

# Ionising Radiation (Medical Exposure) Regulations

## **Significant accidental and unintended exposures under IR(ME)R**

### **Guidance for employers and duty-holders**

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Care Quality Commission

Healthcare Inspectorate Wales

The Regulation and Quality Improvement Authority

Healthcare Improvement Scotland

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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. It replaces the previous guidance on investigation and notification of medical exposures much greater than intended (MGTI) under IR(ME)R 2000, and is jointly agreed by the English, Welsh, Scottish and Northern Ireland enforcement authorities.

## 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 verification systems

Regulation 8(1) refers to the employer's responsibilities when an incident is considered as 'clinically significant', which must be notified to the appropriate enforcing authority under Regulation 8(4). See the [table](#) on page 8 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(I), 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.

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.

### Interventional radiology and cardiology

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 compare the dose with the estimated intended exposure if it is quantifiable.

You may also consider submitting a notification if it will lead to wider learning. This is at the discretion of the employer.

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

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

## Under-exposures

Regulation 8(4)(b) requires employers to make notifications of **radiotherapeutic** exposures that are significantly lower than intended. This includes molecular 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 1-8, 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.

**Clinically significant:** incidents involving 'clinically significant' exposure(s). The criteria for these are developed and published by professional bodies.

**Multiple individuals (more than one):** incidents where a theme has been identified over a number of incidents or where a single incident has involved multiple individuals.

**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, it **must** also be accompanied by a notification code 1-8, to indicate the most relevant exposure category for the incident.

## Incidents that do not meet the 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

Incidents involving medical and non-medical ionising radiation that do not meet the dose threshold and notification criteria for SAUE 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.

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.

This is particularly important for incidents that were previously reported as MGTI under IR(ME)R 2000. Examples included referral errors, the wrong individual or wrong anatomy, timing errors, use of wrong radiopharmaceutical, and radiotherapy partial geographical misses.

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.

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](http://www.cqc.org.uk/irmer-notification)

### Wales:

Healthcare Inspectorate Wales

[www.hiw.org.uk](http://www.hiw.org.uk) email: [IRMERIncidents@Wales.GSI.Gov.uk](mailto:IRMERIncidents@Wales.GSI.Gov.uk)

### Northern Ireland:

The Regulation and Quality Improvement Authority

[www.rqia.org.uk](http://www.rqia.org.uk)

### Scotland:

Healthcare Improvement Scotland

[www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org) email: [hcis.irmer@nhs.net](mailto: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 <sup>a, b</sup>  |
|--|--|--|
| <b>Accidental exposure</b>   |  |  |
| <b>1</b><br>(England only)   | All modalities including therapy               | 3 mSv effective dose or above (adult)<br>1 mSv effective dose or above (child) <sup>c</sup>  |
| <b>1</b><br>(Northern Ireland, Scotland & Wales)                                       | All modalities including therapy               | All, regardless of dose  |
| <b>Unintended exposure</b>   |  |  |
| <b>All radiology modalities including nuclear medicine and radiotherapy CT imaging</b> |  |  |
| <b>2.1</b>   | Intended dose less than 0.3mSv                 | 3mSv or above (adult)<br>1mSv or above (child)   |
| <b>2.2</b>   | Intended dose between 0.3mSv and 2.5mSv        | 10 or more times than intended   |
| <b>2.3</b>   | Intended dose between 2.5mSv and 10mSv         | 25mSv or above   |
| <b>2.4</b>   | Intended dose more than 10mSv                  | 2.5 or more times than intended  |
| <b>3</b>   | Interventional/cardiology                      | Where there has been <b>NO</b> procedural failure <b>AND</b> 10 or more times the Local Diagnostic Reference Level <b>AND/OR</b> observable deterministic effects excluding transient erythema |
| <b>4.1</b>   | Radiotherapy planning (CT)                     | 2.5 or more times than intended  |
| <b>4.2</b>   | Radiotherapy verification imaging              | 2.5 or more times than intended <sup>d</sup> (single fraction) <b>OR</b> when 5 repeat exposures have been necessary for an individual patient over a course of treatment                      |
| <b>5</b>   | Foetal<br>All modalities                       | Where there has been a failure in the procedure for making pregnancy enquiries <b>AND</b> the resultant foetal dose is 1mGy or more  |
| <b>6</b>   | Breast feeding infant<br>Nuclear medicine only | Where there has been a failure in procedure <b>AND</b> the resultant infant effective dose is 1 mSv or more  |

| Therapy delivered dose (including nuclear medicine)    |   |   |
|--|---|---|
| 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 or administered activity |
| 7.2  | Therapy under-exposure  | Delivered dose to the planned treatment volume is 0.9 or less times the intended dose or administered activity (whole course) <sup>e</sup>  |
| Therapy geographical miss (including nuclear medicine) |   |   |
| 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 <sup>f</sup> <b>AND</b> the guideline dose factors above (as 7.1 & 7.2) for the PTV or OAR are exceeded               |
| Complementary notification codes                       |   |   |
| M  | More than one individual exposed within the same incident/theme.<br>(plus suffix with relevant 1 to 8.2 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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