Complementary notification codes

As well as notification codes 1 to 10, 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.

- IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine
- Ionising radiation medical exposure regulations implications for clinical practice in radiotherapy

Multiple individuals

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.

Unintended exposures may 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:

- Medicines & Healthcare products Regulatory Agency (MHRA)
- The Northern Ireland Adverse Incident Authority (Northern Ireland only)
- Health Facilities Scotland (Scotland only)

Where a notification specifies a complementary notification code as the basis for an incident, you **must** also provide a notification code 1 to 10, 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 any unintended exposures resulting in observable tissue reactions must be reported to the relevant enforcing authority. This is irrespective of whether or not there is a procedural failure.

Some examples of notifiable incidents include, but are not limited to:

- An operator chooses an incorrect dose setting for an interventional procedure, leading to an exposure higher than intended. The patient subsequently reports a transient erythema.
- An equipment fault means that a dose reduction feature, such as automatic filtration, is not correctly applied during a procedure. The equipment fault is picked up following the procedure, and the patient reports an observable tissue effect. This would still be notifiable despite there being no procedural failure.

We remind employers that all other notification criteria for accidental and unintended exposures still apply for interventional and cardiology exposures.

You may submit a voluntary notification for incidents where there is no observable tissue effect if this will lead to wider learning. This is at the discretion of employers.

Radiotherapy treatment verification imaging

Incidents for radiotherapy treatment verification imaging should be reported when:

- a set-up error and/or hardware or software failure leads to 3 or more imaging exposures in a single fraction (including the intended image, which is 3 images in total).
- the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **protocol failure**.
- 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. The dose threshold for foetal exposures is 10mGy, which is in line with the 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

All administrations of an incorrect radiopharmaceutical, regardless of the dose to the patient, must be reported. 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.