Ionising Radiation (Medical Exposure) Regulations

Significant accidental and unintended exposures under IR(ME)R

Guidance for employers and duty-holders

Version 2, August 2020

Updates to June 2019 version:

- Redefined notification criteria for radiotherapy planning and verification imaging with added examples (page 5)
- New notification criteria for nuclear medicine therapy incidents (page 5)
- Guidance on applying notification criteria to laterality errors (page 6)

Care Quality Commission

The Regulation and Quality Improvement Authority

Healthcare Improvement Scotland

Healthcare Inspectorate Wales

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Introduction

The Ionising Radiation (Medical Exposure) Regulations 2017 and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 are designed to protect people while undergoing examinations and treatment using ionising radiation.

When there is an accidental or unintended exposure to ionising radiation, and the IR(ME)R employer knows or thinks 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)).

This guidance tells you which incidents you need to report and is jointly agreed by the English, Scottish, Welsh and Northern Ireland enforcement authorities.

Some areas of this guidance have been updated since first publishing in June 2019.

Definition of significant accidental or unintended exposures

Regulation 2 of IR(ME)R defines accidental and unintended exposures. When accidental and unintended exposures are judged to be ‘significant’ (or SAUE), they need to be notified to the enforcement authority under Regulation 8(4). To help you make notifications, we categorise 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, 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.

Unintended exposures can also include exposures to individuals resulting from an equipment malfunction. Under IR(ME)R, the term ‘equipment’ includes equipment that delivers radiation and ancillary equipment that directly influences the dose to the individual. This can include, but is not limited to:

- contrast injectors
- software
- picture archiving and communication systems (PACS) and radiology information systems (RIS) or similar
- radiotherapy planning systems
- treatment recording and verification systems

Regulation 8(1) refers to the employer's responsibilities when an incident is considered as 'clinically significant', which must also be notified to the appropriate enforcing authority under Regulation 8(4). See the table on page 10 for notification codes and criteria.

When to investigate and notify the enforcement authority

The employer's responsibilities are set out in Regulation 8(4). As the employer, if you suspect, or are informed, that a SAUE has, or may have occurred, you must first carry out a preliminary investigation **as soon as possible**.

If the preliminary investigation shows beyond reasonable doubt that the incident meets the specified criteria for a SAUE, you must notify the appropriate enforcing authority **as soon as possible**.

This means that, depending on the circumstances, employers need to make the notification **no later than 2 weeks after discovering the incident.** You must then carry out a detailed investigation of the circumstances of the exposure or arrange for this to happen.

Keeping records of investigations

There must be a record of the investigations and what they found. You need to keep these records in accordance with your local procedures and with Regulation 8(3). You must do this regardless of whether an incident needs to be notified to the appropriate enforcing authority or not.

For SAUE incidents, you must send a report on the outcome of the investigation to the appropriate enforcing authority. The report should include:

- what happened
- an estimate of the dose(s) received by the exposed individual(s)
- a detailed account of the root causes and contributory factors
- whether any similar previous incidents have occurred where individuals might have been over or under exposed, or if there are any trends that show a possible systematic failure
- whether local duty of candour requirements have been met
- whether local procedure, required under Regulation 8(1), schedule 2(l), has been applied
- any learning from the investigation and how this has been shared
- the corrective measures adopted and/or remedial actions implemented to reduce the likelihood or prevent this type of incident from happening again.

The appropriate enforcing authority needs to receive the investigation report as soon as possible, regardless of the severity of the incident or any complications. Employers need to submit the report **no later than 12 weeks** after the incident was discovered. This is irrespective of any timeframes of a health board or an employer's own timeframes for reporting serious incidents.

You must redact names of individuals in the report to comply with GDPR requirements.

If you cannot submit the report within the expected timeframe, you need to discuss with an inspector from the appropriate enforcing authority as early as possible.

Criteria for making a notification

The table shows the criteria for a significant accidental or unintended exposure (SAUE) that must be notified to the appropriate enforcing authority.

We use the 'effective dose' as the principal dose parameter, including for radiotherapy planning and verification imaging. However, where it is difficult to assess the effective dose or where alternative dose units are more relevant, the notification form allows you to add this information in the relevant section.

In England only, there are age-related dose thresholds for notifications of accidental and unintended exposures.

Interventional radiology and cardiology (including interventional CT procedures)

Determining the extent of any 'unintended' dose across a range of examinations and treatments in interventional radiology and cardiology is complex.

Where there is a local diagnostic reference level (DRL), enforcing authorities have determined that a dose greater than or equal to 10 times the local DRL will help you to determine what incidents are notifiable. This applies even when there has been **no procedural failure.**

Where local DRLs are not available, you should refer to national or European DRLs and/or review historical doses delivered for the same or similar procedures.

We also include deterministic effects (excluding transient erythema) in the criteria for making notifications of interventional radiology and cardiology exposures.

You can also submit a notification if it will lead to wider learning. This is at the discretion of the employer.

Radiotherapy

The previous notification threshold of 2.5 times the intended dose is amended to:

- **Pre-treatment planning scans:** you only need to make a notification when a scan needs to be repeated twice to obtain an appropriate data set. This means that three scans in total would be notifiable, including the intended exposure.
- **Treatment verification images:** you now only need to make notifications when:
    - due to set up error or equipment malfunction, **three** or more images are taken in one fraction to obtain an appropriate data set

      OR

    - if the **number** of additional imaging exposures is 20% greater than intended (according to a provider's own protocols) over the course of treatment.

> **Example:** If a kV verification image was intended on a single fraction but a CBCT image was used instead, this would previously have met the threshold for notification as the dose difference is greater than 2.5 times.
>
> Under this updated guidance it would not be notifiable as the acquired image would be useable and would not need to be repeated, although under IR(ME)R Regulation 8(3) it would still require an internal investigation and audit.

There is no change to the thresholds for reporting under and overdosing of delivered therapeutic dose.

Nuclear medicine therapy

Therapeutic nuclear medicine is now categorised separately from external beam radiotherapy and brachytherapy (notification codes 9.1 and 9.2).

For most nuclear medicine therapies, the existing notification threshold is still +/- 10%. However, there is now a separate category for Selective Internal Radiation Therapy (SIRT) procedures. This is because of the more complex delivery method and complications that can arise during these procedures.

For SIRT procedures, you should now report incidents to the relevant authority when the delivered activity falls outside +/- 20% of the prescribed activity.

As well as all notifiable therapy incidents, departments can consider making a voluntary notification for non-notifiable and near-miss incidents, due to the high-risk nature of these procedures and the opportunity for shared learning around incident themes. All clinically significant incidents **must** be reported to the relevant authority. There are examples in the latest guidance from professional bodies on IR(ME)R: Implications in clinical practice in radiotherapy: Guidance from the Radiotherapy Board.

Laterality errors

If an incident involves an exposure to the incorrect laterality, for example left shoulder instead of right, it is categorised as an unintended exposure. In this case, you should apply the multiplication or threshold values shown in the 'Criteria for notification' column.

Under-exposures

Regulation 8(4)(b) requires employers to make notifications of **radiotherapeutic** exposures that are significantly lower than intended. This includes nuclear medicine therapy, radiotherapy, brachytherapy and intraoperative therapy.

You **do not** need to make a notification of exposures lower than intended for non-radiotherapeutic modalities.

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.

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 there has been **no** 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.

Incidents involving medical and non-medical ionising radiation that do not meet the dose threshold and notification criteria for SAUE, including near misses, still need to be investigated and analysed locally under Regulation 8(3). Employers must record the analyses of these events, which should consider any thematic reviews and trend analyses.

Examples could include wrong patient exposures, wrong radiopharmaceutical, or wrong radiotherapy treatment plan – even where there is no harm to the patient.

You should also consider coding all incidents to understand total numbers of similar incidents irrespective of whether they are notified or below the relevant notification threshold. The appropriate enforcing authority will review these analyses through regulatory monitoring activity and will collect data from employers periodically. This type of evidence, together with SAUE notifications and knowledge of local governance processes for managing radiation incidents, may be used to assess compliance with Regulation 8 more generally and may be requested as part of an IR(ME)R inspection.

This guidance will be reviewed periodically and revised as necessary, based on analyses of notifications received by enforcing authorities. This is to ensure consistent notification practice among employers and to share wider learning of SAUE incidents.

Appropriate UK enforcement authorities

To submit a notification, the appropriate IR(ME)R enforcement authorities are:

England:
The Care Quality Commission
www.cqc.org.uk/irmer-notification

Wales:
Healthcare Inspectorate Wales
www.hiw.org.uk **email**: HIW.IRMERIncidents@gov.wales

Northern Ireland:
The Regulation and Quality Improvement Authority
www.rqia.org.uk

Scotland:
Healthcare Improvement Scotland
www.healthcareimprovementscotland.org **email**: hcis.irmer@nhs.net

Reporting device-related incidents

Where there are risks to individuals relating to medical devices, employers should consider reporting all device and medicine-related incidents to other agencies including:

England and Wales:

The Medicines and Healthcare Products Regulatory Agency (MHRA)

http://www.gov.uk/report-problem-medicine-medical-device

Scotland:

Health Facilities Scotland

Northern Ireland:

The Northern Ireland Adverse Incident Centre

It is good practice for employers to report such incidents (even if they have not resulted in SAUE). This enables the UK Competent Authority for the Medicines and Medical Device Regulations (MHRA) to take appropriate action with the manufacturer.

Public or occupational exposures

Where members of the public or workers receive over-exposures to ionising radiation, these need to be reported to the **Health and Safety Executive** under Regulation 26 of The Ionising Radiation Regulations 2017.

http://www.hse.gov.uk/radiation/ionising/index.htm

Health and Safety Executive Northern Ireland
https://www.hseni.gov.uk/articles/ionising-radiation#toc-3

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 Health and Safety Executive.

Notification codes, categories and criteria

Notification code	Exposure category	Criteria for notification [a], [b]
Accidental exposure		
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) [c]
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose
Unintended exposure		
All modalities including nuclear medicine and radiotherapy pre-treatment imaging		
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 **NO** procedural failure **AND** either: the dose is 10 or more times the Local Diagnostic Reference Level **OR** there are observable deterministic effects excluding transient erythema
4.1	Radiotherapy pre-treatment planning scans	If CT planning scan needs to be repeated twice to obtain an appropriate data set (3 scans in total, including the intended scan)
4.2	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, i.e. 3 images in total) **OR** when the number of additional imaging exposures is 20% greater than intended over the course of treatment or than was described in the protocol [d]
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

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
	Radiotherapy delivered dose (including brachytherapy)	
7.1	Therapy over-exposure	Delivered dose to the planned treatment volume and/or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose
7.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course) [(e)]
	Radiotherapy geographical miss (including brachytherapy)	
8.1	Total	All total geographical misses, even for a single fraction or significant part thereof
8.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin [(f)] **AND** the guideline dose factors above (as 7.1 & 7.2) for the PTV or OAR are exceeded
	Nuclear medicine therapy	
9.1	Selective Internal Radiation Therapy	Delivered activity is outside +/- 20% of the prescribed activity.
9.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity.
Complementary notification codes		
M	More than one individual exposed within the same incident/theme. (plus suffix with relevant 1 to 9 code)	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)	

Notes to the table

(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, 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.

(d) Excluding where there has been no breakdown in protocol and repeat verification imaging has facilitated correction of a 'setup' error so preventing a geographical miss in treatment.

(e) Excluding where the under-exposure to the target volume is a result of a geographical miss, which is reportable under 8.1 or 8.2.

(f) A surrogate for the locally defined error margin might be a displacement of 2.5 times the local imaging action level for specific anatomical site and treatment intent.

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www.cqc.org.uk

enquiries@cqc.org.uk

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