure that the incident is recorded in a manner	Quality Governance Lead / Incident Handler
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.	

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 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.

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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.

In addition, 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

## 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 EX	POSURE (ALL RADIOLOGY MODALITIES)
2.1	Intended dose <0.3mSv	>/= 3mSv (adult)
		>/= 1mSv (child)
2.2	Intended dose 0.3mSv -	10 or more times than the intended dose
	2.5mSv	
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	Where there has been a failure in the department
	ONLY)	procedure and infant dose IS >/= 1 mSv
7	Incorrect	Any administration of the incorrect
	radiopharmaceutical	radiopharmaceutical to a patient, regardless of
		dose.
10.1	Selective internal radiation	Delivered activity is outside +/- 20% of the
10.1	therapy	prescribed activity
10.2	All other nuclear medicine	Delivered activity is outside +/- 10% of the
10.2	therapies	prescribed activity

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<sup>&</sup>lt;sup>a</sup> 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**.

# **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

<sup>&</sup>lt;sup>b</sup> 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.