

### 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.

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. When reviewing and updating this guidance, the IR(ME)R enforcing authorities consider relevant IAEA (International Atomic Energy Agency) safety standards applicable to SAUE incidents.

# 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
- equipment malfunction

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.

# 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
- IR(ME)R: Implications for clinical practice in radiotherapy: Guidance from the Radiotherapy Board

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

### 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
- undiagnostic images due to contrast extravasation or movement.

### 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 license 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 license.

(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.

© Care Quality Commission