

Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

Guidance updated 19 April 2023

Since the August 2020 version of this guidance, we have:

- updated information on clinically significant accidental and unintended exposures (CSAUE)
- added notification criteria for incorrect radiopharmaceutical administration

We have also revised some codes in the table, and amended the notification criteria for:

- interventional radiology and cardiology
- radiotherapy
- foetal dose

We enforce the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) in England

Medical ionising radiation is used widely in hospitals, dental care, clinics and in medical research to help diagnose and treat conditions. Examples are x-rays and nuclear scans, and treatments such as radiotherapy.

The regulations aim to make sure that it is used safely to protect patients from the risk of harm when being exposed to ionising radiation.

They set out the responsibilities of duty holders (the employer, referrer, IR(ME)R practitioner and operator) for radiation protection and the basic safety standards that duty holders must meet.

Responsibilities include:

- minimising unintended, excessive or incorrect medical exposures
- justifying each exposure to ensure the benefits outweigh the risks
- optimising diagnostic doses to keep them “as low as reasonably practicable” for their intended use.

The regulations apply to both the independent sector and the public sector (NHS).

Regulations

The Ionising Radiation (Medical Exposure) Regulations 2017 are on legislation.gov.uk:

- [The Ionising Radiation \(Medical Exposure\) Regulations 2017](#)
- [The Ionising Radiation \(Medical Exposure\) \(Amendment\) Regulations 2018](#)

Notify us 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 enforcing authorities in England, Scotland, Wales and Northern Ireland.

Significant accidental or unintended exposures (SAUE)

Regulation 8 of IR(ME)R details the employer's duties for making statutory notifications about 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

Regulation 8(1) refers to the employer's responsibilities when an incident is considered as 'clinically significant' (CSAUE). These incidents are also statutory notifications and must 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.

IR(ME)R licensing breaches

Regulation 5 requires employers and practitioners to hold a licence for the administration of radioactive substances. Licences are required by:

- each employer at each medical radiological installation where radioactive substances are to be administered to humans
- every practitioner to justify the administration of radioactive substances to humans.

The Administration of Radioactive Substances Advisory Committee (ARSAC) issues licenses on behalf of the licensing authority. Each licence sets out the specific purposes for which the person is licensed. It is a breach of Regulation 5 if radioactive substances are administered without having the appropriate licence.

(Any valid ARSAC certificates issued after 6 February 2018 are only considered equivalent to a current licence when they meet the requirements set out in the ARSAC notes for guidance.)

You should notify the ARSAC Support Unit of any licensing breaches. We also encourage you to report these incidents to us.

Make an IR(ME)R notification

We are changing our survey tool. If you experience any issues submitting your notification please email IRMER@cqc.org.uk.

Use our report forms



To bookmark these forms for future use, bookmark this page and not the link for the form itself. This makes sure your report has a unique reference number.

IR(ME)R incident report form: statutory notification

IR(ME)R licensing breach form

What happens next?

After you submit the form we will send you an automated email with your IR(ME)R notification reference number. Use this reference number whenever you contact us. If you do not see the automated email, check your junk email folder.

If we need more details we may contact you. Otherwise, we will wait until you have submitted your full report before we review it.

When you have completed an investigation report, send it to us within the timeframe stated in the guidance. The report must be anonymised and must not include any patient identifiable information in line with GDPR.

How we process statutory notifications

We

1. conduct initial risk triage
2. review the full report
3. progress the notification by email correspondence or a site visit
4. signal closure of the notification by email
5. categorise the incident for internal reporting
6. publish headline findings in our annual report

Criteria for making a notification

The following tables detail the criteria for notifying the appropriate enforcing authority of a significant accidental or unintended exposure.

Notes: As well as the changes to criteria, we have improved the layout of the table to make the footnotes easier to read.

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

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
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1 (England only)	All modalities including therapy	<p>3 mSv effective dose or above (adult)</p> <p>1 mSv effective dose or above (child) (c)</p> <p>Note: 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.</p>
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	<p>Where there has been a procedural failure resulting in observable deterministic effects.</p> <p>Procedures that do not have a procedural error but result in unintended or unpredictable observable deterministic effects.</p>
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).

Notification code	Exposure category	Criteria for notification
4.2a	Radiotherapy treatment verification images	<p>Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, 3 images in total).</p> <p>This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).</p>
4.2b	Radiotherapy treatment verification images	<p>When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of protocol failure.</p> <p>This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).</p>

Notification code	Exposure category	Criteria for notification
4.2c	Radiotherapy treatment verification images	<p>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.</p> <p>This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).</p>
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	<p>Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course).</p> <p>This excludes where the under-exposure to the target volume is a result of a geographical miss, which is reportable under either 9.1 or 9.2.</p>

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.

Notification code	Exposure category	Criteria for notification
9.2	Partial	<p>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.</p> <p>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.</p>

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. As well as notification codes 1 to 10. 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)

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 (see [Notification codes, categories and criteria](#))

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 [Notification codes, categories and criteria 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 to 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 UK enforcing authorities have determined that the following must be reported:

- 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 [Notification codes, categories and criteria table](#) provides guidance on this.

You may submit a voluntary notification when 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 and 4.2c).

In this 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 now captures 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 example 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:

[Care Quality Commission: IR\(ME\)R notification](#)

Wales:

[Healthcare Inspectorate Wales](#)

email: IRMERIncidents@Wales.GSI.Gov.uk

Northern Ireland:

[The Regulation and Quality Improvement Authority](#)

Scotland:

[Healthcare Improvement Scotland](#)

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 \(MHRA\)](#)

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 needs to 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.

[Health and Safety Executive: Ionising radiation](#)

Health and Safety Executive Northern Ireland

[Health and Safety Executive Northern Ireland: Ionising radiation](#)

IR(ME)R inspections

Our specialist inspectors assess compliance with the Ionising Radiation (Medical Exposure) Regulations 2017. This includes both NHS and independent healthcare providers.

We have a programme of planned inspections and may inspect a provider at any time when we receive a notification of a significant accidental or unintended exposure that we consider to be a serious incident. We may also inspect when we receive concerns from a whistle-blower or through information from CQC inspection colleagues.

Our inspection team includes clinical specialists who are either state registered radiographers or clinical scientists with experience in medical physics.

When we inspect, we assess compliance against all IR(ME)R regulations unless the inspection is part of a specific programme or theme. We usually announce the inspection in advance and normally spend one day on site.

When we are responding to a notification of a serious incident, the inspection may be announced or unannounced. We may either focus on the area of concern or assess all regulations if appropriate.

Themed inspection programmes

We are running three separate inspection programmes to focus on assessing compliance with IR(ME)R in:

- nuclear medicine
- radiotherapy
- diagnostic radiology

For each area, we will inspect a sample of:

- radiotherapy in independent health care
- nuclear medicine departments, initially concentrating on therapy services
- interventional radiology and cardiology departments
- chiropractors

- dental providers (by self-assessment)

This is in line with CQC's risk-based approach for inspections.

Following an inspection, we provide formal written feedback. This may include recommendations to improve practice or specify actions required to achieve compliance.

We do not award a rating following IR(ME)R inspections and our findings do not change a provider's existing ratings.

We are not required to publish reports of findings from IR(ME)R inspections. However, sometimes we may publish details of compliance with IR(ME)R where it is relevant to our regulatory activity under the Health and Social Care Act 2008.

Enforcing IR(ME)R

CQC is the enforcing authority for England under IR(ME)R 2017. We enforce IR(ME)R using our powers under the Health and Safety at Work Act etc. 1974.

Our specialist IR(ME)R inspectors monitor and inspect premises that use ionising radiation. If a provider (employer) is not complying with IR(ME)R, we will recommend improvements. These must be made within a certain timescale.

In serious cases we can use our powers to take enforcement action to keep people safe.

[Ionising Radiation \(Medical Exposures\) Regulations 2017: Enforcement policy](#)

Enforcement action register

When we take enforcement action against a provider, we publish a summary.

[Earlier enforcement action summaries are available on the National Archives.](#)

Current enforcement action summaries

[See all](#)

[IR\(ME\)R enforcement notice summary: The Mid Yorkshire Hospitals NHS Trust \(July 2022\)](#)

Enforcement notice compliance results

[See all](#)

[IR\(ME\)R enforcement notice compliance: Maidstone and Tunbridge Wells NHS Trust \(September 2023\)](#)

[IR\(ME\)R enforcement notice compliance: University Hospitals North Midlands NHS Foundation Trust \(October 2023\)](#)

[IR\(ME\)R enforcement notice compliance: Nottingham University Hospitals NHS Trust \(August 2023\)](#)

[IR\(ME\)R enforcement notice compliance: York and Scarborough Teaching Hospitals NHS Foundation Trust \(September 2023\)](#)

[IR\(ME\)R enforcement notice compliance: Leeds Teaching Hospitals NHS Trust \(July 2023\)](#)

[IR\(ME\)R enforcement notice compliance: Chesterfield Royal Hospital NHS Foundation Trust \(July 2023\)](#)

[IR\(ME\)R enforcement notice compliance: University Hospitals of Derby and Burton NHS Foundation Trust \(August 2023\)](#)

[IR\(ME\)R enforcement notice compliance: Royal Papworth Hospital NHS Foundation Trust \(November 2022\)](#)

[IR\(ME\)R enforcement notice compliance: Gloucestershire Hospitals NHS Foundation Trust \(December 2022\)](#)

[IR\(ME\)R enforcement notice compliance: Royal Free London NHS Trust \(November 2022\)](#)

IR(ME)R information and reports

We publish reports to share learning, improve compliance with the regulations and keep people safe.

These summarise findings from our inspections and investigations of notifications using real examples to illustrate what we found. Reports include recommendations for improvements and how to maintain good practice.

[IR\(ME\)R annual report](#)

In addition, we publish reports that relate to a specific theme.

Themed inspection summary reports

[IR\(ME\)R: specialist paediatric radiology services inspection programme findings](#)

Guidance and supporting information

Departmental of Health and Social Care:

- [Guidance on the Ionising Radiation \(Medical Exposure\) Regulations 2017](#)

Gov.UK

- [Administration of Radioactive Substances Advisory Committee](#)

UK Health Security Agency:

- [Medical radiation – uses, dose measurements and safety advice](#)
- [Guidance for the implementation of the ionising radiation \(medical exposure\) regulations](#)

Professional bodies:

- [IR\(ME\)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine](#)
- [IR\(ME\)R: Implications for clinical practice in radiotherapy](#)