

Medical Device and Equipment Safety Notice Procedure

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NHS Shetland Document Development Coversheet*

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Please record details of any changes made to the document in the table below

| Date | Record of changes made to document |
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| December 2011 | <p>Additional detail on:</p> <ul style="list-style-type: none"> • Arrangements re: equipment lent for home use and role of Department Equipment Controllers • Customer Alert Notices (CANs) • Issuance of internal Safety Notices • Timescale and clarification of response times to Notices including arrangements for single person departments • Use of email 'read receipts' • Role of Equipment Co-ordinator (para.5.3) • Role of local leads (Appendix A) including addition of Community Nursing contact • Role of Finance and Procurement Staff <p>Addition of three flowcharts as appendices to illustrate responsibilities of Supplies Staff</p> <p>(Graham Southern, Chief Medical Physics Officer; Laurence Hughes, HoD - Orthotics; Fiona Smith, HoD – Physiotherapy; Fiona Morgan, Clinical Audit Officer, Karl Williamson, HoD – Finance and Procurement; Chris Brown, Physiological Measurements Officer; Kerry Russell, Assistant Director of Clinical Services; Edna Mary Watson; Assistant Director of Nursing (Community))</p> |
| January 2012 | <p>Para 5.2 outlines the requirement to identify individuals and a deputy in each department to be the focal point for the receipt and cascade of Notices. CAG members suggested that when the procedure is agreed and circulated, the Safety and Risk Support Team ask departments to provide information and then compile a list of responsible people</p> |
| January 2012 | <p>Two minor amendments from CSMT:</p> <ul style="list-style-type: none"> • Para 4.1(d) Add in Healthcare Improvement Scotland to Liaison Co-ordinator • Appendix A – Add 'prosthetics and Orthotic' to wheelchairs |
| March 2015 | <ul style="list-style-type: none"> • Document content reconfigured • CGCG changed to CCGG • Inclusion of New Safety Action Notices (SANs) which has replaced NHS England Patient Safety Alerts. • Bibliography - Addendum to CEL 43 (2009) Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities, 21st November 2013 • Appendix A updated |

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|-------------|---|
| | <ul style="list-style-type: none"> • Appendix C changed to D, E and F • Appendix B, C, and G added |
| August 2019 | <p>Minor changes to content of procedure.</p> <ul style="list-style-type: none"> • Contacts in Appendix A have been updated. • Flowchart updated in Appendix B regarding Local Leads actions. • Appendix G, CCGG changed to Health and Safety Committee. |
| May 2022 | <p>Amend procedure title to Medical Device and Equipment Safety Notices.</p> <p>Remove references to Health & Safety Committee and replace with Health, Safety and Wellbeing Committee.</p> <p>Remove all references to Health and Safety manager and replace with Health and Safety Lead.</p> <p>Para 2 and 8 - Add reference to SHTN 00-04 - Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services Jan 2021.</p> <p>Remove references to Equipment Coordinator and replace with Incident and Alerts Safety Officer.</p> <p>Remove all reference to CEL 43 2009 and replace with SHTN 00-04 2021.</p> <p>Add Responsible Medical Director, Medical Device and Equipment Risk Manager and Technical Specialist under "Roles and Responsibilities" within Section 5.</p> <p>Appendices reviewed and amended.</p> |

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1. Executive summary

NHS Shetland Board ('the Board') has a mandatory requirement to take all steps to minimise the risks to which patients, staff and others are exposed, as a result of the Board's undertakings.

The Medical Device and Equipment Safety Notice Procedure does not describe how to assess risks or report incidents. The Medical Device and Equipment Safety Notice Procedure forms part of the Board's Safety and Risk Management arrangements and should be read in conjunction with the following documents:

- Risk Management Strategy
- Health and Safety Policy
- Risk Assessment Procedure and Risk Register Guidance
- Incident Reporting, Investigation and Management Policy

All can be found on the Health, Safety and Wellbeing Committee and Risk Management pages of the intranet.

The Medical Device and Equipment Safety Notice Procedure:

- Explains the statutory requirements in relation to Safety Notices
- Defines the phrase 'Safety Notices' in terms of current practice
- Contains descriptions of the responsibilities for co-ordination and cascade of Safety Notices
- Sets out the measures that need to be undertaken to ensure appropriate action on receipt of a Safety Notice
- Contributes to the Board's objectives by aiming to improve the reliability and safety of everyday healthcare systems and processes.

2. Introduction and legislative framework

The Medical Device and Equipment Safety Notice Procedure reflects the responsibilities set out in the Board's Risk Management Strategy and Health and Safety Policy to meet the duty of care to staff, patients, visitors, others and to the organisation. This duty is enshrined in the Health and Safety at Work etc Act (HSWA) 1974 (and subordinate legislation) and outlined in the Core Dimension 3 (Health, Safety and Security) of the NHS Knowledge and Skills Framework (KSF). National guidance on the management of medical devices is contained in the SHTN 00-04 - Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services (January 2021).

This Procedure sets out the requirements to maintain patient and staff safety where information identifying potential risk is received by NHS Shetland 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 all Safety Notices received by the Board.

The Medical Device and Equipment Safety Notice Procedure does not include the management of Drug Alerts issued by the Medicines and Healthcare Regulatory Agency. These are received and managed directly by the Pharmacy Department under SOP Number 023.

3. Types of Safety Notices and receipt

'Safety Notice' (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:

| Type of Notice | Description |
|---|--|
| Customer Alert Notices (CAN) | 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. All CANs are received by the Supplies Department and the Health and Safety Team. |
| Product Recall Notifications (PRN) | These Notices are issued by NHS National Services (Scotland) – National Procurement. All PRNs are received by the Supplies Department the Health and Safety Team. |
| Safety Action Notice (SAN) | SANs contain information about significant safety issues which affect the Scottish health and social care system |
| Safety Information Message (SIM) | SIMs contain information about less significant safety concerns which affect the Scottish health and social care system. |
| National Patient Safety Alert (Nat PSA) | NatPSAs are published by partner organisations in England including MHRA and NHS Improvement. They contain information about serious safety issues — including issues affecting medical devices. |
| MHRA Device Safety Information (MDSI) | MDSIs capture safety information from MHRA. The information is about safety concerns which do not meet MHRAs criteria for a national patient safety alert. |
| Medical Device Alert (MDA) | MDAs contain information about safety issues which affect medical devices. MDAs are no longer issued. |
| Estates and Facilities Alert (EFA) | EFAs contain information about engineering, fire and property related risks. |

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| <p>Manufacturer Field Safety Notice (FSN)</p> | <p>FSNs contain important safety information about medical devices. They include guidance on how to reduce or eliminate the risks from affected devices.</p> <p>Device manufacturers and suppliers send field safety notices directly to affected customers.</p> |
|---|--|

Notices are occasionally received independently by individual members of staff e.g. the Medical Director. Any member of staff receiving a Notice must inform the Health and Safety Team to ensure that the team are aware of the notice and that appropriate action has been taken.

Rarely, it might 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. Management of Safety Notices

4.1. Assessment of Safety Notices

All notices are assessed when received by the Health and Safety Team and it is determined whether it needs to be disseminated further.

Occasionally 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 the relevant local leads to ascertain if the device is in use/stocked by NHS Shetland. This group includes technical and specialist managers e.g. Chief Medical Physics Officer, Transport and Purchasing Manager and Physiological Measurements Officer who will support the process by providing information and guidance. A list of key Safety Notice local leads is included as Appendix A.

In the case of PRNs and CANs, the National Distribution Centre normally indicates whether or not the product in question has been ordered by NHS Shetland. Supplies staff are responsible for determining if any of an affected product is in use/stocked and ensuring that this information is communicated to the relevant personnel, including the Health and Safety Team.

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

- Reply as requested – for example by completing and returning any customer acknowledgement slip to the manufacturer
- Forward a copy of the FSN to the Health and Safety Team noting any actions planned and/or taken
- Send a copy of any completed customer acknowledgement slip to the Health and Safety Team.
- Following these steps will help to ensure co-ordinated action on issues raised by manufacturers.

4.2. Cascade of Safety Notices

If it is established that a particular device/product is in use/stocked in NHS Shetland then a Safety Notice will be cascaded appropriately throughout the organisation.

Notices are distributed by electronic mail (e-mail) according to an agreed distribution list with an obligation to respond detailing action taken. These responses are then collated by the Health and Safety Team and reported to on a quarterly basis to the Health, Safety and Wellbeing Committee.

The Medical Physics Department maintains a comprehensive data base of medical equipment with a purchase value > £100.00. 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 Shetland.

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 inured as to 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. If a more comprehensive

4.3. Internal Safety Notices

All staff should use the organisation's risk management software system (Datix) to report incidents or near misses involving:

- Medical equipment and supplies. This includes medical devices, laboratory equipment, medical supplies and certain dietary products.
- Estates equipment, including engineering plant, installed services, piped medical gas and gas scavenging systems, buildings, building fabrics and vehicles.

NHS Shetland managers will review all incidents/near misses reported in this way and, where appropriate, inform the Board's Incident and Alerts Safety Officer (see Section 5 below) who will liaise with other key staff such as the Chief Medical Physics Officer 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 equipment or supplies need to be quarantined and this will be done via a global email from the Incident and Alerts Safety Officer giving the relevant details.

4.4. Product recalls

Where it is necessary to remove a device or product from use, this is co-ordinated by the Incident and Alerts Safety Officer in liaison with the Supplies / Estates Department as appropriate.

5. Roles and responsibilities

5.1. Chief Executive

The Chief Executive is responsible for ensuring that all senior managers and relevant staff in their organisation are aware of the information contained in SHTN 00-04(2021) and that procedures are in place to promote its effective and accurate implementation. The Chief Executive is also required to ensure that these procedures are 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. The Chief Executive must also identify a single point of contact within the Board who shall be nominated as 'Incident and Alerts Safety Officer'. In the case of NHS Shetland, this role is fulfilled by the Health and Safety Lead and IRIC have been advised of the appointment and contact details of the post holder.

5.2. Responsible Medical Director

The NHS Shetland Medical Director is designated as the 'Responsible Medical Director' as required under the SHTN 00-04(2021) guidance.

The Responsible Medical Director shares responsibility with other NHS Shetland Executive Directors for strategic discussions concerning governance and service design around equipment and duty of candour adverse events framework, as well as managing adverse events larger than one health board.

5.3. Medical Device and Equipment Risk Manager

An expert in medical devices and the systems that support them.

The Medical Device and Equipment Risk Manager is responsible for:

- Monitoring and ensuring medical devices and equipment are functioning.
- Acts in support of the Responsible Medical Director role, in the capacity of the lead medical device risk management expert within an organisation.
- The operational working knowledge and detailed technical understanding of legislation, standards and guidance covered within the SHTN 00-04 2021 guidance document.
- Formal responsibility (not necessarily a full-time commitment) for medical devices and equipment.

5.4. Senior managers

Senior managers are responsible for ensuring that within their areas of responsibility a named individual (normally the Head of Department 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 to be logged with the Health and Safety Team. This is of particular importance in single-handed departments.

The Chief Executive has appointed the Medical Director as the Senior Manager with specific responsibility to oversee medical device safety and risk management strategy throughout the Board.

5.5. Incident and Alerts Safety Officer

The Incidents and Alerts Safety Officer is a formal role assigned to the Health and Safety Lead, (supported by the PA to the Director of HR and SS) by the Chief Executive and this includes responsibility for:

- Ensuring managers and staff are aware of the procedures for reporting adverse incidents and for implementing safety advice
- Monitoring all adverse incidents reports from within own organisation

- Receiving emails from Incident Reporting and Investigation Centre (IRIC) notifying of alerts and bulletins, and cascading within own organisation
- Monitoring relevant websites for information on equipment safety and management issues
- Discussing equipment safety issues with IRIC
- Promoting equipment safety by staff education and training in conjunction with IRIC
- Building and maintaining communication links with IRIC
- Attending Incident and Alerts Safety Officer's conferences and seminars
- Monitoring internal cascade systems to ensure Notices are received, assessed and acted upon.

To support the work of Incident and Alerts Safety Officers, an 'Incidents and alerts Safety Officer (ISO) Network' Group is established, which meets biannually. The Health and Safety Lead is required to participate on behalf of the Board.

5.6. Technical Specialist

The Technical Specialist carries organisation-wide responsibility in the fields of Medical Physics and Clinical Engineering, in Laboratory Medicine, in Facilities Management, in Infection Prevention and Control, and in eHealth and Health Informatics. The Technical Specialist, (Head of Medical Physics), is the operational and strategic lead for medical equipment lifecycle management within NHS Shetland. Due to the size and management structure within NHS Shetland, the Medical Device and Equipment Risk Manager and the Technical Specialist roles are normally undertaken by the same officer.

5.7. The Health and Safety Team

The Health and Safety Team are responsible for:

- Receipt and recording of Notices
- Assessing the relevance of Notices (see section 4.1 above)
- Distribution and liaison to local leads, including collation of any local responses
- Determining cascade distribution
- Liaison with the Supplies / Estates Department
- Maintaining an information point for inquiries on Notices
- Day to day management of the Notice system including ensuring cover during holidays and sickness absence.

5.8. Local leads

Local leads have a role as initial contacts for the Health and Safety Team and play a key role in the initial assessment of Safety Notices. Their clinical, technical and organisational expertise helps to ensure that Notices are targeted appropriately. See Appendix A

5.9. Supplies Department

The Supplies Department are responsible for:

- Reading carefully each and every Safety Notice they receive, paying particular attention to the full description of the device/product and the affected lot/serial numbers
- Determining whether or not an affected product/device has ever been ordered as a stock item by the Board
- Collecting and quarantining of affected items from wards/departments/stores as required
- Liaising with manufacturers, the NDC and Health and Safety Team in relation to affected products.

5.10. Heads of Departments and Ward Managers

- Reading carefully each and every Safety Notice they receive, paying particular attention to the full description of the device/product and the affected lot / serial numbers
- Responding to Safety Notice emails without delay, particularly 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 will be requested when emails are sent
- Appointing a Deputy to respond to Safety Notices in their absence.
- Ensuring that Safety Notices relating to their area are easily accessible to all staff and that staff are made aware of the Notices. Where bank staff – or staff from other wards or clinics – are working in a particular area, Safety Notices directly relating to patient need and equipment must be highlighted
- Ensuring that local systems for single-handed departments take account of holidays and sickness absence
- Reporting incidents and near misses involving medical equipment and/or devices promptly via Datix, ensuring that full details are included in the 'Equipment' section of the electronic IR1 form.

5.11. All staff

All staff are responsible for:

- Co-operating with this procedure as this is a vital part of ensuring the health, safety and security of patients, clients, the public, colleagues and themselves
- Reading Notices relevant to their department and implementing measures introduced in response to Notices.

6. Governance

Governance of the Safety Notice Procedure will be achieved through:

- Periodic audits of the Procedure within the Human Resources and Support Services Directorate
- Periodic reviews within operational areas

- Quarterly reporting the Health, Safety and Wellbeing Committee
- 'As requested' reports to the Risk Management Group
- Audits on an 'as requested' basis by Internal Auditors.

All can be found on the Health and Safety and Risk Management pages of the intranet.

7. Equality and Diversity Impact Assessment (EDIA)

The EDIA carried out as part of the Risk Management Strategy recognises that in complying with the Health and Safety at Work etc Act 1974, the Board meets its duty of care towards employees and others who may be affected by its activities. The strategy recognises the statutory requirement to give special consideration to other groups including night workers, lone workers and workers with disabilities.

As the strategy makes clear, the promotion of a fair, open culture is an essential component of an effective risk management system.

The impact of the Risk Management Strategy and supporting documents has been assessed as positive in relation to equality and diversity.

8. Bibliography

<https://www.nss.nhs.scot/media/1220/shtn-00-04-guidance-on-management-of-medical-devices-v20.pdf> dated January 2021.

Appendix A – Safety Notices local leads

When a Notice is received by the Health and Safety Team they will make contact with local leads to determine the most effective distribution strategy. This contact can be made by telephone or email.

Each of these leads will find out if the device or product is in use within NHS Shetland, establish if action plans are already in place and indicate the course of action that should be taken by the recipients of the notice. This information is then used in the distribution email.

| Notice relating to: | Job title | Comments |
|--|---|---------------------------------|
| Beds | Maintenance Manager. Chief Nurse Acute and Specialist Services. Chief Nurse Health and Social Care. | Estates: type and make of bed |
| Mattresses: Full Replacement therapy Pressure Relieving | Maintenance Manager. Chief Nurse Acute Infection Control Manager. | |
| Community Nursing | Chief Nurse (Community). | |
| Estates issues | Head of Estates and Facilities. Maintenance Manager. | |
| Hoists and patient lifting equipment | Maintenance Manager. Chief Nurse Acute and Specialist Services. Head of Physiotherapy. Training Advisor- Moving and Handling | Estates: type and make of hoist |
| Implantable cardiac devices such as Pacemakers | Medical Director Head of Physiological Measurements | |
| Medical Devices / Equipment | Head of Medical Devices. | |
| Physiotherapy (including mobility and standing aids) | Head of Physiotherapy. | |
| Wheelchairs, Prosthetics and Orthotics | Orthotic Manager / Principal Orthoptist. | |

| Notice relating to: | Job title | Comments |
|---|---|--|
| Supplies | Transport and Procurement Manager. Procurement Office. | Supplies – single use and disposable, are often categorised under medical devices. If an item is consumable or can be ordered from central stores it is probably supplies. |
| Patient Trolleys / Patient Examination Couches | Maintenance Manager. Chief Nurse Acute and Specialist Services | |
| Patient Standard Chairs / Standard Leg Stools | Chief Nurse Acute and Specialist Services | |
| Occupational Therapy – Patient Specialist Chairs | | |
| Patient Renal Chairs | Senior Charge Nurse- Renal. | |
| Chemotherapy Chair | Maintenance Manager. Macmillan CNS Oncology and Lead Cancer Nurse. Cancer and Palliative care Team. | |

Appendix B – Safety Notice Management Flow Chart

| Types of Safety Notices | Issued by | Received By | Initial Action | Further Action | Product Removal / Recall |
|---------------------------------------|---|--|--|---|--|
| MHRA Device Safety Information (MDSI) | Medicines and Healthcare Products Regulatory Agency | Health and Safety Team (HST) | HST Assess for relevance and Send to appropriate Local Leads (see Appendix A) | Distributed electronically to agreed distribution list with obligation to respond detailing action taken. Responses collated by HST and reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Supplies Department |
| Estates and Facilities Alerts (EFAs) | Health Facilities Scotland | HST | HST Assess for relevance and Send to appropriate Local Leads (see Appendix A) | Distributed electronically to agreed distribution list with obligation to respond detailing action taken. Responses collated by HST and reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Estates Department |
| Product Recall (PR) Notifications | NHS National Services (Scotland) – National Procurement | Supplies Department (some are copied to HST) | Supplies Department Decide if affected product is in stock / use in NHS Shetland | Distributed electronically to agreed distribution list with obligation to respond detailing action taken. Responses collated by HST and reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Supplies Department |
| Customer Alert Notices (CANs) | NHS National Services (Scotland) – National distribution Centre (NDC) | Supplies Department (some are copied to HST) | Supplies Department Decide if affected product is in stock / use in NHS Shetland | Distributed electronically to agreed distribution list with obligation to respond detailing action taken. Responses collated by HST and reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Supplies Department |

| Types of Safety Notices | Issued by | Received By | Initial Action | Further Action | Product Removal / Recall |
|--------------------------------|--|--|--|--|--|
| Field Safety Notices (FSNs) | Manufacturer - often precede a corresponding MDA | Sent anywhere in the organisation | Individual Recipient completes acknowledgement slip and sends to company as soon as possible | Forward a copy of the FSN to the HST Provide a copy of the completed customer acknowledgement slip to HST Responses collated by HST and reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Supplies department |
| Safety Action Notices (SANs) | Health Improvement Scotland (HIS) | Equipment Co-ordinator / HST | Reviewed by HST and Sent to Stores and appropriate Local Leads (See Appendix A) | Distributed electronically to agreed distribution list with obligation to respond detailing action taken. Responses collated by HST and reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Supplies Department |
| Internal Safety Notices | Reported by all staff via DATIX | HST review and inform Board's Equipment Co-ordinator | Liaise with key staff | Online report sent to Health Facilities Scotland Incident Reporting and investigation centre (IRIC) Reported to Health and Safety Committee quarterly. | Co-ordinated by Equipment Co-ordinator in liaison with the Supplies Department |