Safety Action Notice

Reference	Issued	Review Date
SAN(SC)19/01	**10 January 2019**	**03 January 2020**

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

Summary

All NHS Boards and local authorities must have suitable arrangements in place for the safe provision of care supported by local systems for recording and reviewing adverse incidents, sharing learning, and managing safety alerts. Local systems must integrate with national incident reporting and safety alert systems including those operated by IRIC.

Action

- Annually review the effectiveness of local systems for recording and reviewing adverse incidents, identifying trends, sharing learning, and managing safety alerts.

- Ensure that:

  - an Equipment Co-ordinator has been appointed with the ability to function at corporate level and that there is continuity of cover - CEL43 (2009).

  - incidents involving medical devices, social care, estates and facilities equipment are reported to IRIC (how to report an adverse incident).

Action by

- Chief Executives
- Equipment Co-ordinators
- Medical Directors
- Nurse Directors
- Directors of Estates & Facilities
- Risk Managers

Background

All NHS Boards and local authorities in Scotland are required to have suitable arrangements in place for the safe provision and use of medical devices, social care, estates and facilities equipment.

These arrangements are set out in CEL 43 (2009) and its Addendum. They should be supported locally by systems for recording and reviewing adverse events/incidents, sharing learning, and cascading safety warnings.

NHS National Services Scotland (NSS) operates the national adverse incident reporting and safety alert systems for equipment and facilities. These systems cover services provided by NHS Boards, local authorities, partnership organisations and contractors.

NSS has a partnership arrangement through which it shares information on adverse events with the MHRA, the UK competent authority for medical devices. NSS also works closely with Scottish Government, Healthcare Improvement Scotland, NHS Improvement, and partners in devolved administrations in Wales and Northern Ireland.

All adverse events, regardless of their nature, should be managed locally through reporting, review and improvement planning. The National Framework for Learning from Adverse Events published by Healthcare Improvement Scotland (HIS) supports NHS boards to standardise processes of managing adverse events across all care settings in Scotland. The framework 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.

Patients and members of the public can report adverse incidents involving medicines and medical devices to MHRA, the UK's regulatory authority, using the Yellow Card scheme: https://yellowcard.mhra.gov.uk/.

Enquiries

Enquiries (and adverse incident reports) in Scotland 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.iric@nhs.net

Report options are available on the HFS website: How to report an Adverse Incident
Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.