Ionising Radiation (Medical Exposure) Regulations

Notifying significant accidental and unintended exposures under IR(ME)R

Guidance for employers and duty-holders

Version 3, April 2023

Care Quality Commission
The Regulation and Quality Improvement Authority
Healthcare Improvement Scotland
Healthcare Inspectorate Wales

Updates to this guidance since August 2020 version:

- Revised information on CSAUE
- amended notification criteria for interventional radiology and cardiology
- amended notification criteria for radiotherapy
- amended notification criteria for foetal dose
- notification criteria added for incorrect radiopharmaceutical administration
- revised codes in notification table

Contents

We will review and revise this guidance as necessary, based on analyses of notifications submitted to enforcing authorities. This is to ensure consistent practice among employers for making notifications and to share learning from SAUE incidents.

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.

Notifying about an exposure

When there is an accidental or unintended exposure to ionising radiation, and the IR(ME)R employer knows or thinks it is significant or clinically significant, they must investigate the incident and report it to the appropriate UK IR(ME)R enforcing authority (under Regulation 8(4)).

The employer should also tell us if radioactive substances are administered without having the correct licence.

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

Significant accidental or unintended exposures (SAUE)

Regulation 8 of IR(ME)R details the employer's duties for accidental or unintended exposures. When accidental and unintended exposures are judged to be 'significant' (or SAUE), they need to be notified to the enforcing authority under Regulation 8(4). Regulation 2 of IR(ME)R defines accidental and unintended exposures 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 what was intended. For example, in the dose received, there may have been an error in either the:
    - modality or technique carried out
    - anatomy
    - radiopharmaceutical
    - timing of exposure

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.

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, for example:

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

Clinically significant accidental or unintended exposures (CSAUE)

Regulation 8(1) refers to the employer’s responsibilities when an incident is considered as ‘clinically significant’ (CSAUE). These incidents must also be notified to the appropriate enforcing authority under Regulation 8(4).

The regulations do not define CSAUE, but guidance is available from professional bodies to help employers in establishing what constitutes a clinically significant accidental or unintended exposure:

- IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine
- Guidance from the Radiotherapy Board

Employers need to remember their responsibility to apply the duty of candour for CSAUE events.

Criteria for making a notification

The table on page 11 details the criteria for notifying the appropriate enforcing authority of a significant accidental or unintended exposure.

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

When to investigate and notify the enforcing authority

The employer's responsibilities are set out in Regulations 8(3) and 8(4). As the employer, if you suspect that a SAUE has, or may have occurred, or if you are informed about an incident, you must follow these steps:

- First, carry out an immediate preliminary investigation. 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.
- Depending on the circumstances, you need to make the notification **no later than 2 weeks after discovering the incident.**
- Carry out a detailed investigation of the circumstances of the exposure or arrange for this to happen.
- Submit the report of this investigation to the appropriate enforcing authority **no later than 12 weeks** after the incident was discovered, regardless of the severity of the incident or any complications. 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.

Incidents involving 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). This includes near misses. You must record the analyses of these events, which should consider any thematic reviews and trend analyses.

Keeping records of investigations

There must be a record of the investigations and what they found. You must keep these records in accordance with your local procedures and with Regulation 8(3). This is 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 relating to CSAUE, 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 or remedial actions implemented to reduce the likelihood or prevent this type of incident from happening again.

You must redact names of individual people in the report to comply with UK data protection legislation.

Assessing the dose

We use ‘effective dose’ to define what is notifiable for some categories (table on page 11).

The effective dose is 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.

The report should include an assessment of intended and unintended dose to the patient(s).

Equipment errors

Unintended exposures can also include exposures 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

We encourage you to report device-related incidents to the Medicines & Healthcare products Regulatory Agency (MHRA).

Complementary notification codes

As well as notification codes 1 to 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 to share 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):** these are notifiable regardless of the doses received by each individual person, where either:
    - a theme has been identified over a number of incidents
    - a single incident has involved multiple individuals
    - a separate but similar incident has been identified that affects more than one individual.
- **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.

Interventional radiology and cardiology (including interventional CT procedures)

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

The enforcing authorities have determined that the following must be reported to the relevant enforcing authority:

- all procedural failures resulting in observable deterministic effects (excluding transient erythema)
- procedures that do not have a procedural error but result in unintended or unpredicted observable deterministic effects.

The table provides guidance on this.

You may submit a voluntary notification if there is no procedural failure if doing so will lead to wider learning. This is at the discretion of employers.

Radiotherapy treatment verification imaging

There is no change to the threshold relating to images in a single fraction (category 4.2a). However, the thresholds for notifications relating to imaging exposures over the course of treatment have changed (4.2b & 4.2c).

In the previous threshold:

“when the number of additional imaging exposures is 20% greater than intended over the course of treatment due to protocol failure or equipment error”

The threshold has increased to 50%. This is to reflect the increase in short course fractionation treatments and the relatively low dose of verification images.

You now only need to make notifications in the following situations:

- Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, which is 3 images in total).
- When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **protocol failure**.
- When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **thematic hardware or software failure**.

These thresholds apply to all radiotherapy treatment regimes, including radical short course fractionation (classed as 10 fractions or less). Examples of thematic failure could be a persistent equipment fault or repeated human factor error. However, we rely on employers to use professional judgement to identify themes.

Examples of notifiable events

- Patient set up is incorrect as a result of protocol failure, for example incorrect moves from tattoo or incorrect immobilisation applied, and 3 or more images are needed in a single fraction of treatment.
- During a 5 fraction stereotactic ablative radiotherapy (SABR) treatment, 3 additional images were acquired on different days due to incorrect patient immobilisation (this threshold was previously set at 20% and would have triggered a notification with only 1 additional image).
- During a 5 fraction SABR treatment, 3 additional images were acquired on different days due to a multi-leaf collimator (MLC) fault, or the same MLC fault affects 3 or more patients (this threshold previously was set at 20% and would have triggered with only 1 additional image).

Foetal exposure

The reporting threshold for foetal exposures has changed. Previously a procedural failure was needed to instigate reporting, but this is no longer the case. However, the dose threshold has been raised from 1 mGy to 10 mGy, in line with guidance Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation (Royal College of Radiologists).

Therefore, you must report if a foetus has an exposure over 10 mGy – even when procedures were followed.

Incorrect radiopharmaceutical administration

A new reporting category has been added to capture all administrations of an incorrect radiopharmaceutical, regardless of the dose to the patient. This applies even when the correct isotope was given but with the wrong tracer, for instance technetium-99m MAA instead of technetium-99m HDP.

Under-exposures

Regulation 8(4)(b) requires employers to make notifications of **radiotherapeutic** exposures that are significantly lower than intended, as set out in the criteria in the table (codes 8.1 and 8.2). This includes:

- nuclear medicine therapy
- radiotherapy
- brachytherapy
- intraoperative therapy.

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

Laterality errors

If an incident involves an exposure to the incorrect laterality it is categorised as an unintended exposure. In this case, apply the multiplication or threshold values shown in the 'Criteria for notification' column.

Appropriate UK enforcing authorities

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

England:

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

Wales:

Healthcare Inspectorate Wales www.hiw.org.uk **email**: IRMERIncidents@Wales.GSI.Gov.uk

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 this type of incident (even if they have not resulted in a 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 a member of the public or a worker receives an over-exposure to ionising radiation, this should be reported to the Health and Safety Executive under Regulation 26 of The Ionising Radiation Regulations 2017.

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.

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

Notification codes, categories and criteria

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

Accidental exposure

Notification code	Exposure category	Criteria for notification
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) *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.*
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose

These notification 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**.

Where the exposure is not easily estimated in mSv or the dose unit is not specified, you may apply an alternative recognised unit and specify this in the notification.

Unintended exposure

All modalities including nuclear medicine and radiotherapy imaging

Notification code	Exposure category	Criteria for notification
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 a procedural failure resulting in observable deterministic effects. Procedures that do not have a procedural error but result in unintended or unpredicted observable deterministic effects.
4.1	Radiotherapy planning scans	If a planning scan needs to be repeated twice to obtain an appropriate dataset (3 scans in total, including the intended scan).
4.2a	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, 3 images in total). *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
4.2b	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **protocol failure**. *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
4.2c	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **thematic hardware or software failure**. *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
5	Foetal All modalities	Where there is an unintended foetal exposure **AND** the resultant foetal dose is **10mGy** 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.
7	Incorrect radiopharmaceutical	Any administration of the incorrect radiopharmaceutical to a patient, regardless of dose.

Radiotherapy delivered dose (including brachytherapy)

Notification code	Exposure category	Criteria for notification
8.1	Therapy over-exposure	Delivered dose to the planned treatment volume or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose.
8.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course). *This excludes where the under-exposure to the target volume is a result of a geographical miss, which is reportable under either 8.1 or 8.2.*

Radiotherapy geographical miss (including brachytherapy)

Notification code	Exposure category	Criteria for notification
9.1	Total	All total geographical misses, even for a single fraction or significant part thereof.
9.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin AND the guideline dose factors (codes 8.1 and 8.2) for the planning target volume or organs at risk are exceeded. *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.*

Nuclear medicine therapy

Notification code	Exposure category	Criteria for notification
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.

Complementary notification codes

For these codes, you need to add the relevant suffix code 1 to 9. For example:

- M1 (accidental exposure of more than one individual within the same incident or theme)
- M2.1 (unintended exposure of more than one individual within the same incident or theme)

Notification code	Exposure category	Criteria for notification
M	More than one individual exposed within the same incident or theme. (plus relevant suffix code 1 to 9)	All cases regardless of dose.

Notification code	Exposure category
E	Equipment fault exposure (plus relevant suffix code 1 to 9)
V	Voluntary notification (plus relevant suffix code 1 to 9)
C	Clinically significant event (plus relevant suffix code 1 to 9)

Published by:

Care Quality Commission

www.cqc.org.uk

enquiries@cqc.org.uk

Tel: 03000 616161