Safety Action Notice

Reference: SAN2401 **Issued:** 08 January 2024 **Review Date:** 08 January 2025

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

Summary

Councils and health boards must have local systems in place for managing adverse events and safety alerts. This notice is an update of the requirements of Chief Executive Letter CEL43[1].

Action

1. Annually review local systems for:
   a) identifying, recording and reviewing adverse events
   b) ensuring incidents are reported to IRIC (report an incident)
   c) identifying trends and sharing learning from adverse events
   d) 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:
   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[2]
Risk Managers

Background Information

Councils and health boards have a duty to ensure care services are delivered safely. Learning from adverse events and managing safety alerts are both fundamental to the safe delivery of care services. Specialist support is provided to NHS Boards and councils by the Incident Reporting and Investigation Centre (IRIC).

IRIC has a specific remit from Scottish Government[1] to provide specialist safety and risk management support for medical devices, in-vitro diagnostic medical devices (IVDs), estates, facilities, social care equipment and personal protective equipment (PPE). Support is provided through the delivery of national adverse incident reporting, trending & investigation services and safety alert systems.

Background Information (continued)

These systems cover all services provided by local authorities, health boards, partnership organisations and contractors. National guidance[2] has been issued on the arrangements which local authorities and health boards should have in place.

For NHS organisations, IRIC services have been integrated to the framework for learning from adverse events[3] 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 the health or care professional responsible for managing their care. Once notified, these incidents should be recorded on local systems (normally referred to as Datix, InPhase or Ullyses) and they should be reported onward to IRIC. Members of the public who have used their own private funds to purchase equipment, for example from community pharmacies, should report incidents to their supplier and/or MHRA using the Yellow Card scheme.

NSS has a partnership arrangement through which it shares information on adverse events with the Medicines and Healthcare products Regulatory Agency (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 and other resources

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.

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure NHS National Services Scotland, Tel: 0131 275 7575, email: nss.iric@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 CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

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/