Medical Devices Policy

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Executive Summary

This document describes the responsibilities and procedures concerned with the management of medical devices in NHS Lothian. It is intended for staff, carers and patients responsible for the safe use and management of medical devices and aims to help develop practices and systems which promote the use of the medical devices for safe and effective healthcare. Medical devices have an important role in the monitoring, diagnosis, therapy, rehabilitation and care of patients within NHS Lothian.

Proactive management of medical devices supports the delivery of high quality patient care and effective clinical and financial governance, which works to minimise the risk of adverse events, and the potential for harm caused if they do occur.

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1.0 Purpose

The purpose of this policy is to ensure that a consistent approach is taken by all services in relation to medical device management. This policy exists to protect the wellbeing of staff, carers and patients by promoting systems that ensure medical devices used within NHS Lothian are managed successfully at every level. The prevention of mismanagement of medical devices is crucial in providing safe care, particularly in the current circumstances where medical devices are used routinely throughout NHS Lothian.

2.0 Policy statement

The policy sets out the responsibilities of staff managing medical devices within NHS Lothian. Successful management is achieved by verifying that medical devices are:

- Purchased according to standing instructions and regulations, and with due regard to national / international guidance
- Suitable for their intended purpose
- Used only by a competent member of NHS Lothian staff, a patient or carer who has received appropriate training in the use of the device
- Used only in the appropriate environment for the designed use
- Traceable from equipment inventory records
- Maintained in a safe and reliable condition
- Disposed of safely at the end of their working life
- Replaced having regard to the procedures and guidance aligned with this policy

3.0 Scope

This policy and supporting documentation applies to all medical devices used by NHS Lothian. Topics covered include: procurement, medical devices on loan, standardisation, training, maintenance, repair, adverse events (including near misses), safety alerts, security, decontamination, decommissioning and disposal. See Section 6.0 ‘Associated Materials’.

4.0 Definitions

'Medical Device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by the manufacturer to be used specifically for the diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

'Accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

'Acceptance' refers to the checks and tests to establish that the correct equipment has been delivered and that it is all in good working order. This allows the order to be signed off and paid for.

'Commissioning' is the process of putting a new piece of equipment into clinical service and includes signing off building work or minor works, equipment configuration, clinical training and attending to safety infrastructure.

'Installation' involves setting the equipment in good working order in the appropriate clinical area.

Abbreviations

ACCORD = Academic and Clinical Central Office for Research and Development
AHP = Allied Health Professional
CEL = Chief Executive Letter
HAI = Healthcare Associated Infection
HAI-SCRIBE = Healthcare Associated Infection Systems for Controlling Risk in the Built Environment
HFS = Health Facilities Scotland
HSCP = Health and Social Care Partnership
HSDU = Hospital Sterilisation and Decontamination Unit
IPC = Infection Prevention and Control
IRAS = Integrated Research Applications System
IRIC = Incident Reporting Investigation Centre
LMERG = Lothian Medical Equipment Review Group
MDC = Medical Devices Committee
MHRA = Medicines and Healthcare products Regulatory Agency
QIST = Quality Improvement Support Team
RSC = Radiation Safety Committee
SHTG = Scottish Health Technologies Group

5.0 Implementation roles and responsibilities

This policy is managed by the NHS Lothian Medical Devices Committee. All NHS Lothian staff are affected by this policy. Staff have the following responsibilities:

5.1 NHS Lothian Chief Executive

The Chief Executive has overall responsibility for NHS Lothian Board affairs. Responsibility for ensuring the efficient, effective and safe planning, operation, management and disposal of medical devices and equipment for all NHS Lothian Services has been delegated to the Executive Medical Director.

5.2 Deputy Chief Executive, Chief Officer Acute Services, Chief Officer or Directors of Health and Social Care Partnerships

The Deputy Chief Executive, Chief Officer Acute Services and Chief Officer or Directors of Health and Social Care Partnerships are accountable for the overall implementation of this policy and ensuring that procedures exist for the reporting of adverse events, the dissemination of safety advice and the control of risks relating to health, social care, estates and facilities equipment, including medical devices.

5.3 Executive Medical Director

The Executive Medical Director is responsible for ensuring doctors provide evidence of training in the specification, suitability and use of relevant medical devices. This can be agreed locally with Clinical Directors. The Executive Medical Director has delegated responsibility for the Medical Devices Policy and for keeping the Chief Executive up to date with information regarding the organisation's medical devices and equipment.

5.4 Medical Directors for Acute and Primary Care Services

The Medical Directors for Acute and Primary Care Services are responsible for the monitoring of:

- Investment in training on equipment (including Medical Devices)
- Optimum utilisation of major items of equipment (including Medical Devices)
- Appropriate clinical engagement in equipment procurement programmes

5.5 Associate Director for Quality Improvement and Safety and the Quality Improvement Support Team (QIST)

As outlined within CEL43(2009), the responsibility for some aspects of the Incidents and Alerts Safety Officer (previously known as the Equipment Co-ordinator) role have been delegated by the Chief Officer to the Associate Director for Quality Improvement and Safety and fulfilled by the Quality Improvement Support Team (QIST). These duties include:

5.5.1 Safety Alerts

As outlined in the NHS Lothian Operational Procedure for addressing Clinical Governance related guidance: Safety Alerts. (available on NHS Lothian intranet)

- To provide a single point of contact within NHS Lothian for the receipt, of Safety Alerts, to ensure that all safety alerts and similar communications such as field safety notices received are appropriately assessed before being issued to the service for action, when appropriate and relevant to do so
- Ensure a system is in place to facilitate the raising and sharing of Internal Safety Alerts
- Provide assurance and reporting around the above processes

5.5.2 Adverse Event Management

As outlined in the organisation's Adverse Event Management Policy and Adverse Event Management Procedure

- To ensure managers and staff are aware of their responsibilities for reporting, reviewing and learning from adverse events
- To provide a system, support and training to facilitate the management of adverse events within NHS Lothian, including the Datix Risk Management Information System
- Provide a framework to encourage and monitor the sharing and reporting of medical device related adverse events with external organisations such as the Health Facilities Scotland, Incident Reporting Investigation Centre (IRIC) when relevant to do so
- Build and maintain communication links with Health Facilities Scotland (HFS) and other NHS Boards and organisations by attending networking events such as the Incidents and Alerts Safety Officers meetings on behalf of NHS Lothian

5.6 Directors, Associate Medical Directors, Directors of Nursing, Associate Directors of Nursing, Chief Allied Health Professionals and Healthcare Science Professional Leads

Directors, Associate Medical Directors, Directors of Nursing, Associate Directors of Nursing, Chief Allied Health Professionals and Healthcare Science Professional Leads:

- Are accountable to the Deputy Chief Executive / Chief Officer(s) or equivalent for ensuring that this policy is implemented within their respective Service Units and Directorates

5.7 Clinical Directors

Clinical Directors in hospital and HSCP settings must ensure that:

- All grades of doctors working within their service including locum doctors are appropriately trained on the medical devices they are expected to use in their working environment and that a record is kept of this
- Medical equipment is released to the relevant Scientific/Technical service as required for routine maintenance

5.8 Clinical Nurse Managers, Charge Nurses, Community Nurse Team Leads, Hub Managers and Cluster Managers

Clinical Nurse Managers, Charge Nurses, Community Nurse Team Leads, Hub Managers and Cluster Managers will ensure that:

- Nurses, midwifes, health visitors and students working in ward, clinic and community settings are adequately trained to use and care for the medical devices they require to perform their duties and that a record of the training is kept
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance
- Agency and Bank staff, only use, medical equipment that they are trained on

5.9 Allied Health Care Professionals (AHP) Leads and managers of AHP services

AHP Leads and managers of AHP services will ensure that:

- AHPs working in ward, clinic and community settings are adequately trained to use and care for the medical devices they require to perform their duties and that a record of the training is kept
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance
- Agency and Bank staff, only use, medical equipment that they are trained on

5.10 Clinical Physiology Leads and Managers of clinical physiology services

Clinical Physiology Leads and managers of clinical physiology services will ensure that:

- Clinical Physiologists working in clinic or ward settings are adequately trained to use and care for the medical devices they require to perform their duties and that a record of the training is kept
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance or calibration. The equipment may be on an external maintenance contract
- Agency and Bank staff, only use, medical equipment that they are trained on

5.11 General Managers and equivalent

General Managers and equivalent will ensure that the procurement of medical devices is carried out correctly, in particular that:

- Standing Financial Instructions are followed
- Applications for medical devices are adequately described, justified, costed and prioritised prior to submission
- Recurring costs are identified and included in the bid
- The impact of the bid on other management groups has been considered and agreed (i.e. installation costs, maintenance and support costs, additional patient numbers etc)
- The Head of the relevant Scientific / Technical Department is consulted before medical devices are purchased and as appropriate during their use
- Infection control is consulted to ensure that the device can be safely used and decontaminated according to NHSL Policy and Procedures
- Facilities are contacted to ensure the equipment can be disposed of according to NHS Lothian Policy
- Digital and IT is contacted prior to purchase to consider any networking or IT security requirements are met
- Revenue expenditure for purchase, maintenance and support is managed

5.12 Service Managers and Locality Managers

Service Managers and Locality Managers will ensure that:

- Their department is adequately equipped to carry out its function
- Department staff members are adequately trained to use and care for the medical devices they require to perform their duties
- Safety Alerts relating to medical devices, staff and patient safety, are locally assessed and appropriate actions taken, including when appropriate, distributing to all staff members who may use the medical device in question. Maintaining a local assurance process to record alerts received, actions taken and responding to the Quality Improvement Support Team (QIST) to confirm actions complete.
- Hazards relating to medical devices are identified, assessed and the risks associated with these hazards are managed and recorded on a risk register
- All medical equipment has a funded maintenance and replacement programme

5.13 Director of Finance

The Director of Finance will be responsible for the monitoring of:

- Capital expenditure on equipment (including Medical Devices)

- Total replacement value
- Estimated replacement value for non-capitalised equipment items
- Net book value
- Annual depreciation
- Revenue expenditure for purchase, maintenance and support.
- Lease expenditure

And will ensure that:

- Professional financial advice is available where required
- Capital and revenue budgets are adequate to meet the requirements set out in this policy
- Standing financial instructions are followed at all times
- All appropriate funding routes are considered

5.14 Head of Procurement

The Head of Procurement will ensure that:

- Competitive financial tenders are obtained according to the Board's standing financial instructions and applicable regulations in the UK
- Procurement advice is available to all procurement exercises
- Best value for money and optimal clinical outcome is obtained in the procurement of medical devices

5.15 Heads of Departments with responsibility for medical device maintenance

Heads of Departments (or equivalent) with responsibility for medical device maintenance will ensure that medical devices are fit-for-purpose, safe and effective, and will:

- Provide scientific and technical advice to the Board's medical devices procurement committees, General Managers, Heads of Service and medical device users
- Provide maintenance, repair, calibration, performance verification and safety testing services for medical devices
- Advise on medical devices management issues and identify medical devices that may need to be replaced for safety or operational reasons
- Lead and assist medical device users to carry out medical device evaluations
- Ensure that medical devices which have been obtained on loan for the purposes of evaluation comply with national guidance regarding indemnity
- Facilitate the prioritisation of requests
- Identify suitable programme leads for equipment management and procurement

5.16 Associate Director for Infection Control and the Infection Prevention and Control Team

The Associate Director for Infection Control and the Infection Prevention and Control (IPC) Team will:

- Ensure that manufacturer's instructions for use align with the national IPC policy requirements and advise NHS Lothian on safe implementation of these
- Ensure advice regarding any clinical infection risks identified in relation to the safe use or decontamination and disposal of medical devices is available to purchasers and users
- Ensure that policies and procedures on decontamination are appropriate and up-to-date
- Ensure HAI-SCRIBE documentation is adhered to when replacing medical devices that require specific environmental conditions (e.g. ventilation, water, drainage) for safe use or impact on the integrity of the built environment for installation

5.17 The Lead for Decontamination

The Lead for Decontamination is responsible for disinfection and sterilisation processes in the Hospital Sterilisation and Disinfection Unit (HSDU) for Dental and Theatres and for decontamination processes for all reusable endoscopes.

SHTM 01-01 Parts A – F (SHTM 01-01) describe a framework for ensuring the safe reprocessing of re-usable surgical instruments and endoscopes.

The Lead for Decontamination and the Authorising Engineer (Decontamination) have a responsibility to ensure the reprocessing equipment within NHS Lothian meets regulatory requirements via audit and equipment certification.

5.18 The Surgical Instruments Manager (SIM)

This is a developing role first introduced in 2018 under the tracking and traceability project. The Surgical Instruments Manager (SIM) leads NHS Lothian asset and inventory management of re-useable surgical instruments and:

- Ensures that the inventory of surgical instruments is proactively reviewed and managed, in accordance with the key result areas, guidance, clinical requirements and industry best practice
- Liaises with all stakeholders that have a relationship with surgical instruments and takes direction from the Lead for Decontamination in relation to instruments management infrastructure and processes
- Is the key point of liaison who must be involved when new surgical instrumentation is being considered or when issues with instruments arise
- Provides leadership, support and expertise to clinical and decontamination services (HSDU) in relation to the management of surgical instruments to ensure that the

instrument and set use cycle for the entire process is effective from beginning to end, to cover stock holding, storage and transportation and set integrity

- Identifies processes and introduces innovation into the process that can impact results, enhance efficiency and assist NHS Lothian to meet its business objectives and goals and ensure compliance with national and international standards

5.19 Director of Digital and IT

The Director of Digital and IT will ensure that:

- Advice is available on how medical devices can or cannot be connected to the NHS data network
- Advice is available on security and virus protection when required

5.20 All NHS Lothian staff, Agency, Bank and locum staff, and students

All NHS Lothian staff including agency, bank and locum staff and students have an individual responsibility to engage in equipment training for all medical devices and equipment that they use. This includes induction, refresher and new equipment training programmes.

All NHS Lothian staff will:

- Carry out the appropriate day-to-day maintenance or calibration required of the clinical user on the medical devices that they use
- Know how to safely and effectively operate the medical devices that they need to use to perform their duties
- Only use equipment they have been trained on unless they are using the equipment under direct supervision of another competent individual.
- Know how to decontaminate the medical devices that they use
- Check that medical devices are clean and in good working order prior to use
- Check the service label before use, and contact the department/company responsible for maintenance if the device is out with its service date. (Medical devices that have passed their “service due” date must only be used if there is a strong clinical need e.g. the medical device is attached to a long-term patient and there is no other device available). Sufficient spares will usually allow swapping equipment out for servicing.
- Know how to report faulty medical devices
- Know how to report adverse events where a medical device may have been a contributing factor both locally (on Datix) and when appropriate to do so, nationally to IRIC
- Know how to safely store medical devices in order to protect them from environmental contamination and damage
- Liaise with members of the Medical Devices Committee as required

5.21 NHS Lothian Medical Devices Committee

The role of the NHS Lothian Medical Devices Committee is:

- To develop and audit policies and procedures to help ensure the safe and effective management of medical devices within the NHS Lothian
- Examine guidance on medical device use and management from the MHRA, Health Facilities Scotland, Scottish Government, Scottish Health Technologies Group (SHTG) and other appropriate competent organisations and recommend appropriate responses to help ensure that NHS Lothian complies with the guidance
- To help ensure the standardisation of medical devices where appropriate
- To bring shortfalls in the provision of medical devices to the attention of the Medical Director and the services concerned
- To work with the Department of Nursing, Clinical Educators, Medical Directors, Clinical Directors, Allied Health Practitioners and Healthcare Scientists to ensure that all staff are competent in the use of medical devices relevant to the area where they work
- To monitor events (near misses and accidents) involving medical devices, working with the Quality Improvement Support Team (QIST) to ensure that lessons are learnt to help avoid recurrences of events

5.22 Lothian Medical Equipment Review Group (LMERG)

The role of the Lothian Medical Equipment Review Group (LMERG) is:

- To manage the replacement of the Board's inventory of medical devices in line with the Board's targets and best clinical practice
- To balance financial and clinical risk in line with the available budget and report to the Director of Finance and Executive Medical Director
- To develop and manage replacement programmes of capital medical equipment in line with 10-year replacement plans
- Tie the 10-year capital replacement plan in with Lothian's overall capital plan and building strategy
- To ensure the correct governance is in place for the funded replacements

5.23 Lothian Radiation Protection Committee (LRPC)

The role of the Lothian Radiation Protection Committee (LRPC) is to ensure that the use of medical devices involving ionising or non-ionising radiation is compliant with:

- NHS Lothian Radiation Protection Policy
- Ionising Radiations Regulations 2017
- Ionising Radiation (Medical Exposure) Regulations 2017
- Environmental Authorisations (Scotland) Regulations 2018

- Control of Artificial Optical Radiations at Work Regulations 2010

5.24 Academic and Clinical Central Office for Research and Development (ACCORD)

The role of the Academic and Clinical Central Office for Research and Development (ACCORD) is:

- To oversee the governance arrangements for clinical trials involving medical device developments or modifications. Management and ethics approvals are obtained via the Integrated Research Applications System (IRAS).

5.25 Clinical Educators (Nursing), Medical Educators (Doctors) and educators for other professional groups

Clinical educators (nursing), medical educators (doctors) and educators for other groups will ensure that:

- Clinical skills education is provided for their respective professional groups within NHS Lothian
- An education programme is available covering medical devices where appropriate

These educators will design and develop workshops, study days and competency education in relation to clinical skills for their respective professional groups.

5.25.1 Specialist medical equipment

Training on specialist medical equipment is delivered by trainers within the relevant service.

5.25.2 New medical equipment

Training on medical equipment new to NHS Lothian is delivered by the respective company most commonly on a Train the Trainer basis. Training will be part of the purchasing contract.

5.26 Clinical Services that loan medical devices to patients and carers

Clinical Services that loan Medical Devices to patients and carers must ensure that:

- For devices that are owned by NHS Lothian and loaned to end users in the community, the responsibility for ensuring that the device is delivered and is safe to use is the responsibility of the service. Incident reporting to IRIC is also the responsibility of the service.
- For devices that are owned and managed by a commercial supplier, the manufacturer's pre-dispatch tests in combination with end user pre-use checks will assure safety. Record keeping is the responsibility of the manufacturer with input from the end user as appropriate. Incident reporting to the MHRA is the responsibility of the manufacturer who must also inform the relevant NHS Lothian

service. NHS Lothian conducts periodic supplier audits. All suppliers must co-operate with and help facilitate, such audits.

- There is a robust process in place for the return of medical devices, accessories and equipment which have been loaned to patients.
- Patients relying on electrical power or a water supply for critical medical equipment in the community should be encouraged to register on the priority register system for people in need. This system can provide early alerts from the power or water companies to possible outages or support in the event of an unexpected outage.
- Applicable health critical equipment is labelled with the distribution network (power) operator emergency helpline number “105”.

5.27 Patients and Carers issued with a medical device

Patients and carers issued with a medical device must:

- Attend training provided by the clinical service on the relevant equipment and the associated procedures. Provision of the training and assessment of the acquired competency is the responsibility of the clinical service.
- Know how to safely and effectively operate the medical devices that they need to use out with the hospital/clinic environment. Written evidence of this is held by issuing department.
- Check that medical devices are clean and in good working order prior to use.
- Carry out appropriate routine checks and maintenance on the medical devices that they use.
- Know when to and how to obtain servicing for the equipment they use and understand the importance of this requirement.
- Know how to report faulty medical devices and to whom.
- Only use equipment they have been trained on or provided an appropriate level of instruction on. Instructions for use should be available and in a format that is appropriate to the abilities and understanding of the end user.
- Know how to and to whom they should return medical equipment that they no longer need.

5.28 Primary Care Practitioners

Primary Care Practitioners directly employed by NHSL have a contractual responsibility to follow the NHSL Medical Devices Policy.

Primary Care Practitioners who work as independent contractors to the NHSL have a professional responsibility to follow the principles of the NHSL Medical Devices Policy.

5.29 Third-party contractors

NHS Lothian work with a range of third-party contractors who provide a range of services, including the supply and/or maintenance of medical devices. This falls under the remit of the Control of Contractors Policy.

6.0 Associated materials

Adverse Event Management Policy approved by the Policy Approval Group

Adverse Event Management Procedure approved by the Policy Approval Group

NHS Lothian Radiation Protection Policy approved by the Policy Approval Group

NHS Lothian: Clinical Governance and Risk Management Documents: Key Papers

NHS Lothian Capital Planning Guidance

NHS Lothian Standing Orders Pack approved by the Lothian NHS Board

NHS Lothian Operational Procedure for addressing Clinical Governance related guidance: Safety Alerts (available on NHS Lothian intranet)

The Medical Devices Committee will provide a lead author or authors for relevant supporting documents which will be circulated to the Medical Devices Committee for comment and finally approved by the Medical Devices Committee and linked to this Medical Devices Policy. The following documents have been approved by the MDC.

Medical Devices Minimum Data Set

Guidance for clinicians leading an LMERG equipment replacement programme

Medical Devices – NHSL Structure

Nursing and Midwifery Training on medical equipment

Medical Devices Committee – Risk Reports

7.0 Evidence base

The Medical Devices Regulations 2002. Statutory Instrument 2002 No.618. ISBN 0110423178.

In-house manufacture of medical devices, UK Government.

NSS: Health Facilities Scotland: Master Indemnity Agreement Terms and Conditions

UK Government: Medicines, medical devices and blood regulation and safety-guidance: Custom-made medical devices. From MHRA August 2013

Healthcare Improvement Scotland, Healthcare Associated Infection (HAI) Standards, February 2015 / Scoping Report, January 2021

CEL 43 (2009) Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities

CEL35 (2010) A Policy for Property and Asset Management in NHS Scotland

Managing Medical Devices: Guidance for Healthcare and Social Services Organisations, MHRA, 2021

SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services, Health Facilities Scotland, 2021

Decontamination of medical devices in a Central Decontamination Unit (SHTM 01-01) | National Services Scotland (nhs.scot)

8.0 Stakeholder consultation

The policy was drafted by the Medical Devices Committee, which is a multidisciplinary group. The document has been shared for comment with other relevant parties which include LMERG which is another multidisciplinary group, the Medical Director of Acute Services, the Medical Director of Primary Care, Senior Leadership staff in all four NHSL Health and Social Care Partnerships, the Executive Medical Director, the Director of Allied Health Professionals, the Director of Medical Education, the Deputy Head of Education and Development (Nursing), the Associate Director of Infection Prevention and Control, the Lead Clinical Physiologist for Clinical Neurophysiology, the Lead Audiologist in RHCYP and Clinical Physiologist in the Sleep Lab in RHCYP.

The preceding policy 2017 v3.4 was posted on the consultation zone. Feedback for this version was sought from young people and carers who attended the Royal Hospital for Sick Children as service users in April 2016. This has not been repeated as the relevant section of the policy has not altered significantly. A Rapid Impact Assessment for the policy 2017 v3.4 was performed in August 2015.

9.0 Monitoring and review

The Medical Devices Committee will monitor and review the policy as follows:

- Medical Device inventory review
- Maintenance targets for groups of medical devices will be reviewed
- Repair records will be reviewed
- Clinical and Technical training levels will be reviewed
- Themes from adverse events relating to medical devices are reported to the Medical Devices Committee
- Risk Registers from a range of services will be audited for medical devices related issues
- The policy and related guidance documents will be reviewed by the Medical Devices Committee every 3 years