Safety Action Notice Policy

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Responsible Lead Executive Director:	**Director of Human Resources**
Endorsing Body:	**Human Resources Forum**
Governance or Assurance Committee:	**Occupational Health and Safety Performance Group (OHSPG)**
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CONTENTS

i) CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author(s)	Head of Technical Services
Consultation Process / Stakeholders:	• Human Resources Director • Occupational Health and Safety Forum Members • Divisional Service Leads
Distribution:	• All staff through Staff Briefing • NHS Lanarkshire Corporate Polices Open Access Web Portal

`CHANGE RECORD

Date	Author	Change	Version No.
30/05/18	Risk Dept	GDPR statement added into section 3 and updated name of Data Protection Act	1
27/05/20	K. Torrance	Extended until October 2021 (COVID-19)	1
03/02/23	G Gray	• Minor revision to policy template to reflect NHS Lanarkshire Policy Template 'Developing Organisation Policies' Version 3.0, 2022 – Policy Template Document • Minor amendments to reflect outline responsibilities required by Scottish Government CEL 43 (2009) and Addendum CEL 43 (2009) • Scope of Policy amended to restrict management of healthcare safety related alerts and notices issued by Health Facilities Scotland and suppliers of equipment and devices • Responsibility for managing alerts designated to the appropriate Head of Service for Procurement, PSSD, Radiology, IM&T, Laboratories, Pharmacy or Primary Care. Policy reflects that responsibility for managing alerts can also be delegated by Service leads where considered appropriate to do so • Removal of the Equipment Co-ordinator role being undertaken exclusively by the Head of Medical Physics. • Resource implications and communication plan updated	1.1

1. Introduction

This Policy reflects the responsibilities set out in the Board's Risk Management Strategy and Health and Safety Policy Statement to meet the duty of care to NHS Lanarkshire staff, students, visitors, contractors, volunteers and partner companies/agencies, patients, visitors, others and to the organisation. This duty is enshrined in the Health and Safety at Work etc. Act 1974.

This Policy sets out the requirements to safeguard patient and staff safety where information identifying potential risk is received by NHS Lanarkshire from external bodies / agencies and from within the organisation.

The information is disseminated throughout the organisation in the form of Safety Notices and this procedure summarises the practical arrangements in place to manage the receipt, assessment, cascade and implementation of safety related alerts and/or notices received.

2. Aim, Purpose and Outcomes

2.1 Aims

Chief Executives Letter CEL 43 (2009) Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities was issued by the Scottish Government on 30 October 2009. It relates to the arrangements for the reporting of adverse incidents, the dissemination of safety advice and the control of risks relating to health, social care, estates and facilities equipment.

The principles and processes described in this document are in keeping with the Scottish Government CEL 43 (2009) issued on 30 October 2009 and Addendum CEL 43 (2009) November 2013. CEL 43 (2009) requires that "A single point of contact within each organisation shall be nominated as 'Equipment Co-ordinator' (in the case of NHS Boards preferably a Risk Manager)".

The 'Equipment Co- ordinator' will form part of a network for the promotion of equipment safety throughout Scotland. The name, designation and contact details (including email address) of the appointed Equipment Co-ordinator requires to be notified by email to Health Facilities Scotland. The aim and purpose of this policy is to comply with CEL 43 (2009) which includes the following:

2.1.1 'Ensuring managers and staff are aware of the procedures for reporting adverse incidents and for implementing safety advice'.

2.1.2 'Monitoring all adverse incidents reports from within own organisation'.

2.1.3 'Receiving emails from Health Facilities Scotland (HFS) notifying of alerts and bulletins, and cascading within own organisation'.

2.1.4 'Monitoring relevant websites for information on equipment safety and management issues'.

2.1.5 'Discussing equipment safety issues with Health Facilities Scotland (HFS)'.

2.2 Purpose And Outcomes

This policy describes the processes that are to be employed to disseminate national and local healthcare related safety alerts and notices to the affected service areas within NHS Lanarkshire.

The objective of this policy is to:

2.2.1 Ensure that healthcare related safety alerts and notices are circulated.

2.2.2 The appropriate staff are aware of healthcare safety related alerts.

2.2.3 Where appropriate that corrective action is identified and implemented in reaction to healthcare safety alerts and notices.

2.2.4 Healthcare safety alerts risks are being appropriately controlled.

3 Scope

The policy encompasses the processes required for the management of healthcare related alerts issued via Health Facilities Scotland (HFS) and other healthcare related notices. This policy applies to all Directorates and services.

3.1 Who is the Policy intended to Benefit or Affect?

NHS Lanarkshire staff, patients, visitors and other users that have access to the premises.

3.2 Who are the Stakeholders?

The policy lead has consulted with the listed stakeholders on this policy, setting out good practice on the development, implementation, monitoring and review of healthcare safety alerts and notices.

3.3 General Data Protection Regulation

NHS Lanarkshire takes care to ensure personal information is only accessible to authorised persons. Our staff have a legal and contractual duty to keep personal information secure, and confidential. In order to find out more about current data protection legislation and how we process your information, please visit the Data Protection Notice on our website at www.nhslanarkshire.scot.nhs.uk or ask a member of staff for a copy of the NHS Lanarkshire Data Protection Notice.

4 Principal Content

4.1 Management of Healthcare Safety Related Alerts and Notices

Definitions

A 'Safety Notice' is a generic term which covers a number of different types of alerts and notices. The main types of Notices received by the Board are listed below:

4.1.1 **Medical Device Alerts [MDAs]** – These Notices are issued by the Medicines and Healthcare Products Regulatory Agency [MHRA].

4.1.2 **Estates and Facilities Alerts [EFAs]** – These Notices are issued by Health Facilities Scotland [HFS].

4.1.3 **Product Recall Notifications [PRNs]** – These Notices are issued by NHS National Services (Scotland) – National Procurement.

4.1.4 **Customer Alert Notices [CANs]** - These Notices are issued by NHS National Services (Scotland) – National Distribution Centre [NDC] to bring the attention of customers to issues with products following advice from manufacturers and/or complaints to NDC.

4.1.5 **Field Safety Notices [FSNs]** – FSNs are issued directly by manufacturers when they become aware of a problem with a product. FSNs are often sent some weeks in advance of a corresponding MDA.

4.1.6 **Safety Action Notices [SANs]** – SANs are a Scotland Only Safety Notice issued by Health Improvement Scotland. SANs can be issued for Medical Devices, Estates / Facility and Patient Alerts etc. SANs relay Alerts issued by England which are relevant to Scotland.

Notices are occasionally received independently by individual members of staff e.g. Pharmacy, Medical Physics, PSSD, etc. Any member of staff receiving a notice should inform the Equipment Co-ordinator and their Service lead who will seek to ensure that appropriate action has been taken.

On rare occasions, it may be necessary for an internal Safety Notice to be issued as a consequence of a local problem and/or personal knowledge or experience of staff.

4.2 Assessment of Safety Notices

4.2.1 Unless specified within local arrangements and agreed by the relevant governance group, MDA's and SANs for medical devices are the responsibility of the Head of Medical Physics. EFA's are the responsibility of the General Manager for PSSD. Other notices which are related to specific service areas will normally be administered by the relevant department i.e. Medical Physics, Pharmacy, Procurement, Finance, Acute and PSSD will continue to manage alerts they receive in line with current process (including custom and practice) unless advised to change by nominated Executive Director(s) Policy lead(s). The department receiving the notice will be responsible for assessing the Notice and determine whether or not it needs to be disseminated further. This will include considering any recommended circulation contained within each notice.

4.2 Assessment of Safety Notices (continued

4.2.2 At times this decision can be straightforward – if, for example, the Notice is marked 'We understand this Device was not supplied to Scotland' - however, in the normal course of events, the Notice will be sent initially to local leads to ascertain if the device is in use / stocked by NHS Lanarkshire. This group includes technical and specialist managers e.g. Head of Medical Physics, General Manager Procurement, Head of Radiology, Head of Laboratories, Head of IM&T, General Manager PSSD and Chief Pharmacist who will support the process by providing information and guidance.

4.2.1 If required, the notice will be cascaded to relevant departments by the Technical or Specialist Manager following publication on the database by the Equipment Coordinator.

4.2.2 PRN's and CAN's are assessed by Procurement staff. In the case of PRN's, the National Distribution Centre is normally able to indicate whether or not the product in question has been ordered by NHS Lanarkshire. The Head of Service for Procurement is responsible for determining if any of an affected product is in use / stocked and ensuring that this information is communicated to the relevant service leads.

4.2.3 FSN's must be assessed and actioned by the member of staff receiving them. On receipt of an FSN staff should:

4.2.3.1 Forward a copy of the FSN to the Equipment Co-ordinator noting any actions planned and/or taken.

4.2.3.2 Send a copy of any completed customer acknowledgement return to the Equipment Co-ordinator.

Following these steps will help to ensure coordinated action on issues raised by manufacturers.

4.3 Cascade of Safety Notices

Responsibility for managing alerts will be undertaken by the appropriate Head of Service for Procurement, PSSD, Radiology, IM&T, Laboratories, Pharmacy or Primary Care, etc. Responsibility for managing alerts can also be delegated by Service leads where considered appropriate to do so.

If it is established that a particular device / product is in use / stocked in NHS Lanarkshire then a Safety Notice will be cascaded appropriately to relevant service leads / areas.

Where notices are distributed by electronic mail (e-mail) according to an agreed distribution list by the Equipment Coordinator. Recipients of these notices issued by the Equipment Coordinator are responsible for taking appropriate action and confirming to the Equipment Coordinator that they have done so.

The Medical Physics Department maintains a comprehensive data base of medical equipment with a purchase value > £1000.00. The data base includes the department that equipment is issued to. Notices concerning medical equipment are sent initially to the Medical Physics Department to assess the relevance of the Notice to NHS Lanarkshire.

4.3 Cascade of Safety Notices (continued)

Unless the situation requires it, blanket distribution of Notices does not take place as it can lead to staff becoming overwhelmed with information and consequently downgrade the importance of Notices. Having a process for filtering Notices ensures that – as far as possible – staff only receive those Notices relevant to their area of work. Please refer to Appendix 1.

4.4 Reporting Structures

The governance structure to support the management of Safety Action Notices are outlined within Appendix 2.

4.5 Internal Safety Notices

Medical Physics will issue Recordable Incident Reports for all incidents involving Medical Equipment, unless the Head of Medical Physics decides that the incident has a wider impact. In which case the issue will be escalated to the Equipment Coordinator or other designated lead to report the incident to IRIC / MHRA who will issue an adverse incident report.

4.5.1 Where considered appropriate, all staff should use the organisation's risk management software system (Datix) to report incidents or near misses involving:

4.5.1.1 Medical equipment and supplies, this includes medical devices, laboratory equipment, medical supplies and certain dietary products.

4.5.1.2 All incidents involving Medical Equipment should be reported to Medical Physics along with a copy of the DATIX report.

4.5.1.3 Estates equipment, including engineering plant, installed services, piped medical gas and gas scavenging systems, buildings, building fabrics and vehicles.

NHS Lanarkshire managers should review all incidents / near misses reported in this way and, where appropriate, inform the relevant service lead i.e. General Manager Procurement and / or General Manager PSSD to file an online report to the Health Facilities Scotland Incident Reporting and Investigation Centre [IRIC] if necessary. An internal Safety Notice may be issued as a consequence, for example if medical equipment or supplies need to be quarantined and this will be done via a global email outlining the relevant details.

4.6 Product Recalls

Where it is necessary to remove a device or product from use, this should be coordinated by the relevant Service lead i.e. Procurement, PSSD, Radiology, IM&T, Laboratories, Pharmacy or Primary Care, etc. as appropriate.

5 Roles and Responsibilities

NHS Lanarkshire has a statutory obligation to as far as is reasonably practicable to eliminate or where this is not possible to reduce the risks to which patients, staff and others are exposed as a result of the Board's undertakings.

5.1 Accountabilities and Responsibilities

5.1.1 The Chief Executive

The Chief Executive has overall responsibility for the effective implementation of the Safety Action Notice policy. This responsibility may be delegated by the Chief Executive to a designated representative.

The Chief Executive or their designated representative is responsible for ensuring that all senior managers and relevant staff in their organisation are aware of the information contained in CEL 43 (2009) and that procedures are in place to promote its effective and accurate implementation.

The Chief Executive or their designated representative is also required to ensure that this policy is extended to all contractors and private or independent service providers who provide care, staff, equipment, buildings or other services or facilities for the direct care of patients or clients. This may be achieved through the posting of the policy on the NHS Lanarkshire public policy portal through library services.

The Chief Executive or their designated representative should also identify a single point of contact within the Board who shall be nominated as 'Equipment Co-ordinator'.

5.1.2 The Director of Human Resources is responsible for:

Acting on behalf of the Chief Executive to ensure that the Safety Action Notice policy is implemented. The General Manager for SALUS will act on behalf of the Director of Human Resources to ensure the policy is revised and updated as required.

5.1.3 Acute University Hospital Directors / Divisional General Managers / Heads of Service and Service Managers

Acute University Hospital Directors / General Managers may choose to delegate these responsibilities to Heads of Service or (Operational) Service Managers; however, the overall responsibility for policy implementation and monitoring cannot be delegated.

Senior Managers are responsible for ensuring that within their areas of responsibility a named individual (normally the Head of Department, Device Manager or Ward Manager) and a deputy are appointed to be the focal point for the receipt and cascading onwards of Safety Notices to end recipients and for the collating of responses where this is requested.

5.1.4 The Equipment Co-ordinator

Where an Equipment Co-ordinator is appointed this represents a formal role assigned by the Chief Executive for NHS Lanarkshire or their designated representative. Each Division can also designate their own Divisional Equipment Coordinator. The Equipment Coordinator is responsible for:

5.1.4.1 Ensuring managers and staff are aware of the procedures for reporting adverse incidents and for implementing safety advice.
5.1.4.2 Monitoring all medical equipment related adverse incidents reports for their service.
5.1.4.3 Receiving emails from Health Facilities Scotland [HFS] notifying of alerts and bulletins, and cascading within own organisation.
5.1.4.4 Monitoring relevant websites for information on healthcare equipment safety and management issues relevant to their service.
5.1.4.5 Where required, discussing equipment safety issues with IRIC/MHRA.
5.1.4.6 Promoting equipment safety for NHS Lanarkshire Acute and Primary Care Division by staff education at Device Managers training courses.
5.1.4.7 Building and maintaining communication links with HFS, IRIC/MHRA.
5.1.4.8 Monitoring internal cascade systems to ensure Notices are added to the database. It is the responsibility of each person who accesses the database to ensure that they have taken appropriate action and to record this action on the database.
5.1.4.9 Receipt and recording of Notices.
5.1.4.10 Assessing the relevance of Notices.
5.1.4.11 Distribution and liaison to local leads who have responsibility to acknowledge receipt of the notices and to confirm that appropriate action has been taken.
5.1.4.12 Where required liaison with the relevant services i.e. Procurement / PSSD / Radiology / IM&T / Laboratories / Pharmacy / Primary Care / etc.
5.1.4.13 Maintaining an information point for inquiries on Notices.
5.1.4.14 Day to day management of the Notice system including ensuring cover during holidays and sickness absence.

5.1.5 Divisional / Department / Line Managers are responsible for:

5.1.5.1 Reading carefully Safety Notice relevant to their servicer and role that they receive, paying particular attention to the full description of the device/product and the affected lot/serial numbers.

5.1.5.2 Responding to Safety Notice emails and being mindful when responses are required within a specific timescale. Note that response times notified will vary according to the urgency of the action required and read receipts may be requested when emails are sent.

5.1.5.3 Where practical to appoint a Deputy to respond to Safety Notices in their absence.

5.1.5.4 Ensuring that Safety Notices relating to their area are easily accessible to all staff and that staff are made aware of the Notices. This may include bank staff or staff from other wards or clinics are working in a particular area where active Safety Notices directly impacting their role and duties for patient care and/or use of equipment affected.

5.1.5 Divisional Department / Line Managers are responsible for: (continued)

5.1.5.5 Local systems for managing alerts take account of holidays and sickness absence.

5.1.5.6 Reporting incidents and near misses to Medical Physics Procurement / PSSD/ Radiology/ IM&T / Laboratories or Pharmacy. Equipment involved in incidents should be quarantines and labelled appropriately. Whenever practical, consumables used should also be quarantined to enable investigation.

5.1.5.7 Where appropriate reporting incidents and near misses and/or devices promptly via Datix, ensuring that full details are included in the 'Equipment' section of the electronic IR1 form.

5.1.6 Employees are responsible for:

5.1.6.1 Ensuring that all maintenance records they are responsible for administering are maintained and kept up to date.

5.1.6.2 Taking reasonable care to look after their own health and safety and that of others affected by their acts, decisions and / or omissions.

5.1.6.3 Being aware of responsibility for the safety of themselves and/or others who may be affected by their actions.

5.1.6.4 Co-operating by following all procedures designed for safe working.

6 Resource Implications

6.1 Time and support of managers' and / or those identified as responsible persons to administer the process of managing alerts and/or the work of reviewing and communicating alerts to all relevant staff.

6.2 The cost of taking any action(s) relevant to each alert which may include ordering replacement parts or equipment and/or the cost commissioning contractors to undertake work to resolve.

7 Communication Plan

This policy is posted on the NHS Lanarkshire public website. From revision of the policy, there will be no further formal programme of introduction or cascade, however, there will be general notification of the revision through the staff briefing process.

8 Quality Improvement - Monitoring and Review

8.1 Policy Review

This Policy will be reviewed either every 3 years and / or following legislative changes related to moving and handling by the author and contributing author(s) and circulated to Stakeholders. The reviews, including qualitative and quantitative data, will be reported through the Occupational Health and Safety Performance Group.

9 EQUALITY AND DIVERSITY IMPACT ASSESSMENT

EQIA completed? Yes ✔

10 Summary or Frequently Asked Questions (FAQs)

There are no FAQ's list to be read in conjunction with this Policy.

11 References

- The Scottish Government CEL 43 (2009) Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities, October 2009. Link address: https://www.sehd.scot.nhs.uk/mels/cel2009_43.pdf
- The Scottish Government Addendum to CEL 43 (2009) Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities, 21st November 2013. Link address: https://www.sehd.scot.nhs.uk/mels/cel2009_43add.pdf

Appendix 1 Safety Notice Management (this is provided as a best practice guide only)

Types of Safety Notices	Issued By	Received By	Initial Action	Further Action	Product Removal/Recall
Medical Devices Alerts (MDAs)	Medicines and Healthcare Products Regulatory Agency	Head of Medical Physics	Head of Medical Physics assess for relevance and Send to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads
Estates and Facilities Alerts (EFAs)	Health Facilities Scotland	PSSD General Manager or their designated representative	Assessed for relevance and sent to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads
Product Recall (PR) Notifications	NHS National Services (Scotland)-National Distribution Centre (NDC)	General Manager Procurement (some are copied to Equipment Co-ordinator)	Assessed for relevance and sent to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads
Customer Alert Notices (CANs)	NHS National Services (Scotland)-National Distribution Centre (NDC)	General Manager Procurement (some are copied to Equipment Co-ordinator)	Assessed for relevance and sent to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads
Field Safely Notices(FSNs)	Manufacturer – often precede a corresponding MDA	Sent anywhere in the organisation	Assessed for relevance and sent to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads
Safety Action Notices (SANs)	Health Improvement Scotland (HIS)	Relevant service leads	Assessed for relevance and sent to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads
Internal Safety Notices	Reported by all staff via DATIX	Equipment Co-ordinator(s)	Assessed for relevance and sent to appropriate Local Lead	Where appropriate distributed electronically to agreed distribution list with obligation to respond detailing action taken	Co-ordinated in liaison with the relevant Service leads