

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 Incident Reporting and Investigating Centre (IRIC)

email: nss.iric@nhs.scot

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 <u>Health and Safety Executive</u> 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

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