The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

Safety Of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities

Purpose

1. This Directors Letter (DL) sets out responsibilities of Chief Executives for ensuring that policies and procedures are in place to achieve effective implementation of the safe management of Health and Social Care Estates and Facilities, Equipment and Devices. It supersedes CEL 43 (2009) and its addendum.

2. The scope of this DL includes all medical devices (including Software as a Medical Device and Software in a Medical Device), In Vitro Diagnostic devices, estates, facilities, social care equipment and personal protective equipment (PPE).

3. This DL describes key roles and responsibilities, remit of relevant organisations and documentation to support the safe management of Health and Social Care Estates and Faculties Equipment and Devices. Operational content is now retained within the Incidents and Alerts Safety Officer (IASO) Manual which will be managed by the IASO network (IASON).

Summary

4. This DL highlights:

4.1 Local Board governance and the roles and responsibilities of Chief Executives, Responsible Directors and Incidents and Alerts Safety Officers (IASO) and their deputies.

4.2 The central role of the Incident Reporting and Investigation Centre (IRIC) and the Incidents and Alerts Safety Officers Network (IASON) in the safety of medical devices and equipment.

4.3 The application of SHTN 00-04 The Safe Management of Medical Devices and Equipment in Scotland's Health and Care Services.

4.4 The importance of the use of Unique Device Identifiers (UDI) in safety and alerting and in the management of device recalls.

From Director of Health and Social Care Finance and National Clinical Lead for Quality & Safety

16 December 2024

DL (2024) 32

Addresses

For action
Chief Executives, NHS Boards
Chief Executives, Local Authorities

For information
Incidents and Alerts Safety Officers, NHS Boards and Local Authorities
NHS Board Medical Directors
NHS Board Nurse Directors
NHS Board AHP Directors
NHS Board Healthcare Science Leads
Executive Directors Responsible for Medical Device Policy, NHS Boards
NHS Board, Chairs, Medical Device Committees
NHS Board Clinical Engineering Leads
NHS Board Digital Leads
NHS Board Directors of Estates and Facilities
COSLA
Care Inspectorate

Further Enquiries to:

Incident Reporting and Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
EDINBURGH EH12 9EB

Tel: 0131-275 7575
Email: nss.iric@nhs.scot

5. IRIC receives and shares incident information and learning including the distribution of safety alerts to all Health Boards via the IASO Network. The role and responsibilities of IRIC are outlined in Annex 1 (section 1.3).

6. The requirements of this DL should be applied in conjunction with SHTN 00-04 The Safe Management of Medical Devices and Equipment in Scotland's Health and Care Services which provides detailed, regularly updated information regarding the statutory and regulatory requirements and mechanisms for appropriate risk management of medical devices and equipment.

7. Unique Device Identifiers (UDI) are alphanumeric or numeric codes which conform to international standards and ensure accurate and specific device identification. The use of UDI in reporting, issuing alerts and providing device traceability is a key improvement in patient safety and should be used where available in local reporting. The NHS Scotland Scan for Safety Programme is a national approach to UDI electronic capture to deliver traceability currently focused on implantable devices in acute care.

Action

8. Chief Executives must ensure that relevant staff are aware of this DL and that procedures are in place for effective implementation and monitoring.

9. Chief Executives should ensure that these procedures are extended to:

9.1 All health and care staff.

9.2 All contractors.

9.3 Private and independent service providers who provide equipment, buildings or other services or facilities for the direct care of patients or clients.

10. Chief Executives should ensure that the following roles are assigned:

10.1 **Responsible Director**: this is a designated executive lead responsible for the overall management of medical devices and equipment. The duties and responsibilities of the Responsible Director are set out in Annex 1.2.

10.2 **Incidents and Alerts Safety Officers (IASO)**: a single point of contact within each organisation which co-ordinates procedures for reporting adverse incidents and the distribution and implementation of safety alerts. The duties and responsibilities of the IASO are set out in Annex 1 (section 1.1).

11. Clear written policy and procedures must exist for:

11.1 The reporting of adverse incidents by all health and care professionals to their local health board or local authority system and to the IRIC. The role and responsibilities of IRIC are outlined in Annex 1 (section 1.3).

11.2 The receipt, assessment, distribution and implementation of safety alerts and processes for monitoring recommended actions and communicating lessons learned.

11.3 Processes for the management and reporting of adverse incidents and distribution of safety alerts should extend to the contract terms of independent contractors who

provide care, staff, equipment, buildings and other services for the care of the patients or service users (Annex 2).

Timescales

12. This update supersedes CEL 43 (2009) and its addendum effective from the date of this DL's issue.

Annexes included:

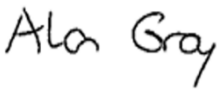
Annex 1: Roles and Responsibilities for Responsible Director/ IASO/ IRIC

Annex 2: Example of contract wording

Glossary

References

Yours sincerely



Alan Gray
Director of Health and Social Care Finance

Dr John Harden
National Clinical Lead for Quality & Safety

Roles and Responsibilities

1.1 Incidents and Alerts Safety Officers (IASO) and Deputy IASO roles and responsibilities:

a) Incident and Near Miss Reporting
   - ensure managers and staff are familiar with national and local procedures for reporting adverse incidents/ events
   - ensure incidents and near misses involving health and care technologies are reported to the Incident Reporting and Investigation Centre (IRIC)
   - monitor and resolve any issues or queries that may result in non-reporting of incidents and near misses to IRIC
   - co-ordinate with local staff, IRIC, equipment manufacturers and MHRA when necessary to ensure provision of further information to enable investigation of incidents and identification of their root causes, assess risks, evaluate or implement remedial actions, etc.
   - notify equipment safety concerns to IRIC, e.g. where a safety matter is identified before an incident or near miss is known to have occurred.

b) Safety Alerts, Notifications and Manufacturers' Field Safety Notices
   - receive and log safety alerts and notifications from IRIC, identify persons responsible for implementing corrective actions in affected departments, arrange onward distribution and track implementation to corporate sign-off
   - act as a corporate single point of contact to receive manufacturers' field safety notices (FSNs) as facilitated by IRIC through its partnership with MHRA. Identify persons responsible for implementing corrective actions in affected departments within organisation, arrange onward distribution and track implementation to corporate sign-off

c) Incidents and Alerts Safety Officer Network (IASON)
   - attend IASON meetings and events or send a deputy to represent the health board or local authority and report back
   - ensure local standard operating procedures are compliant with the IASON Manual
   - contribute to national initiatives such as IASON short life working groups and development of guidance, SOP, report, audit arrangements etc

d) Education, Training and Information
   - promote attendance at relevant educational and engagement events such as spotlights, open sessions and workshops
   - promote uptake of relevant courses such as Medical Device and IRIC e-learning courses on TURAS
   - monitor relevant websites, such as MHRA, Health and Safety Executive for information on health and care technology safety and management issues

1.2 Responsible Director responsibilities:

a) appoint suitable persons to carry out the role of Incidents and Alerts Safety Officer (IASO) and Deputy IASO, the organisations may split these roles between a few individuals if required
b) designate appropriate time, administrative support and resource to carry out the role
c) provide guidance, instruction, authorisation and executive support to IASO and Deputy IASO; including briefing of any matters to be raised at IASON meetings
d) inform IRIC (nss.iric@nhs.scot), at the earliest opportunity, the up-to-date contact details of the IASO and Deputy IASO (or re-confirm their details if they remain un-changed)

1.3 IRIC roles and responsibilities

a) manage national databases related to health and care technology incidents reported by health and care professionals at health boards, local authorities and their independent contractors
b) coordinate the investigation of adverse events reported to IRIC ensuring suitable feedback is provided to the person(s) who reported the incident
c) coordinate the submission of comments on draft safety alerts or lead the development of safety alerts
d) distribute safety alerts through the IASO at each health board and local authority in Scotland
e) support improvement in the safety of health and care technologies through facilitation of educational and engagement events, publication of guidance such as SHTN 00-04 The Safe Management of Medical Devices and Equipment in Scotland's Health and Care Services etc
f) collaborate and share information with the MHRA, Scottish Government, Healthcare Improvement Scotland and other UK health departments
g) maintain the list of IASO contact details and facilitate IASON meetings and activities
h) publish relevant safety alerts, IASO contact details and other relevant information on the publicly accessible NHS National Services Scotland website or other platforms
i) provide periodic update at IASON meetings and annual reports to each Health Board and Local Authority on incidents reported by their healthcare professionals, and summary of IRIC activities that have been delivered to the service

An example of contract wording

[1.1]	The [contractor] is responsible for ensuring that arrangements exist for the reporting of adverse incidents, the retaining of material evidence, the handling of contaminated items, the dissemination of safety advice and the control of risks relating to health and care technologies (medical devices, in vitro diagnostic devices, estates, facilities, social care equipment and personal protective equipment) in line with the information and guidance in DL (2024) 32 and SHTN 00-04 (Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Social Care Services), provided that such updated, amended or replacement guidance is published and publicly available on line, publicly displayed, or the content of it has been notified to the [contractor] by [the commissioning /contracting organisation].	
[1.2]	In particular, but without prejudice to the generality of the provisions of clause [1.1] hereof, the [contractor] shall:	
	[1.2.1]	ensure that its managers, staff, sub-contractors and agents are aware of the procedures for reporting adverse incidents, retaining material evidence, handling contaminated items and for implementing safety advice and the [contractor] shall ensure that such procedures are implemented
	[1.2.2]	monitor relevant websites for information on equipment safety and management issues e.g. MHRA, Health and Safety Executive
	[1.2.3]	monitor safety alerts and bulletins, and cascade within its own organisation
	[1.2.4]	monitor internal cascade systems to ensure alerts are received, assessed and acted upon
	[1.2.5]	discuss equipment safety issues with [the commissioning / contracting organisation]
	[1.2.6]	promote education and training related to health and care technology

Glossary

Adverse incident	an event that causes, or has potential to cause, unintended or unwanted effects involving the health and safety of patients, staff and others. The term incident is considered interchangeable with similar terms such as accident, adverse event and adverse occurrence.
Health and care technologies	Medical devices (including software as a medical device), in vitro diagnostic devices, estates, facilities, social care equipment and personal protective equipment (PPE).
Near miss	An unplanned event which did not result in injury, illness, or damage - but had the potential to do so.
Responsible Director	The senior executive with delegated responsibility for medical device/equipment management as described in SHTN 00-04 The Safe Management of Medical Devices and Equipment in Scotland's Health and Care Services.
Safety alert	A notification which identifies a previously unknown or under-recognised risk to health and safety.
Safety concern	An emerging safety issue which requires to be assessed, or is under assessment, but is not associated with a known incident or near miss.