

Guidance on investigation and notification of medical exposures much greater than intended.

16 January 2017

1. Scope

Regulation 4(5) of the Ionising Radiation (Medical Exposure) Regulations 2000 and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 (IR(ME)R) requires that incidents should be investigated and reported when a person undergoing medical exposure is exposed to ionising radiation to an extent much greater than intended, other than those as a result of equipment defect or malfunction.

This guidance is jointly agreed by the English, Welsh, Scottish and Northern Ireland Health Departments and establishes which incidents should be reported to the UK IR(ME)R enforcement authorities under IR(ME)R regulation 4(5). Appendix 1 gives details of incidents that may require notification to other agencies.

2. Incident investigation and reporting

When an employer suspects, or is informed, that a medical exposure may have resulted in exposure to ionising radiation to an extent which is much greater than intended, they need to undertake an immediate preliminary investigation.

If this investigation shows beyond reasonable doubt that the medical exposure was not much greater than intended (Section 3), then a record of the investigation and its findings must be kept in accordance with the Employer's procedures, and with due regard to the NHS Code of Practice for Records Management^{1,2}.

If this investigation shows that an exposure much greater than intended has occurred, the employer must '*forthwith*' notify the appropriate IR(ME)R enforcement authority and make or arrange for a detailed investigation of the circumstances of the exposure. The resulting report to the appropriate authority (Section 4) should include:

- what happened
- a detailed account of the causes of the incident
- an estimate the dose(s) received by the individual(s) exposed
- under duty of candour, whether or not the individuals involved were fully apprised of the circumstances of the incident and the dose received (and if not, why not)
- what remedial action has been taken to minimise or prevent the chances of a recurrence of an incident of this type
- whether any previous patients might have been similarly overexposed, or if there are any trends to suggest that there might have been a systematic failure

3. Guidelines for notification

Table 1 lists examples of incidents that require notification to the IR(ME)R enforcement authority. The guideline factors listed in Table 2 should be applied to diagnostic and interventional procedures, pre-treatment (planning) imaging and during treatment (verification) imaging for radiotherapy purposes.

The guideline factors in Table 2 are defined as the ratio of the total exposure (original exposure **plus** necessary repeat/additional exposure(s)) to that intended. These factors are not based solely on increased risk to the individual, but are considered to adequately identify incidents that might require further investigation.

In radiotherapy, an imaging episode is defined as the imaging associated with an individual attendance for a procedure (planning episode or treatment fraction), and may involve multiple exposures. In considering whether an additional exposure is an incident, or requires to be notified, the total imaging episode dose delivered to the patient should be compared to the intended imaging episode dose. Delivered doses that are less than the notifiable level but are greater than intended should be subject to local audit, and should be reported to NRLS or equivalent to aid national learning.

Notification is **not** required where the exposure is:

- (i) less than intended, or
- (ii) greater than intended, but less than the relevant guideline factor in Table 2.

However, where the employer considers it valuable, for example leading to wider learning, the employer may in any event take the opportunity to voluntarily notify the appropriate IR(ME)R enforcement authority.

Table 1 – Examples of unintended medical exposures that require notification

All Modalities	When to notify (what constitutes an exposure much greater than intended)
Wrong patient exposed	All cases – regardless of dose
Wrong radioactive medicinal product administered	All cases – regardless of dose
Unintended planning or verification exposures. Examples include wrong protocol/plan, patients placed in the imaging pathway in error.	All cases – regardless of dose
Wrong examination including incorrect body part or modality. Excluding diagnostic imaging laterality errors in the anatomy distal to the hip and shoulder. These incidents do not require notification but should be investigated locally.	Apply guideline factors in Table 2
Timing errors when an additional unintended examination is undertaken e.g. outside clinically acceptable time frame of the intended date	Apply guideline factors in Table 2
Where an incident involves exposure of several people to an extent that is greater than intended (but less than the guideline factors) as a result of a systematic process or clinical failure	All cases – regardless of dose
Failure to follow procedure regarding pregnancy and breastfeeding enquiries resulting in an unintended exposure to the foetus or unintended exposure of a child through breastfeeding	All cases – regardless of dose
Unintended foetal exposure where there was no failure to follow procedure regarding pregnancy enquiries	When the foetal dose is greater than 10 mGy
Any other situation where a patient has been exposed to ionising radiation, which in the judgement of the employer, is much greater than was intended for that patient	All other cases – regardless of dose at the employer's discretion
Radionuclide therapy (unsealed sources)	
Errors in scheduling of the treatment or otherwise	When there is an unintended clinical impact or compromise in the effectiveness of treatment, regardless of dose
Delivered dose	When actual dose is 1.2 times (any administration) the intended dose

Cont/d.

Table 1 continued - Examples of unintended medical exposures that require notification

Radiotherapy Treatment (External beam therapy, brachytherapy)	
Delivered dose	When the delivered dose to the planned treatment volume and/or organs at risk is 1.1 times (whole course) or 1.2 times (any fraction) the intended dose
Geographical errors	All total geographical misses should be reported even if only for a single fraction. Any errors resulting in a partial geographical miss that exceeds the locally defined error margin AND the guideline dose factor above for the tissue unintentionally exposed, should be reported. Local error margins should be anatomical site specific and set with due regard to national standards established by professional bodies
Errors in scheduling the treatment or otherwise	When there is an unintended clinical impact or compromise in the effectiveness of treatment, regardless of dose

Table 2 – Guideline factors for diagnostic and interventional procedures, including pre-treatment (planning) imaging and during treatment (verification) imaging

Diagnostic and Interventional exposures	Guideline factor applied to intended dose
High dose examinations, where the intended dose is greater than 5mSv, to include interventional radiology, radiographic, and fluoroscopic procedures involving contrast agents, diagnostic nuclear medicine, PET-CT and CT examinations	When the total exposure is at least 2.5 times greater than the intended dose
All radiotherapy planning and verification imaging	When episode dose is 2.5 times the intended whether through multiple repeats or through the unintended use of high dose procedures. Or, when five repeat exposures* (for procedural or human error) have been necessary for an individual patient over a course of treatment.
Intermediate dose examinations, where the intended dose is within the range 0.5 - 5mSv, to include mammography, CT scout examinations, and all other radiographic examinations not referred to elsewhere in this table	When the total exposure is at least 10 times greater than the intended dose.
Low dose examinations, where the intended dose is less than 0.5mSv, to include DEXA, skull, dentition, chest, in-vitro nuclear medicine	When the total exposure is at least 20 times greater than the intended dose.

*The 'repeat' criteria is intended to ensure repeated imaging born from poor practice or breakdown in the verification imaging protocol are highlighted.

4. Notification

Contact information for the IR(ME)R enforcement authorities is listed below:

England

<http://www.cqc.org.uk/content/reporting-irmer-incidents>

Northern Ireland

hall.graham@rqia.org.uk

Scotland

arthur.johnston@nhs.net

Wales

[IR\(ME\)Rincidents@wales.gsi.gov.uk](mailto:IR(ME)Rincidents@wales.gsi.gov.uk)

5. References

1. Department of Health; Records Management: NHS Code of Practice Part 1, London: DH, 2006
2. Department of Health; Records Management: NHS Code of Practice Part 2, London: DH, 2009
3. Health and Safety Executive. Equipment used in connection with Medical Exposure. Guidance Note PM77 (Third Edition). London: HMSO, 2006

Appendix 1: Notification to other agencies

While the guidance in this document focuses on human or procedural errors leading to exposures much greater than intended, readers are directed to HSE guidance³ on exposures to patients arising from equipment malfunction.

The employer should consider reporting device related incidents to other agencies including the Medicines and Healthcare products Regulatory Agency (MHRA) (for England and Wales) Health Facilities Scotland (for Scotland) and the Northern Ireland Adverse Incident Centre (for Northern Ireland) where there are risks to patients concerning medical devices. The employer is encouraged to report such incidents (even if they have not resulted in exposures much greater than intended) as this enables the UK Competent Authority for the Medical Device Regulations (MHRA) to take appropriate actions with the manufacturer.

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm>

<https://www.health-ni.gov.uk/publications/niaic-adverse-incident-reporting-guidance-and-forms>

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/how-to-report-an-adverse-incident/>