

Safety Action Notice

Reference: SAN2601

Issued: 06 January 2026

MDR preparedness: DL(2024)32 - national adverse incident reporting and safety alert systems

Summary

Health boards and local authorities must maintain systems for managing adverse events and safety alerts. This notice updates the obligations outlined in Directorate Letter [DL\(2024\)32](#), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities*, issued by Scottish Government on 16 December 2024.

Action

1. **Annually review local systems to ensure:**
 - a) identification, recording and reviewing of adverse events
 - b) reporting incidents to **IRIC** ([report an incident](#))
 - c) trend analysis and sharing of learning from adverse events
 - d) management of safety alerts
2. **Appointment of an Incidents and Alerts Safety Officer (IASO)**
 - a) ensure the IASO is supported and enabled to function at corporate level
 - b) put in place arrangements for continuity of cover.
3. **Complete** the [Directorate Letter DL\(2024\)32 survey](#) to help assess compliance.
4. **NHS Boards - ensure the ISO has ready access to:**
 - a) executive lead for management of serious adverse events
 - b) quality improvement lead
 - c) procurement lead
 - d) medical devices committee and/or head of medical physics

Action by

Chief Executives
Directors of Estates & Facilities
Incidents and alerts Safety Officers
Health & Safety Managers

Medical Directors
Nurse Directors
Responsible Directors
Risk Managers

Background Information

Health boards and local authorities have a duty to deliver care services safely. Learning from adverse events and managing safety alerts are essential to this duty¹. IRIC provides specialist support for medical devices, in-vitro diagnostic devices (IVDs), estates and facilities, social care equipment, and personal protective equipment (PPE)^{2,3}.

IRIC delivers national adverse incident and safety alert systems which cover all services provided by health boards, local authorities, partnerships, and contractors. This makes the obligations outlined in [DL\(2024\)32](#) integral to NHS Boards' and Local Authorities compliance with medical device regulation preparedness and post market surveillance requirements.

For NHS organisations, IRIC services align with the Healthcare Improvement Scotland (HIS) Framework for Reviewing and Learning from Adverse Events, which requires boards to manage adverse events through reporting, review, and improvement planning. Resources are available via Healthcare Improvement Scotland's website¹.

Reporting Guidance

Appendix A provides reporting guidance for:

- patients
- service users
- health and care professionals
- health boards and local authorities
- the public

Partnership Collaboration

IRIC collaborates with partners to improve the safety of health and care technologies. To achieve this, incident information is shared with:

- National Procurement
- Scottish Health Technologies Group
- Equipment manufacturers
- Healthcare Improvement Scotland
- Scottish Government
- Devolved administrations in Wales and Northern Ireland

References and other resources

1. [Learning from adverse events](#), *A national framework for reviewing and learning from adverse events in NHS Scotland: February 2025*. Healthcare Improvement Scotland.
2. [DL\(2024\)32](#), *Safety of health, social care, estates and facilities equipment: NHS board and local authority responsibilities*, Scottish Government, 16 December 2024
3. [SHTN 00-04](#), *Guidance on management of medical devices and equipment in Scotland's health and social care services*, Health Facilities Scotland, version 2.0, June 2021.

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure
NHS National Services Scotland, Tel: 0131 275 7575, email: nss.irc@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in [DL\(2024\)32](#), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities*, issued 16 December 2024.

To find safety alerts:
scan the QR code or [click this link to visit our website](#)



To report an incident:
scan the QR code or [click this link to visit our website](#)



NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service <https://www.nss.nhs.scot/>

Appendix A Diagram of medical device incident reporting routes

