Other IR(ME)R related activity

Guidance on significant accidental and unintended exposures

In January 2023, we completed a complete review of the SAUE guidance and statutory notification criteria in consultation with the devolved administrations of Scotland, Northern Ireland and Wales, and with advice from the Medical Exposures Group at the UK Health Security Agency. This was to ensure that the notification criteria keep pace with developments and changes in clinical practice and that the requirement for notifying the relevant enforcing authorities remains accurate.

Summary of the changes

Clinically significant accidental and unintended exposures

Regulation 8(1) refers to the employer's responsibilities when an incident is considered as 'clinically significant' (CSAUE), which must also be notified to the appropriate enforcing authority under Regulation 8(4). The regulations do not define CSAUE, but the Royal College of Radiologists and other professional bodies provide guidance 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
- Radiotherapy Board guidance

We remind employers of their responsibility to apply the duty of candour for CSAUE events.

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.

Interventional radiology and cardiology: summary of change

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.

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.

Foetal dose

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 from the Royal College of Radiologists Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation.

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

Statutory instrument review

The Department of Health and Social Care must review the regulations every 5 years. The review process began in 2022, comprising a post-implementation review and is being followed with a full review of the IR(ME)R in consultation with relevant stakeholders and enforcing authorities.

The review process has been ongoing through 2022/23 and the conclusion is expected to be published in April 2024.