MEDICAL DEVICES
POLICY FOR ACUTE SERVICES

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1. **Introduction**

   1. This document describes the responsibilities and policies concerned with reusable medical devices [definition in glossary] in NHS Lothian Acute Division. It covers: procurement, medical devices on loan, standardisation, training, maintenance, repair, adverse events (including near misses), safety alerts, security, decontamination, decommissioning and disposal. Single use medical devices are subject to a separate policy. However the interface of single use items with reusable items is of relevance to the Medical Devices Committee.

2. **Aim of the policy**

   2. The aim of this policy is to ensure that whenever medical devices are used within NHS Lothian Acute Division, they will be:

      • 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

      • 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 contained in this policy

      • This policy version is written for the governance structure for NHS Lothian Acute Division.

      • Many of the principles apply for other divisions of NHS Lothian however further work is to be done with respect to the lines of accountability for these divisions.

      • The Terms of Reference of the Medical Devices Committee (covering NHS Lothian Acute Division) is currently under review.
3. Key objectives

3. All ward and departmental managers should be familiar with this policy to ensure they understand their responsibilities and are able to cascade their knowledge and skills to their teams.

4. This policy will be monitored by the Medical Devices Committee to ensure wards and departments have understood the policy, and are able to feedback to the Committee any issues regarding implementation or revision of the policy.

5. The Medical Devices Committee will review this policy and systems for managing the use of medical devices on an annual basis, and an annual report will be submitted to the Clinical Management Group.

6. This document is also required for the Scottish Government via the Property and Asset Management Strategy (PAMS).

4. Policy scope

7. This policy applies to all re-usable medical devices used by NHS Lothian Acute Division.

5. Evidence Base


6. Roles and Responsibilities

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

10. The Chief Officer is responsible 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. The Chief Officer chairs the Lothian Medical Equipment Review Group (LMERG).

11. The Executive Medical Director is the responsible officer for revalidation of doctors and is responsible for ensuring doctors provide evidence of training in
the use of relevant medical devices. This can be agreed locally with Clinical Directors.

12. The **Medical Director for Acute Services** will be responsible for the monitoring of:

- Investment in training on equipment (including Medical Devices)
- Optimum utilisation of major items of equipment (including Medical Devices)

13. As outlined within CEL43(2009)\(^1\), the responsibility for some aspects of the **Equipment Co-ordinator** role have been delegated by the Chief Officer to the Associate Director for Quality Improvement & Safety and fulfilled by the Quality Improvement Support Team (QIST). These duties include:

**Clinical Safety Alerts**
As outlined in the **NHS Lothian Operational Procedure for addressing clinical governance related guidance: Clinical Safety Alerts**\(^5\).

- To provide a single point of contact within NHS Lothian for the receipt, of Safety Alerts, to ensure that all clinical 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

**Adverse Event management**
As outlined in the organisations Adverse Event Management **Policy** and **Operational 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 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 Equipment Co-ordinators’ meetings on behalf of NHS Lothian.

14. The **Medical Director, the Director of Nursing, Associate Medical Directors and Clinical Directors** are accountable to the Chief Officer for
ensuring that this policy is implemented within their respective Service Units and Directorates.

15. **General Managers / Heads of Health** 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 & 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 and Estates are consulted to ensure that the device can be decontaminated and/or disposed of according to NHS Lothian Policy

16. **Heads of Service / Service 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.
- Medical Device Alerts and Safety Alert Action Notices are distributed to all staff who may use the medical device in question and feedback is received from staff who use the device and passed on to the Quality Improvement Support Team (QIST).
- All medical equipment has a funded maintenance and replacement programme.

17. **Charge Nurses / Nurse Team Managers** will ensure that:

- Nurses and ward staff are adequately trained to use and care for the medical devices they require to perform their duties.
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance.

18. 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
• Standing financial instructions are followed at all times
• All appropriate funding routes are considered

19. The **Head of Procurement** will ensure that:
• Competitive financial tenders are obtained according to the Board’s standing financial instructions and EU regulations
• Procurement advice is available to all procurement exercises
• Best value for money and clinical outcome is obtained in the procurement of medical devices

20. **Heads of Departments 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 obtained on loan for the purposes of evaluation complies with national guidance regarding indemnity, see section 9.
• Facilitate the prioritisation of requests
• Identify suitable programme leads for equipment procurement whether for replacement or new purchase.

21. The **Lead for Infection Control/ Decontamination** will:
• Ensure that advice regarding appropriate decontamination and disposal of medical devices is available to purchasers and users
• Ensure that policies and procedures on decontamination and disposal of medical devices are appropriate and up-to-date
• Ensure HAI-SCRIBE documentation is adhered to when replacing medical devices that have major build implications

22. The **Head of eHealth** 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

23. **All NHS Lothian staff** will:
• Carry out the appropriate user maintenance 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
• Not use equipment they have not been trained on unless they are using the equipment under direct supervision of another competent individual or an appropriate risk assessment has been made.
• 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 concerning medical devices

24. The role of NHS Lothian’s **Medical Devices Committee**
   • To develop and audit policies and procedures to help ensure the safe and effective management of medical devices within the NHS Lothian Acute Division.
   • 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

25. The role of the **Lothian Medical Equipment Review Group** (LMERG) (Full Terms of reference in Appendix B) is:
   • To manage the replacement of the Board’s inventory 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.

26. The role of the **Lothian Radiation Safety Committee** (RSC) is:
   • To ensure that the use of medical devices involving ionising or non-ionising radiation is compliant with:
27. 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)

28. **Clinical Educators** will ensure that:

- Clinical skills education is provided for all professional groups within NHS Lothian. The clinical education staff design and develop workshops, study days and competency education in relation to clinical skills. A programme is available covering Medical Devices.

29. **3rd Party contractors**

- This issue is the remit of the Control of Contractors Policy

30. **Patients And Carers** must:

- Know how to safely and effectively operate the medical devices that they need to use out with the hospital 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.
- Not use equipment they have not 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.

In addition:

- For devices that are owned by healthcare services 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 healthcare service. Incident reporting to MHRA is also the responsibility of the healthcare service.
• For devices that are owned and managed by a commercial supplier (such as enteral feeding pumps), 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 healthcare provider.

31. Services must put a robust process in place for the return of medical devices, accessories and equipment which have been loaned to patients.

7. Acquisition and Procurement

7.1 Procurement

32. The medical devices procurement process allows the Board to maintain a consistent approach to medical devices acquisition, which takes into consideration the constantly changing nature of clinical practice.

33. All medical devices that are to be procured or leased within NHS Lothian must be approved by the NHSL Scientific and Technical Department who support the device. (Loan devices are covered in section 9)

34. Essential infrastructure requirements must be considered and planned at this stage. This must also include running costs associated with power especially with high end imaging equipment.

35. Environmentally friendly options should be considered. Aspects to consider include carbon footprint and sustainability.

36. When any medical device is accepted by NHSL, there must be an agreed plan for maintenance and training agreed with the department with responsibility for maintenance. The medical device will be added to a medical device register.

37. All procurement and funding requests for capital medical devices are managed through one of the following groups (managed by Capital Planning):

• The Lothian Medical Equipment Review Group (LMERG) – for replacement of existing medical devices

• The Capital Steering Group (CSG) – for new medical devices purchased with Lothian capital or for medical devices purchased with charitably donated funds including endowments.

7.2 Due Diligence

38. The procurement process will involve multi-disciplinary collaboration: Capital Planning, Scientific and Technical Services, Finance, Infection Control,
Manual Handling, Estates, Facilities, Procurement and the full range of operational services where relevant. Externally, there should be regular liaison with 3rd Party contractors (e.g. Consort Healthcare), National Procurement, Health Facilities Scotland, and the many suppliers and installers of medical devices. This process covers the full lifecycle of the medical device and therefore includes the maintenance and disposal of the asset once redundant. This process helps ensure that value for money is achieved.


40. Medical devices approved for purchase will be procured following Standing Financial Policies and Procedures. These are available on the Intranet.

41. The procurement processes should follow due diligence and withstand internal and external audit.

7.3 Revenue

42. The responsibility for this lies with the service and it is incumbent on the purchaser to minimise the impact on this.

7.4 In-house manufacture

43. Medical devices manufactured or modified within NHS Lothian and supplied to another legal entity (e.g. another Health Board) are subject to the Medical Devices Regulations and must be CE marked.

44. Medical devices manufactured or modified and used solely within NHS Lothian are exempt from the Medical Device Regulations and do not require CE marking. However, they will be manufactured / modified to the same standards as a similar CE marked device, following the guidance issued by the MHRA. They will also be subject to a risk assessment and, where appropriate, ethics approval.

7.5 Custom-made medical devices

45. Custom-made medical devices are:

- manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of their professional qualification, which gives under their responsibility, specific characteristics as to its design; and

- intended for the sole use of a particular patient

46. Examples of devices that may be custom-made include: Orthopaedic footwear, hearing aid inserts / moulds and maxillofacial prosthesis
47. Custom-made medical devices are subject to the Medical Devices Regulations but do not require to be CE marked. The prescription and manufacture of custom made devices within NHS Lothian will follow the guidance issued by MHRA.\textsuperscript{10}

7.6 Humanitarian use of non-CE marked device

48. The use of an individual medical device that does not bear a CE-mark, for a single named patient, is allowable only in exceptional circumstances such as:
   - No alternative CE-marked device is available for treatment or
   - Where it has been demonstrated that the morbidity and/or mortality are significantly reduced with the use of the device in question as compared to those using alternative available treatment

49. The clinician and relevant scientific or technical specialist should ensure an appropriate risk assessment has been documented.

8. Standardisation of Medical Devices

50. To minimise clinical risk, training issues and costs, NHS Lothian will standardise on particular models of medical devices wherever practicable.

51. Where equipment looks similar but has different configurations which may cause confusion the value in ensuring these items look different must be recognised.

52. Standard medical devices will be selected by formal tender and evaluation or via an existing framework agreement.

9. Medical Devices on Loan

53. National Guidance on accepting medical devices on loan will be followed. This can be found on the Health Facility Scotland website.\textsuperscript{9}

54. All loan medical devices will be accepted by the relevant department with responsibility for maintenance, before entering service. Indemnity forms will be completed by the lender to certify that appropriate insurance is in place to indemnify NHS Lothian against patient injury or death resulting from use of the device or damage to the medical device loaned.

55. All medical devices loaned to NHS Lothian must be approved by the department with responsibility for maintenance and by the procurement department before delivery. (procured and leased devices are covered in section 7.3)
Medical Devices Policy

9.1 Medical Devices on short-term loan for evaluation

56. The lender will provide the device, training, consumables and maintenance for the evaluation. The lender will remove the medical device immediately at the agreed end date of the evaluation.

57. Medical Devices on short-term loan for evaluation must not be accepted for the purpose of establishing or maintaining a service.

9.2 Medical Devices on long term loan to be used in clinical service

58. The lender will provide the device and training. Purchase of consumables will be the responsibility of the clinical service. Maintenance arrangement will be agreed before the beginning of the loan period. The lender will remove the medical device immediately at the agreed end of loan date.

9.3 Medical Devices issued individually on long-term loan

59. When a medical device is issued to a patient or carer, responsibility for its safe use will transfer either to the individual or to a healthcare worker or carer.

60. The departments with responsibility for medical device maintenance will remain responsible for:
   • maintenance and records
   • availability of up-to-date user instructions
   • period and type of use

61. The relevant clinical service will remain responsible for:
   • decontamination procedures
   • information supplied to any discharged patients/users
   • medical device identification
   • passing on of manufacturer’s user instructions to end users
   • contact details (users and NHS Lothian)

62. NHS Lothian remains accountable for medical devices while they are with the user.

10. Training in the Use of Medical Devices

63. All staff must be competent in the use of the medical devices that they will be expected to use in the course of their work. They have a professional duty to ensure their own training and skills are up to date.

64. Training will encompass the operation of the medical device, user maintenance, cleaning and identification of faults. Staff must not attempt to
use medical devices that they have not been trained to use unless under direct supervision. Managers must ensure that adequate training is provided.

65. Each clinical service must provide training on relevant medical devices to Trainee Doctors as part of induction and ongoing clinical training. Supervised use of medical equipment should continue until competence is achieved.

66. When a medical device is issued to a patient or carer, relevant training will be delivered so that they understand the intended use and normal functioning of the device in order to use it safely and effectively. Records must be kept of this training. Relevant training is detailed in MHRA DB April 2015 section 6.

67. A record of individual staff members trained in relevant pieces of equipment must be held by each department. Staff training level (number of staff trained as a percentage of staff who should be trained) must be recorded and monitored.

68. All equipment installations must ensure that appropriate equipment training is in place prior to use and that appropriate refresher training programs are repeated regularly.

69. The content of all medical device training delivered by a 3rd party will be agreed with the relevant NHS Lothian service before any training takes place. The 3rd party will follow the agreed training plan and provide NHS Lothian with a record of the staff members that have completed the agreed training.

70. Investment in training on medical devices will be monitored by the Medical Director for Acute Services, see section 6.

11. Commissioning of Medical Devices for Clinical Use

71. Where practical, all new medical devices will be delivered to the relevant department with responsibility for maintenance to be commissioned according to current procedures, following best practice.

72. Large medical devices will be installed where they are to be used and commissioning will take place there. This will include the sign off of any enabling building works providing essential infrastructure.

73. An up-to-date inventory record will be kept of all medical devices. Additions will be made as medical devices enter service. It is recommended that medical device data should be held in a single inventory. For this reason, medical devices not within the remit of the departments with responsibility for maintenance will still be included within the inventory wherever possible.

74. The inventory record will include a minimum dataset agreed by LMERG and contained in Appendix C.
75. The departments with responsibility for maintenance will ensure that relevant details from the inventory are passed on to those responsible for the day-to-day management of medical devices as needed.

12. Maintenance of Medical devices

76. The inventory record for each medical device will identify the scientific and technical department responsible for providing support, management and contract monitoring. It should also be clear to all users, who is responsible for keeping this record.

77. The on-going maintenance requirements of each medical device will be assessed and monitored by the department with responsibility for maintenance.

78. Maintenance arrangements will be regularly reviewed to ensure optimum performance of the medical device and best value for money.

79. Where medical devices are maintained using external contracts clear records of an active maintenance contract and service dates should be kept.

12.1 Maintenance by Users

80. It is essential that users of medical devices are able to operate their medical device correctly, safely and effectively. This will require training by a suitably qualified person. If a medical device is not working correctly, users must be aware of this and take action. A functional test can often be carried out by the operator prior to clinical use to establish if the device is working normally. These tests must be carried out at appropriate intervals.

81. Maintenance instructions for users are contained in the user manual provided with the medical device. This may be in hard copy or in electronic format. For specific items, detailed test instructions will be formally agreed and disseminated by NHS Lothian via the relevant group or committee (e.g. Resuscitation Committee for defibrillators).

82. The majority of re-usable medical devices are maintained on a regular basis and carry a service label with a “service due” date. All staff that use medical devices must ensure they check that the device is clean and in good working order prior to use. They must also check the service label before use, and contact the department/company responsible for maintenance if the medical 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 device is attached to a long-term patient and there is no other device available. The device must then be swapped out for servicing as soon as an alternative device becomes available.

83. Users must not carry out repairs to medical devices unless they are competent to do so.
84. Medical devices that require replacement parts and/or active calibration when serviced will be entered as "missing" on the management database if they have not been located for a period of 2 months following the due service date. For devices that do not require replacement parts and/or active calibration, the relevant period will be 6 months following the service due date. Written notice will be sent to the relevant Chief Nurse / Clinical Director listing items that are missing, so that action can be taken by the clinical service concerned.

13. Repairs

85. Repair requests will uniquely identify the medical device by stating its asset identification number or serial number and a description of the fault will be given.

86. Repairs to medical devices will be carried out by appropriately trained and qualified staff.

87. Repair requests will be prioritised and systems will be in place to track each repair from notification to the medical device’s return to the user.

88. Repairs or replacement of parts carried out by a contractor must be formally handed over to the Health Board’s appropriate Scientific/Technical department. Relevant commissioning will be performed prior to clinical use.

89. A robust local procedure must be in place providing contingency plans in the event of a medical emergency.

13.1 Medical device faults occurring out-of-hours

90. Robust local contingency arrangements must be in place to facilitate any immediate repair or remedy for out of hours failures in essential equipment. These arrangements must be known to key senior staff in the relevant area.

91. On discovering a breakdown, staff must follow the procedure detailed in section 13.

14. Adverse Events including near misses

92. An adverse event is defined as; “an event that could have caused, or did result in harm to people, including death, disability, injury, disease or suffering and/or immediate or delayed emotional reactions or psychological harm”. Adverse events experienced as harassment on the grounds of age, disability, ethnicity or race, religion or belief, or sexuality are included.

93. Harm is defined as “an outcome with a negative effect”. Harm to a person includes worsening of a medical condition and the inherent risk of an
94. Harm to parts, or all of, NHS Lothian as an organisation are also included, for example: system failure, service disruption, financial loss or adverse publicity. A near-miss is an adverse event where a harmful outcome was avoided either by chance or by intervention.

95. The actual level of harm (known as severity) is used in NHS Lothian to group adverse events. This will determine communication and escalation and guide the level of review required.

96. All adverse events must be reported via Datix, which can be accessed on NHS Lothian intranet. The asset number of the device must be recorded in the Datix Report. For more details on reporting adverse events see the Management of Adverse Events Policy and Operational Procedure.

97. For events involving medical devices, users must immediately contact the department with responsibility for maintenance to inform them that an adverse event has occurred, and the nature of the event.

98. Where a device has malfunctioned causing a serious risk to patient safety, the device concerned must be quarantined and labelled ‘Do not use’. Where possible, all material evidence relating to adverse events must be preserved, labelled and kept secure. This includes the medical device, consumables, packaging and any other means of batch identification. The evidence must not be interfered with in any way except for safety reasons or to prevent its loss.

99. Where possible, medical devices should be decontaminated prior to handling. Items which have or may have been in contact with hazardous (e.g. cytotoxic or radioactive) chemicals or infectious material (e.g. tissue, bone, blood, other body fluids, or pathological samples) and all disposable devices, whether used or unused, must be sealed in a transparent inner bag or container. Sharp objects such as needles must be enclosed in a suitable rigid container to prevent injury.

100. For minor adverse events, the medical device(s) may be sent to the department with responsibility for maintenance for investigation.

101. The adverse event will be investigated in line with the NHS Lothian Adverse Event Management Policy and Operational Procedure. Health Facilities Scotland will also be involved in the investigation and reporting of any high or very highly graded events involving medical devices.

15. Safety Alerts

102. The Quality Improvement Support Team (QIST) will manage NHS Lothian’s response to Safety Alerts and Hazard Warnings. For more information see NHS Lothian Operational Procedure for addressing clinical
103. Departments with responsibility for maintenance, repair, purchasing or with expertise in the use of medical devices will advise on whether warnings concerning medical devices apply in NHS Lothian and will help ensure appropriate actions are issued and implemented.

**16. Data Security and Storage**

104. Every medical device will be recorded on an inventory and will be uniquely identified as being the property of NHS Lothian.

105. Medical devices may store patient data. When these items move out with NHS Lothian control (for repair, or at end of life) the stored data will be removed. A Certificate of Destruction will be obtained if this is done by a third party.

106. Portable/mobile medical devices that electronically store patient identifiable data must be risk assessed to ensure that appropriate data protection controls are in place. Controls may include encryption, password protection, transfer of data to network storage, and/or use of the medical device in a secure location. Clinical services should seek input from the appropriate scientific and technical department and information governance when carrying out a risk assessment.

107. No software must be installed on a medical device without the written approval of the manufacturer.

**17. Decontamination**

108. Medical devices must be cleaned/decontaminated/sterilised after each episode of patient use in line with manufacturer’s instructions and current national guidance\(^5\).

109. For medical devices that are used on long-term loan in the community, the responsibility of ensuring that the device is clean after use and prior to servicing or collection, lies with the patient or carer. The service loaning the device will ensure that the patients and carers have received appropriate training in how to clean the device.

110. Prior to any equipment being serviced or repaired, departmental staff must complete the decontamination certificate to indicate the perceived level of potential contamination. A suitably trained healthcare worker must sign the certificate to indicate that the equipment is in an appropriate condition, i.e. the equipment is not contaminated and is in ready condition for use.
111. Medical devices which cannot be properly decontaminated must be packed according to the ‘Decontamination Procedures’ (See Infection Prevention and Control Manual - New equipment purchase for NHS) and shall be accompanied by a decontamination certificate when it is sent for repair. Medical devices that are visibly contaminated or dirty will be packaged safely and returned to the sender.

112. After repair, medical devices will be returned clean, but clinical staff must decontaminate each device before use with patients.

18. Decommissioning and Disposal

113. Medical devices that are surplus to requirements or that have reached the end of their useful life will be returned to the department with responsibility for maintenance for decommissioning and disposal.

114. Decommissioning will be recorded in the inventory record. In addition, an Asset Movement / Disposal Form must be completed and submitted to Capital Planning at the time that a replacement is being procured.

115. Many medical devices may themselves be dangerous in untrained hands or contain components that are dangerous. The medical device will be rendered inoperative by the removal of key components. Dangerous components, such as large capacitors will be made safe before disposal. Decommissioning larger installations often involves removal from a purpose-built room or surroundings. Decommissioning of medical devices incorporating radioactive sources must be carried out in accordance with the Ionising Radiations Regulations 1999\(^3\).

116. Any stored patient data will be removed before disposal. A Certificate of Destruction will be obtained if this is done by a third party.

117. Where a medical device may have further useful life but is not required by NHS Lothian, it will be disposed of in accordance with NHS Lothian's Standing Financial Instructions.

19. Condemnation and Removal from Service

118. If a medical device is no longer serviceable but it is still operational, the department with responsibility for maintenance will inform the user that the device is ‘end of life’ as a prompt to replace the device in a timely manner. Capital items are funded for replacement via LMERG. Replacement should be planned prior to an item being condemned where possible.

119. If a medical device is non-operational and no longer serviceable, the department with responsibility for maintenance will issue a ‘condemnation’ certificate to the user. Condemnation normally occurs because it is uneconomic or impossible to repair the medical device.
20. Key Performance Indicators

120. Key indicators capable of showing improvements in medical devices management and training must be developed using data currently available in NHS Lothian. The usefulness of these must be reviewed in time. This is also required for the Property and Asset Management Strategy.
21. References


2. CEL35(2010) A policy for Property and Asset Management in Scotland


21. Appendix

Appendix A – Medical Devices Committee – Terms of Reference

Objectives
- To ensure the effective clinical governance of medical devices across NHS Lothian
- To review and consider the recommendations of the MHRA, the Scottish Government and other appropriate government and regulatory authorities as to their relevance and application in NHS Lothian. Then to develop policies and procedures to ensure that the relevant recommendations are implemented in NHS Lothian.
- There is a role to ensure that medical devices deployed in NHS Lothian are:
  - Suitable for their intended purpose
  - Appropriately procured
  - Standardised where appropriate thus reducing the makes and models across NHS Lothian to minimise clinical risk.
  - Used by appropriately trained end users who may be staff or patients and carers.
  - Appropriately maintained in a safe, reliable condition.
  - Replaced in a timely way.
- There is surveillance of critical incidents relating to medical devices with the timely generation of safety alerts as indicated and that there is the timely response to safety alerts from other sources.
- To develop and work upon common areas of interest with other groups such as Pharmacy.
- To develop liaison with the Community Sectors of NHS Lothian thus allowing spread of good practise examples from NHS Lothian Acute Services to the NHS Lothian Community Sector.

Reporting Structure
- The Medical Devices Committee reports to the Clinical Management Group of NHS Lothian Acute Services.
- The Chair of the Medical Devices Committee will report to the Clinical Management Group twice per year.
- Minutes of the MDC meetings will be sent to the Pan Lothian Service Director and the Director of Pharmacy.
- The Chair of the Medical Devices Committee sits on the Lothian Equipment Management Group.

Responsibility
- To update the Medical Director Acute Services on progress with achievement towards the above objectives and to highlight any barriers to success with the above goals.
Medical Devices Policy

- To identify, describe and mitigate any risks associated with medical devices and inform the Medical Director Acute Services and the Clinical Management Group.
- To identify, describe and monitor any deficiencies in training related to medical equipment and bring them to the attention of the Medical Director Acute Services and the Clinical Management Group.

Scope
- The wide range of medical devices that are used in NHS Lothian Acute Services
- To liaise where necessary with other specialist groups within NHS Lothian Acute Services where there are areas of common interest.
- To develop constructive liaison with and spread good medical device practice to NHS Lothian Community Sector.

Committee Membership
- Chair of the Committee is a Senior Clinician
- The Co-Chair is the Head of Medical Equipment Management
- Head of Medical Physics
- Medical Consultants from the 3 main NHS Lothian acute sites
- Senior nursing staff
- Scientific and technical staff as required for agenda items
- Procurement representatives
- Pharmacy representatives
- E-Health representative
- Infection control representative
- Representation from the Quality Improvement Support Team
- Estates representative

Suitable representation is being sought from:

- Allied Health Professionals
- Community

October 2016
Appendix B – Lothian Medical Equipment Review Group (LMERG)
Terms of Reference

Scope

- All matters relating to the management of, and investment in, medical equipment and continued maintenance of this medical equipment, to deliver the objectives of NHS Lothian.
- LMERG will ensure that appropriate capital budgets are in place to deal appropriately with maintaining Lothian’s equipment replacement programme.
- LMERG will review equipment replacement in the context of clinical and delivery strategies.

Critical deliverables

- To develop NHS Lothian’s corporate objectives for medical equipment, and any supporting strategies and operational plans to deliver these objectives. The objectives are to be informed by wider NHS Lothian strategy on the delivery of clinical services.
- To be the NHS Lothian focal point for all aspects of risk management as it relates to the management of medical equipment. This will include maintaining an LMERG strategic risk register. This will be informed by the content of other risk registers throughout NHS Lothian.
- To ensure that systems are in place to support the required training and education on the use of medical equipment.
- To implement performance management systems (Performance Indicators’) to provide assurance on the delivery of agreed NHS Lothian objectives for medical equipment.
- To ensure that any investment in medical equipment is funded by identified capital and ongoing revenue sources.
- Ask the users to risk assess their proposed replacement medical equipment using a standard risk assessment tool and prioritise and fund replacement accordingly.
- To ensure that the expenditure on medical equipment throughout NHS Lothian secures Best Value.
- Report to the Board annually, in March, outlining progress and highlighting residual risks.

Key Roles and Responsibilities

- The Medical Director will act as the lead Executive Director for medical equipment for NHS in Lothian.
- The Director of Scheduled Care will chair LMERG and report to the Medical Director.
Capital Planning will manage the LMERG programme, development of equipment risk registers, management of budgets, and procurement. The Director of Capital Planning and Projects will deputise as chair in the absence of the Director of Scheduled Care.

Associate Divisional Medical Directors (or authorised deputy) will take the lead role for the Directorates and will bring their prioritised and risk assessed equipment requests to LMERG. Any equipment not purchased will be held on the directorate risk registers and any change in risk reported to LMERG.

LMERG will appoint leads for Medical Equipment Replacement Programmes where an identified group of devices or equipment will be managed on a rolling programme. These leads will take a key role in chairing groups that will manage these programmes and will report to LMERG and Capital Planning on progress and process.

Technical Services will work with Capital Planning and the operational areas to ensure the most appropriate equipment specification and procurement route is chosen.

November 2013
Currently under review
Appendix C – Minimum data set

NHS Lothian minimum dataset for medical devices / equipment

Purpose: To facilitate effective medical equipment management and minimise risk to patients within NHS Lothian; to ensure compliance with CEL 35 (2010).

Scope: Reusable medical devices / equipment that have not been customised for individual patients.

Dataset:

1. Serial Number
2. Location
3. Model
4. Manufacturer
5. Supplier
6. Purchase Date
7. Purchase Cost ex VAT
8. Expected Item Life Cycle (e.g. 7 years)
9. Estimated replacement cost exc VAT
10. Information regarding the type of maintenance (e.g. Manufacturer PM, Manufacturer Comp Contract, In-house PM etc)
11. Service history (inc planned preventative Maintenance, repairs, record of software versions for upgrade purposes) maintenance & repair costs.
12. Maintenance and repair costs (commercial, in-house etc)

The above items are specified in CEL 35, together with annual depreciation which is recorded by Finance for capital items.

The following items are also included in NHS Lothian minimum dataset (rationale given in brackets):

13. Generic Description (standardised descriptor required to identify types of equipment within Lothian, and enables reporting to SG)
14. Asset Number (required because serial numbers are not unique; also provides link to capital asset register)
15. PO Number (supplied by procurement: allows funding source to be identified, links to capital asset register, and also provides evidence to supplier when requesting disposal under WEEE)
16. Installation costs (only required if these form a significant fraction of the purchase cost e.g. major imaging equipment / monitoring systems)
17. Warranty period (essential information for managing equipment contracts/repairs)
18. Lothian dept responsible for managing maintenance (required by Lothian capital process)
19. Date of disposal (required by Lothian capital process)
20. Details of disposal e.g. scrapped / trade-in etc for capital items
(required by Lothian capital process)

Notes:
• Dataset to be held by NHSL dept responsible for managing maintenance.
• The above information may be held either electronically or in hard copy, but
must be readily accessible for reporting / audit.
Some information (e.g. PO Number, purchase date, purchase cost) can only
be entered accurately at the time of purchase and is unlikely to be available
retrospectively.
22. Glossary

'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software 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 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.
23. List of acronyms

ACCORD - Academic and Clinical Central Office for Research and Development

CEL   Chief Executive Letter

CSG   Capital Steering Group

DB    Device Bulletin

EU    European Union

HAI-SCRIBE Healthcare Associated Infection System for Controlling Risk In the Built Environment

HFS   Health Facilities Scotland

IRAS  Integrated Research Applications System

IRIC  Incident Reporting and Investigation Centre

LMERG Lothian Medical Equipment Review Group

MHRA  Medicines and Healthcare Products Regulatory Agency

NHSL  National Health Service, Lothian

NSS   National Services Scotland

PAMS  Property and Asset Management Strategy

QIST  Quality Improvement Support Team

RSC   Radiation Safety Committee

SG    Scottish Government