

Safety Action Notice

Reference **SAN2201** Issued **05 January 2022** Review Date **01 January 2023**

National adverse incident reporting and safety alert systems for medical devices, IVDs, estates, facilities, social care equipment and PPE

Summary

Local authorities and health boards must have local systems in place for managing adverse events and safety alerts. Local systems should integrate with national systems operated by NHS National Services Scotland's Incident Reporting & Investigation Centre (IRIC).

Action

1. Annually review local systems for:
 - recording and reviewing adverse events
 - ensuring incidents are reported to IRIC ([report an incident](#))
 - identifying trends and sharing learning from adverse events
 - managing safety alerts
2. Ensure that an *Incidents and alerts Safety Officer (ISO)*¹ is appointed, supported and enabled to function at corporate level with suitable arrangements for continuity of cover.
3. NHS Boards - ensure the ISO has ready access to:
 - executive lead for management of serious adverse events
 - quality improvement lead
 - procurement lead
 - medical devices committee and/or head of medical physics

Action by

- Chief Executives
- Directors of Estates & Facilities
- Equipment Co-ordinators
- Health & Safety Managers
- Medical Directors
- Nurse Directors
- Responsible Directors (SHTN 00-04)
- Risk Managers

Background

Local authorities and health boards are required to ensure care services are delivered safely. Learning from adverse events and managing safety alerts are fundamental to the safe delivery of care services.

NHS National Services Scotland's Incident Reporting and Investigation centre (IRIC) is a specialist safety and risk management unit with responsibility for:

- medical devices and in-vitro diagnostic medical devices (IVDs)
- estates & facilities
- social care equipment and
- personal protective equipment (PPE)

¹ *Incidents and alerts Safety Officer (ISO)* role was recently renamed from *Equipment Co-ordinator (EC)*

IRIC has a specific remit from Scottish Government¹ to operate national adverse incident reporting and safety alert systems. These systems cover all services provided by local authorities, health boards, partnership organisations and contractors. National guidance² has been issued on the arrangements which local authorities and health boards should have in place.

IRIC services are integral to the framework for learning from adverse events³ published by Healthcare Improvement Scotland (HIS). The framework requires that health boards manage all adverse events through reporting, review and improvement planning. It is supported by the Adverse Events Community of Practice [website](#) which contains policies, tools, templates, learning summaries and other items which boards are able to share.

The arrangements outlined in this notice do not apply to patients, service users and members of the public. Patients and service users who have been provided with equipment should notify incidents to their care team or another designated contact. Once notified, these incidents should be recorded on local systems such as Datix and subsequently reported to IRIC. Members of the public who have procured their own equipment, for example from high street pharmacies, should report incidents to MHRA using the [Yellow Card](#) scheme.

NSS has a partnership arrangement through which it shares information on adverse events with the MHRA which regulates medical devices. NSS also works closely with Scottish Government, Healthcare Improvement Scotland, NHS Improvement and counterparts in devolved governments in Wales and Northern Ireland.

References

1. CEL 43 (2009), [Safety of health, social care, estates and facilities equipment: NHS board and local authority responsibilities](#), Scottish Government, 30 October 2009
2. 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.
3. [Learning from adverse events through reporting and review. A National framework for Scotland](#). Healthcare Improvement Scotland, December 2019.

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.irc@nhs.scot

For information on how to report an incident: [How to report an Adverse Incident](#)

General information about adverse incidents and safety alerts can be found in [CEL 43 \(2009\)](#) or by contacting IRIC at the above address.

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service.

<https://www.nss.nhs.scot/>

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