



NHS Lothian

Medical Devices
Internal Audit Report - Final

February 2026

Level Of Assurance:

Design	Moderate
Effectiveness	Limited

Contents

1. Executive Summary	3
2. Detailed Findings	6
3. Observations	20
4. Appendix I: Medusa data analysis	23
5. Appendix II: Testing data	24
6. Appendix III: Background	25
7. Appendix IV: Definitions	26
8. Appendix V: Terms of reference	27
9. Appendix VI: Staff interviewed	28
10. Appendix VII: Limitations and responsibilities	29

RESTRICTIONS OF USE

The matters raised in this report are only those which came to our attention during our audit and are not necessarily a comprehensive statement of all the weaknesses that exist or all improvements that might be made. The report has been prepared solely for the management of the organisation and should not be quoted in whole or in part without our prior written consent. BDO LLP neither owes nor accepts any duty to any third party whether in contract or in tort and shall not be liable, in respect of any loss, damage or expense which is caused by their reliance on this report.

Distribution list

For action	Andrew Davie	Healthcare Science Professional Lead
	Caoimhe McIntyre	Head Of Medical Physics
	Iain Gorman	Service Director - Diagnostics, Anaesthetics, Theatre And Critical Care
For information	Audit & Risk Committee Members	

Report status

Lead auditor(s):	Jaasi Phelps-Nyakairu
Dates work performed:	08/12/2025 - 21/01/2026
Draft report issued:	26/01/2026
Management responses received:	06/02/2026
Final report issued:	06/02/2026



Executive Summary

Level of assurance: (see appendix IV for definitions)			
Design	Moderate	Generally a sound system of internal control designed to achieve system objectives with some exceptions.	
Effectiveness	Limited	Non-compliance with key procedures and controls places the system objectives at risk.	
Summary of findings			# of agreed actions
H	1		3
M	4		15
L	2		2
Total number of findings: 7			20

Background (further detail in Appendix III)

It was agreed as part of the 2025-26 Internal Audit Plan that Internal Audit would review the arrangements surrounding Medical Devices at NHS Lothian. Effective Medical Device management is crucial to ensure patient safety, efficient healthcare delivery, adherence to relevant standards and optimal use of resources.

The Department of Medical Physics supports a service led approach to device governance and maintains an asset register via Medusa of a sub-set of medical devices within NHS Lothian.

These medical devices are maintained in house or by third party suppliers under contract, with service level agreements in place for some contracts.

The Medical Devices Committee provides governance oversight of Medical Devices, including developing and reviewing policies and procedures, promoting standardisation, supporting competence across services and monitoring incident themes. The Lothian Medical Equipment Review Group (LMERG) manages capital planning and replacement, developing ten-year rolling replacement plans aligned to the capital plan and ensures governance oversight of funded replacements.

There is a Medical Devices Policy in place that outlines a consistent, Board-wide approach to the management of medical devices. There is a Standing Financial Instructions (SFI) policy in place that covers procurement governance and an Adverse Event Management Policy and Procedure to cover the reporting, review, learning and improvement from adverse events and near misses.

Asset management and maintenance are supported by Medusa as the device register and maintenance management system used in Medical Physics. Charge/Lead Nurses ensure training on devices for their team with 'train the trainer' programs rolled out dependent on contract.

Incident reporting and learning is operated through DATIX as the primary system of record with any supplier provided notices of device faults or recalls communicated by the Quality Improvement Support Team.

Purpose

The Medical Devices Internal Audit aimed to provide assurance to management and the Audit and Risk Committee that the controls around medical devices are suitably designed and operating effectively. This review considered the following areas:

- Governance Framework

- Procurement Processes
- Maintenance, Repair and Calibration
- Training and Usage Protocols
- Device Suitability, Certification and Decommissioning
- Continuous Improvement

Conclusion

NHS Lothian has broadly established a suitable control framework and governance structure for the management of medical devices; evidenced by clear procurement guidance, active oversight committees (LMERG and the Medical Devices Committee), robust incident reporting through DATIX, and an effective system for device tracking and location management. These elements collectively reflect strong governance and demonstrate NHS Lothian's commitment to continual improvement.

Despite these positive practices, our review concluded that the operational effectiveness of medical device management requires further strengthening. In particular; inconsistencies in record-keeping and scheduling of preventative maintenance, insufficient oversight of training beyond Charge/Lead Nurses, and gaps in decommissioning practices undermine the overall assurance framework. Our testing also identified incomplete data in Medusa and instances of unclear procurement evidence for certain devices. These deficiencies, if unaddressed, could weaken transparency and risk mitigation across the full lifecycle of medical devices.

Overall, we provide moderate assurance over the adequacy of the design of controls and limited assurance over their operational effectiveness. We have identified seven findings (one high significance, four medium, and two low) which, taken collectively, highlight opportunities to embed more robust processes and central oversight to strengthen NHS Lothian's management of medical devices. By addressing these, the organisation will be better positioned to ensure consistent, safe, and efficient use of its medical device portfolio.



Executive Summary

Summary of good practice

During the course of our review, we identified a number of areas of good practice:

Governance and Organisational Structure

- NHS Lothian has Standing Financial Instructions in place which are publicly available via the organisation's website. The instructions clearly define the procurement process (which applies to medical devices) including thresholds for escalation to higher levels of approval, the process to take dependent on valuation, and the routes that should be considered to ensure best value throughout the procurement process. Additionally clear roles and responsibilities are provided along with the relevant legislation to be considered.
- NHS Lothian has a Lothian Medical Equipment Review Group (LMERG) in place which meets four times a year and considers 10-year plans for medical device procurement and replacement. The group monitors Medical Device procurement activity with a refreshed 10-year plan delivered on an annual basis. LMERG is based on 24 pan-Lothian rolling programmes of replacement for specific equipment types e.g. endoscopy, ultrasound, theatre tables, monitoring, labs etc, and ensures funding for devices is aligned with budgets, along with ensuring a contingency fund is available for urgent equipment replacements or purchases. Our review of the agendas for the year confirmed the meetings covered their areas of responsibilities, taking in updates on medical device spend and reviewing Medical Device Committee updates to keep informed on the medical device environment at NHS Lothian.
- There is also a Medical Devices Committee which meets four times a year and oversees governance of medical devices including promoting good practice and standardising the approach to Medical Devices. We found that the Committee extinguished its responsibilities in monitoring medical device incidents, policies, regulatory updates and compliance reports.
- LMERG's Capital Equipment form utilised for the procurement of medical devices above £5000 records the chosen procurement route, the justification, the recommended supplier(s) (where relevant), costs, requirements, proposed funding sources, and sign offs from the relevant sections to ensure approval from all involved. The forms appendices allow for different types of procurement such as replacements or call-off awards to have specific additional requirements for approval as necessary. The form ensures a consistent and comprehensive approval process for the procurement of equipment.
- The Medical Devices Policy was shared with LMERG, the Medical Director of Acute Services, and the Executive Medical Director, along with undertaking a Rapid Impact Assessment before its publishing. The Policy outlines all roles and responsibilities in relation to Medical Devices from procurement to training, clearly assigning responsibility for each area in relation to medical devices. Our review of the Policy found that it covered all expected areas.

- The Adverse Management Policy and Procedure clearly outline the roles and responsibilities in relation to incident management and provides guidance on how incidents can be reported. The Policy outlines how incidents are rated (by severity of harm), with each severity level clearly defined and the required reporting, recording, and reaction to adverse events. The Procedure also covers good practice principles, event review, and improvement planning and monitoring. The procedure additionally notes reporting requirements under legislation such as to the Health and Safety Executive and RIDDOR requirements.
- NHS Lothian actively participates in various groups to stay updated with legislative changes, enhancing knowledge sharing and collaboration. This includes engagement with regional groups, where information on best practice is shared to improve services, such as with the Renal Technical Managers Group that covers Medical Physics within their quarterly meetings.
- The Quality Improvement Support Team review all significant adverse events and send out alert action sheets to address issues. Additionally, the team communicate any supplier issued field safety notices for medical devices with action sheets including deadlines for confirmation of actions. The Team evidences careful oversight of any significant adverse event and a clear process to ensure lessons learned are recorded, and improvement implemented.

Systems

- There is a set of clear Standard Operating Procedures (SOPs) in place outlining the use of the Medusa system.
- NHS Lothian has a comprehensive Policy Hub accessible online, which includes Medical Devices policies and procedures. Each policy where relevant and based on requirement, includes an executive summary, guidelines, forms, charts, and patient information sections, ensuring clarity and accessibility. The Policy Hub further requires that any new policies are appointed to the 'consultation zone' for four weeks where staff members can provide feedback on the policies.
- DATIX is the system utilised by NHS Lothian to report adverse events. The system is extensive in reporting including sections for the exact causes within the form to be separated by type, such as medical devices, allowing reporters of events and reviewers to maintain a focused view on events. The system additionally provides links throughout to adverse event policies and procedures and general guidance on completing any adverse event form to ensure users are adequately knowledgeable on the form and its definition during its completion.
- Medusa assets are tagged using RFIDs, when possible, with trolley's utilised in the hospital that pick up the location of devices as they pass by. This system ensures automatic updates of device locations, and acts as a method of confirmation for device location. We were able to confirm that the asset location per the system was correct for the devices in our sample.



Executive Summary

Summary of good practice continued

- NHS Lothian utilised the PECOS system to record purchases of equipment which includes clear audit trails of actions performed and the receipt of medical devices. Additionally, the system can store supplier contracts and purchase information, if uploaded, ensuring records can be held for the procurement of medical devices.

Reporting

- Medusa's Workshop Managers who are assigned to specific medical devices are provided with a monthly Preventative Maintenance Analysis extract from Medusa which shows completed and overdue PMs, statistics on how long PMs have been overdue by days, and a list of scheduled PMs upcoming.

Decommissioning

- NHS Lothian has data processing agreement in place to ensure safe disposal/decommissioning of devices, with one example showing an agreement with BMA to securely erase any identifiable data and provide certification of this where items are disposed of via sale by auction

Summary of findings

Notwithstanding the areas of good practice identified, we also identified opportunities for improvement, which are summarised below:

- ▶ **Completeness of Asset Registers:** We found that within Medusa only a few fields are mandatory, with 9% of entries across 15 exportable fields of the minimum data set lacking any input, with purchase numbers, warranty dates and life cycle end showing the highest gaps. It is noted that historical data prior to the move to Medusa (2010) may not be available. Purchase numbers were the highest at over 60% missing entries (full statistics can be found in appendix I). Additionally, we found that the all Laboratory Medicine Teams (Blood Science, Infection Science, and Pathology and Gene Science) currently use the Ideagen Quality Management (IQM) system for medical devices rather than Medusa; we also noted that the Point of Care Team uses IQM for some, but not all, of their devices. It was advised that 'multiple thousands' of assets, especially bulk items cannot be evidenced for preventative maintenance work orders.
- ▶ **Asset Maintenance:** We selected a sample of 15 devices from a database of 84,244 to test PM records, documentation, and location verification. We found that:
 - Two devices sampled had overdue next PM check dates of 16 May 2017 and 17 July 2024 respectively
 - One sample had only one recorded PM dated 24 December 2025, more than four years after purchase, despite a 24-month PM schedule
 - One device sampled was reported as missing and not returned from outpatients; Management advised that they followed this up with the patient, however this could not be evidenced.
- ▶ **Consistency of Decommissioning Process:** We selected a sample of 15 decommissioned devices from a total of 5,420 and checked whether each had appropriate authorisation, clear documentation, and whether the decommission was performed in line with policy and legal requirements. We found that four of the 15 devices sampled were unsatisfactory (27%). One sample did not have sufficient evidence of approval and lacked a signed work order; the decommission request authorisation was also evidenced later than the scrap date that was recorded in Medusa. Two samples were missing signatures on their work order.
 - We found that managers may instruct team members to update Medusa even if those team members are not authorised to scrap assets.
 - Additionally, we found 4.8% of entries in the Medusa decommissioning work order dataset lacked a description. We noted that 14,950 work orders (95%) had no entry in the Customer Message field. The fields for Customer Message and Description often contained empty entries rather than a status such as "NULL", "NA" or "TBC".
- ▶ **Consistency of Procurement Evidence:** We selected 15 devices from a total of 84,244 on the Medusa asset list. For each, we asked for evidence of supplier evaluation, approvals and contracts. We found that five of the 15 samples (33%) were not satisfactory. Two samples did not have appropriate evidence of adequate contracts or documentation stating supplier requirements. Two samples did not have appropriate evidence of supplier evaluation. One sample had insufficient procurement information: management were not aware when the device was received, and advised the item is a tool rather than a medical device, however it is recorded in Medusa. Lastly 5 of the devices sampled included a LMERG Capital Equipment form with sections that were signed but not dated.
- ▶ **Training:** We chose a sample of 15 medical devices from a database of 84,244 to assess whether staff were appropriately trained on the use of the medical device. 10 out of 15 (67%) of the samples did not have clear training records in place. Three out of 15 (20%) of the devices samples lacked SOPs. Additionally, we found through interviews that outside Charge/Lead Nurses there is no consistent oversight or tracking of training. Departmental and service managers do not maintain a training tracker or log, and they do not sign off Charge/Lead Nurses' trackers. There is no set format for tracking training across departments, so practice varies.
- ▶ **Policy Review:** We found that the Medical Devices Policy shows a review date of June 2025 but there is no record of a review having taken place, and the review date has not been updated past June 2025. The LMERG Guidance shows a stated review date of 11 August 2025 and is similarly past due, with no evidence of review completion and no updated review date.

Detailed Findings



Detailed Findings

Risk: Failure to maintain accurate device inventories, perform timely maintenance and calibration, and enforce robust service-level agreements with third-party providers increases the risk of equipment failure, patient harm, regulatory non-compliance, and financial inefficiency for NHS Lothian.

Finding 1 - Consistency of Asset Registers	Type
<p>It is important that an accurate and up-to-date asset register is maintained to provide oversight of medical devices and evidence compliance with maintenance schedules. This protects patients, supports safe care, and shows compliance with NHSL policy and external standards. The Medical Devices Policy requires devices to be traceable from inventory records and maintained in a safe, reliable condition. Medical Physics utilise the Medusa asset system, which can hold around 80 asset parameters, including PM schedules and work orders; although it is noted that Medusa is not the organisation’s medical asset register and the definition of a medical device is broad and nuanced.</p> <p>Our interviews with 17 members of staff across NHSL found that the Medusa system is not used consistently across the Health Board, with some business units not recording their assets on Medusa at all, and others using it to varying degrees to store documentation related to assets.</p> <p>All Laboratory Medicine Teams (Blood Science, Infection Science, and Pathology and Gene Science) currently use the Ideagen Quality Management (IQM) system for medical devices rather than Medusa; we also noted that the Point of Care Team uses Ideagen for some, but not all, of their devices. It was advised that ‘multiple thousands’ of assets, especially bulk items, cannot be evidenced for preventative maintenance work orders because IQM cannot store all assets. The manager advised they could not evidence preventative maintenance for these items. NHSL advised that they are at very early stages of exploring options for adding these assets to Medusa, however, it is noted that there is a financial cost attached to additional Medusa licenses which must be considered.</p> <p>We found that within Medusa only a few fields are mandatory, with departments utilising Medusa differently. We performed a data analytics exercise to identify missing entries across 15 exportable fields of the minimum data set, 9% of the total data set had no input, with purchase numbers, warranty dates and life cycle end showing the highest number of gaps. Purchase numbers were the highest at over 60% missing entries (full statistics can be found in appendix I). We additionally found that of the 15 samples that were checked for maintenance records and verification (refer to finding 2) , four samples had the purchase price recoded in Medusa as £0. These were eq nos 1800014, 92061215, 92061169, and 92104003.</p>	<p>Design & effectiveness</p> 
Implication	Significance
<p>There is a risk, without an accurate and up-to-date central asset register, that devices miss required maintenance, fail in service or are removed late, leading to patient safety incidents, and higher downtimes. Additionally, NHS Lothian may be unable to evidence compliance to regulators and may misjudge replacement needs in LMERG plans.</p>	High



Detailed Findings

Risk: Failure to maintain accurate device inventories, perform timely maintenance and calibration, and enforce robust service-level agreements with third-party providers increases the risk of equipment failure, patient harm, regulatory non-compliance, and financial inefficiency for NHS Lothian.

Recommendations	Action owner	Management response	Completion date
NHSL should investigate the possibility of mandating completion of fields within the minimum data set mandatory within Medusa.	MDC	<p>NHS Lothian will review the minimum data set guidance with clear roles and responsibilities identified for the completion of mandatory fields.</p> <p>This will be reviewed and distributed via the Medical Devices Committee.</p> <p>The minimum data set guidance will be linked as a supporting document to the Medical Device Policy via the Policy Hub.</p>	August 2026
<p>NHSL should reiterate the minimum data set requirement to all users of Medusa to ensure that records are completed fully and consistently. This could be done via an email, intranet post or a “Lunch and Learn” type session.</p> <p>Oversight should be performed at a clinical or department level regularly, such as sample testing, confirming that any assets entered within a period have all necessary information included, with any lack of information actioned and tracked to resolution.</p>	MDC	<p>Following review, the minimum data set requirements will be uploaded to our document control system (Qpulse). This will include details on the mandated fields and outline who is responsible for completion and updating of these data sets.</p> <p>Distribution will be via NHS Lothian “everyone” email framework with hyperlinks to the document via the intranet.</p> <p>A routine programme of audit (sample testing) can be established including the completion of the minimum data set. The outcomes would be reported back to the relevant clinical departments, with actions and timelines. Oversight and tracking to resolution would be monitored via the Medical Devices Committee.</p>	August 2026
	Acute SMT and MDC	Successful implementation of an audit programme would require additional resources	Dec 2026



Detailed Findings

Risk: Failure to maintain accurate device inventories, perform timely maintenance and calibration, and enforce robust service-level agreements with third-party providers increases the risk of equipment failure, patient harm, regulatory non-compliance, and financial inefficiency for NHS Lothian.

Recommendations	Action owner	Management response	Completion date
		which could be estimated following agreement on the size of programme required to provide assurance.	
We recommend that NHSL considers migrating all Medical Devices onto Medusa so that there is a singular, central asset register with the capabilities of capturing all required data. If this is not found to be possible, NHSL should ensure that clear asset register/system requirements are set for any team handling Medical Device records and maintenance to ensure they have a system capable of recording the appropriate information per the Minimum Data Set provided in the Medical Devices Policy.	Director of Finance	NHS Lothian will carry out an options appraisal/feasibility study to assess the operational, technical, financial and resource requirements to utilise Medusa as a singular central asset register for Medical Devices managed by NHS Lothian's Capital Procurement programme. In parallel with this NHS Lothian will identify the asset register(s) in place for services handling medical devices assessing the capabilities of the asset register's ability to record the minimum data set and maintenance records.	Dec 2026



Detailed Findings

Risk: Failure to maintain accurate device inventories, perform timely maintenance and calibration, and enforce robust service-level agreements with third-party providers increases the risk of equipment failure, patient harm, regulatory non-compliance, and financial inefficiency for NHS Lothian.

Finding 2 - Asset Maintenance	Type
<p>It is important that there is a standard process for preventative maintenance (PM) monitoring to ensure that assets are maintained in safe, working order. A clear process with enforced data requirements helps plan PMs, check completion, and follow up quickly on identified issues or non-completion. NHS Lothian uses Medusa to record PM schedules and work orders, and most assets carry RFID tags to support location tracking (except where this would interfere with the functionality of the device). We selected a sample of 15 devices from a database of 84,244 to test PM records, documentation, and location verification.</p> <p>We found that 12 of the 15 devices sampled were not satisfactory (80%) (detailed in appendix II). Specific issues were:</p> <ul style="list-style-type: none"> • Two devices sampled had overdue next PM check dates of 16 May 2017 and 17 July 2024 respectively • One device sampled had only one recorded PPM dated 24 December 2025, more than four years after purchase, despite a 24-month PM schedule • One device sampled was reported as stolen and not returned from outpatients; management advised they followed this up with the patient, however this could not be evidenced. <p>Management advised they are in the process of defining timescales for categorising devices as lost or missing, and creating a corresponding SOP.</p> <p>We found that there is no clear, standard process for monitoring PMs or service agreements across NHS Lothian. Departments record and manage PMs in different ways, and mandatory data in Medusa is limited, which allows for incomplete records and delays or unperformed PMs. Medusa can produce monthly PM analysis reports and trend graphs, which are currently shared on a monthly basis with Workshop Managers. Management informed us that there are no set KPI targets for PM performance and no other KPIs in place for device monitoring. Oversight above Workshop Manager level is limited, with no central consolidation or escalation.</p>	<p>Design & effectiveness</p> 
Implication	Significance
<p>There is a risk that if devices are not regularly maintained; damaged or unsafe equipment stays in use, and issues are missed or addressed too late. Lothian may face patient safety incidents, compliance failures, and service disruption.</p>	Medium



Detailed Findings

Risk: Failure to maintain accurate device inventories, perform timely maintenance and calibration, and enforce robust service-level agreements with third-party providers increases the risk of equipment failure, patient harm, regulatory non-compliance, and financial inefficiency for NHS Lothian.

Recommendations	Action owner	Management response	Completion date
We recommend that SOPs are introduced for the monitoring of PM checks and the monitoring of supplier SLAs and performance in relation to maintenance. The SOPs should clearly outline roles and responsibilities for oversight, such as Clinical Service managers performing monthly reviews of the total overdue PMs of medical devices in their service ,to follow up on any workshops or external third-party supplier NHSL may have an SLA with not aligning with KPIs, or otherwise address issues before they become detrimental. They should also cover the escalation process for any supplier underperformance in relation to maintenance.	Finance (S&V Team)	NHS Lothian has a SOP for the Management of medical device servicing and maintenance contracts: SOP-Service and Maintenance Contracts. v.2.pdf The SOP is overdue for a review and the noted items will be updated in the latest revision: <ul style="list-style-type: none"> Clearly outline Roles and Responsibilities of key stakeholders Escalation process for underperformance Link this as a supporting document to the Medical Device Policy via the Policy Hub.	September 2026
We recommend management complete their exercise to define lost and missing devices and the corresponding SOP as soon as possible.	Department of Medical Physics Medical Devices Committee	The exercise to define appropriate metrics for lost and/or missing devices is close to completion. The SOP will be tabled at the Medical Device Committee for approval and linked as a supporting document to the Medical Device Policy.	June 2026
NHSL should define a set of KPIs for Medical Devices PM performance as soon as possible. These KPIs should be reported to the Medical Devices Committee as part of ongoing compliance monitoring.	Medical Devices Committee	A set of core KPI's will be established via MDC for all clinical and technical services responsible for monitoring PM compliance to adhere too. Routine reporting and monitoring of KPI compliance will be managed via Medical Device Committee.	September 2026



Detailed Findings

Risk: Failure to ensure medical devices are certified, remain fit for purpose, and are properly decommissioned (including managing data security risks) could result in non-compliance, financial and reputational damage, and compromised patient safety for NHS Lothian.

Finding 3 - Consistency of Decommissioning Process	Type
<p>It is important that there is a single, controlled decommissioning process with clear roles, approvals and complete records. This ensures devices come out of service at the right time, are disposed of in the right way, and any data is securely erased. Strong controls deter fraud, protect patient data, and give clean evidence for audit and compliance.</p> <p>NHSL devices are not generally upgraded or refurbished; they are scrapped and replaced or removed if no longer sufficient. The Medical Physics Team uses a decommissioning SOP and flowchart that requires a Medusa ticket and a work order for one of three disposal routes: Waste Electrical and Electronic Equipment (WEEE) bin, trade-in, or sale/auction. The SOP sets authorisation levels by band/position and amount.</p> <p>There is a Medusa decommissioning work order dataset which contained 15,762 entries since 2010. We noted 759 work orders lacked a description (4.8%), with 48 of these registered in the 12 months from December 2024 - November 2025 (1.5% in that period). We noted that 14,950 work orders (95%) had no entry in the Customer Message field. The fields for Customer Message and Description often contained empty entries rather than a status such as "NULL", "NA" or "TBC", increasing the chance that steps were missed at completion. Management advised the customer message field was used in the previous database and historically information was transferred across. This is not a field NHSL are required to complete.</p> <p>We selected a sample of 15 devices decommissioned between December 2024 to December 2025 from a total of 5,420 and checked whether each had appropriate authorisation, clear documentation, and whether the decommission was performed in line with policy and legal requirements. We reviewed the Medical Physics decommissioning SOP and flowchart and discussed process and system controls with management.</p> <p>We found that, of the 15 devices sampled:</p> <ul style="list-style-type: none"> Eq no 357961 did not have sufficient evidence of approval and lacked a signed work order or equipment report; the decommission request authorisation was also evidenced later than the scrap date that was recorded in Medusa. Eq nos 92034961 and 92019307 were missing signatures on the work order. <p>We confirmed the SOP only requires raising a Medusa ticket and placing a work order for one of three disposal routes, and as advised by management, that managers may instruct team members to update Medusa even if those team members are not authorised to scrap assets. Medusa does not apply software locks to prevent unauthorised updates, so the SOP is the only control. As noted under finding 1, not all teams use Medusa, so assets outside the Medical Physics Team do not follow a standardised decommissioning process.</p> <p>Management advised the lack of a software locks is to increase efficiency/prevent reliance on a single member for data upload.</p>	<p>Design & effectiveness</p> 



Detailed Findings

Risk: Failure to ensure medical devices are certified, remain fit for purpose, and are properly decommissioned (including managing data security risks) could result in non-compliance, financial and reputational damage, and compromised patient safety for NHS Lothian.

Implication			Significance
<p>There is a risk that devices are decommissioned inappropriately or too early, or assets are fraudulently removed or misreported. Incomplete approvals and weak records mean you cannot evidence compliance or trace decisions. Empty fields and "NULL" completions undermine process control and follow-up, allowing errors to persist. For devices not decommissioned via the correct route, this could lead to legislative, environmental, and safety risks.</p>			Medium
Recommendations	Action owner	Management response	Completion date
We recommend the decommissioning SOP is updated to include additional steps of verification for higher risk disposals (extensive client data, hazardous, etc) to ensure these are carried out appropriately.	<p>Department of Medical Physics</p> <p>Medical Devices Committee</p>	<p>The decommissioning SOP will be reviewed and updated taking a risk-based approach ensuring all decommissioning processes have been completed, documented and appropriately authorised.</p> <p>The SOP will be tabled at the Medical Device Committee for approval and linked as a supporting document to the Medical Device Policy.</p>	May 2026
We recommend the decommissioning SOP is made available to all teams to ensure medical devices are decommissioned in a consistent manner, specifically the appropriate levels for decommissioning, to ensure medical devices of different values and risks are only disposed of by an employee with an appropriate level of authority. An additional organisation wide SOP should be created for teams not utilising Medusa providing general steps along with the clear approval levels already defined. Both SOPs should include clear guidance that the reason for decommissioning and a sign-off by an employee able to authorise the decommission should be included in the work orders. The Medical Devices Policy should be updated to reflect the additions of the new SOP.	Medical Devices Committee	<p>The decommissioning SOP will be linked as a supporting document to the Medical Device Policy.</p> <p>The decommissioning SOP will identify core decommissioning steps including a reason for decommissioning with a documented and authorised sign-off.</p>	May 2026
We recommend that Medusa datasets include NA, TBC, or otherwise instead of blank spaces going forward to ensure they have been adequately completed.	Department of Medical Physics	NA and TBC will be added to the pre-populate drop down lists on Medusa.	May 2026



Detailed Findings

Risk: Failure to ensure medical devices are certified, remain fit for purpose, and are properly decommissioned (including managing data security risks) could result in non-compliance, financial and reputational damage, and compromised patient safety for NHS Lothian.

Recommendations	Action owner	Management response	Completion date
	Acute SMT	<p>A user guide will be made available to advise staff on the appropriate entry if/when data is not available to them.</p> <p>A routine programme of audit (sample testing) can be established which will include the number of blank fields within the minimum data set. The outcomes could be reported back to the relevant clinical departments, with actions and timelines.</p> <p>Successful implementation of an audit programme would require additional resources which could be estimated following agreement on the size of programme required to provide assurance.</p>	December 2026
We recommend that software locks or inbuilt approvals are considered in Medusa to ensure that only team members authorised to decommission the relevant equipment can process a decommissioning work order.	Department of Medical Physics	<p>The Medusa decommissioning permission is binary (on/off) and applies globally to all equipment a user can access. There is no option for restricting decommissioning based on equipment value or any other equipment attribute.</p> <p>One in built solution is to implement appropriate sign-off for authorisation via raising a ticket on Medusa by the authorised signatory. This will be included within the decommissioning SOP.</p>	May 2026
We recommend regular sample testing is performed on decommissioning orders to confirm they include an appropriate sign-off for authorisation and clear reason for decommission.	Department of Medical Physics	<p>A routine programme of auditing (sample testing) can be established on Medusa including the decommissioning process, confirming the level of authorisation and reason for decommissioning.</p> <p>The outcomes could be reported back to the relevant service leads, with actions and</p>	August 2026



Detailed Findings

Risk: Failure to ensure medical devices are certified, remain fit for purpose, and are properly decommissioned (including managing data security risks) could result in non-compliance, financial and reputational damage, and compromised patient safety for NHS Lothian.

Recommendations	Action owner	Management response	Completion date
	Acute SMT	<p>timelines. Oversight and tracking to resolution will be monitored via the Medical Devices Committee.</p> <p>Successful implementation of an audit programme would require additional resources which could be estimated following agreement on the size of programme required to provide assurance.</p>	December 2026



Detailed Findings

Risk: Failure to implement robust procurement processes for medical devices could lead to inappropriate or unsafe equipment acquisitions, increased financial and compliance risks, and compromised patient safety.

Finding 4 - Consistency of Procurement Supporting Evidence	Type
<p>It is important to keep complete, accessible procurement evidence for every device, including supplier evaluation, approvals and contracts. This shows compliance with the Standing Financial Instructions, supports sound supplier management and gives a clear audit trail linked to each asset.</p> <p>NHS Lothian’s Standing Financial Instructions set the principles for procurement, including using approved suppliers, having adequate contracts, segregating duties and obtaining the right approvals. PECOS can store orders and audit trails. For devices over £5,000, the LMERG Capital Equipment Form captures route, approvals and key considerations. Pre Acquisition Questionnaire PAQ can be used to record supplier capability where frameworks are not used.</p> <p>We selected 15 devices from a total of 84,244 on the Medusa asset list. For each, we asked for evidence of supplier evaluation, approvals and contracts. We reviewed PECOS audit trails and purchase orders, LMERG forms and any pre-purchase questionnaires. We interviewed management to confirm where procurement documents are held and whether Medical Physics can access them.</p> <p>We found that five of the 15 samples (33%) were not satisfactory.</p> <ul style="list-style-type: none"> Eq nos 92091833 and 92098152 did not have appropriate evidence of adequate contracts or documentation stating supplier requirements. Eq nos 92104722 and 92101999 did not have appropriate evidence of supplier evaluation, management stated these devices are managed by the Sleep service. Eq no 92076124 had insufficient procurement information, management were not aware when the device was received, and advised the item is a tool rather than a medical device, although it is recorded in Medusa. <p>We also noted that 5 of the devices sampled: eq nos 92091833, 92097197, 92098088, 92036440, and 92036410, included an LMERG Capital Equipment form with sections that were signed but not dated. Management advised that there may be an issue where e-signatures are used that this conceals the date field and may therefore be missed by those completing the form.</p> <p>Our interviews and sample testing found that information is not consistently recorded or available for medical device procurement, and some services hold information locally which Medical Physics management cannot access.</p>	<p>Design & effectiveness</p> 
Implication	Significance
<p>There is a risk that without appropriate records, compliance with the Standing Financial Instructions and public procurement rules cannot be evidenced, NHSL’s requirements of suppliers are not enforced, and devices may be procured or managed without proper due diligence. This weakens contract performance oversight and can hinder LMERG’s replacement planning.</p>	Medium



Detailed Findings

Risk: Failure to implement robust procurement processes for medical devices could lead to inappropriate or unsafe equipment acquisitions, increased financial and compliance risks, and compromised patient safety.

Recommendations	Action owner	Management response	Completion date
NHSL should consider whether it is possible to distinguish medical tools from medical devices within Medusa.	Department of Medical Physics	NHS Lothian will consider this as a possibility and review the wider impact of potentially introducing a new Equipment Type category within the database hierarchy.	June 2026
We recommend, going forward, all purchase information for medical devices is uploaded to PECOS to ensure procurement information is held in a singular place for reference as required. This should include purchase orders, quotations from the chosen supplier, and any terms and conditions or contract entered into with the supplier.	Deputy Head of Procurement Medical Equipment Asset Team	NHS Lothian will consider the suitability of utilising PECOS for holding all purchase information for medical devices acquired via NHS Lothian's Capital Procurement programme, including quotations, term and conditions of any supplier contracts.	June 2026
NHSL should review the LMERG Capital Equipment form and consider whether the date field needs to be moved to avoid obstruction and ensure this is completed consistently.	Medical Equipment Asset Team	The addition of an individual date field on the LMERG capital equipment form will be reviewed as part of the next annual revision.	June 2026



Detailed Findings

Risk: Failure to ensure adequate staff training, updated usage protocols, and comprehensive incident reporting for medical devices could lead to improper operation, patient harm, regulatory non-compliance, and reputational damage for NHS Lothian.

Finding 5 - Monitoring of Training Completion			Type
<p>It is important that staff are adequately trained in the use of medical devices prior to operating them. Clear records show who is competent, protect patients, and identifies any gaps.</p> <p>The Medical Devices Policy assigns training responsibilities and requires records for doctors, nurses, AHPs and clinical physiologists. Clinical Directors, Clinical Nurse Managers and AHP Leads must ensure staff are trained and keep records. The intranet holds guidance and user manuals for medical devices.</p> <p>We interviewed 17 staff across departments. We asked departmental and service managers to explain how oversight of training is maintained and the processes in place to ensure their teams were appropriately trained. Additionally, we chose a sample of 15 medical devices from a database of 84,244 to assess whether staff were appropriately trained on the use of the medical device.</p> <p>10 out of 15 (67%) of the devices sampled did not have clear training records in place (see appendix II for a listing of relevant device eq nos).</p> <p>Three out of 15 (20%) of the devices sampled lacked SOPs (see appendix II for a listing of relevant device eq nos).</p> <p>We found that beyond Charge/Lead Nurses, there is no consistent oversight or tracking of training. Departmental and service managers do not maintain a training tracker or log, and they do not sign off Charge/Lead Nurses' trackers. There is no set format for tracking training across departments, so practice varies.</p>			<p>Design & effectiveness</p> 
Implication			Significance
<p>There is a risk that training is missed or delayed, and staff use devices without proven competence. This increases the chance of device-related incidents, weakens compliance and creates a single point of failure around Charge/Lead Nurses. It also limits assurance to the Medical Devices Committee that training controls work.</p>			Medium
Recommendations	Action owner	Management response	Completion date
<p>We recommend a standardised training log/tracker is introduced to be utilised by relevant departmental and service managers, as defined in the medical devices policy. As a minimum, fields for inclusion:</p> <ul style="list-style-type: none"> - Training item - Most recent training occurred - Next training due date - Sign off (by manager) 	DATCC Service Director	<p>NHS Lothian will work in collaboration with the clinical education team to consider the introduction of a standardised training log for Medical Devices.</p> <p>A standardised training log could be considered as a support document to the Medical Device Policy.</p> <p>The level/detail of training records will depend</p>	December 2026



Detailed Findings

Risk: Failure to ensure adequate staff training, updated usage protocols, and comprehensive incident reporting for medical devices could lead to improper operation, patient harm, regulatory non-compliance, and reputational damage for NHS Lothian.

Recommendations	Action owner	Management response	Completion date
		<p>on many factors: criticality of the device, is training required for all anticipated users, is the same model of equipment already in use.</p> <p>A risk-based approach will be taken to evaluate the need for adequate training programmes which may include generic and specific training, training delivery (face-to-face, e-learning), who should receive training offered by the manufacturer or supplier and planned training before a new medical device is introduced to the organisation.</p> <p>Any agreed processes will be applied prospectively to new and/or prioritised, high-risk equipment.</p>	
We recommend the Charge Nurse logs are signed reviewed for overall completion regularly by the Clinical Service or Department managers, with any overdue training chased for completion/justification.	DATCC Service Director	As part of the annual appraisal, training logs will be reviewed and updated as required.	December 2026
We recommend training logs are kept digitally to ensure they can be accessed with east by oversight groups.	DATCC Service Director	Existing NHS Lothian digital applications will be assessed for the suitability of holding medical device training records digitally.	December 2026
We recommend the Medical Devices Policy is updated to include the standardised training recording and oversight process once implemented.	DATCC Service Director MDC	<p>A review of the current training guidance will be carried out once a decision is made on the monitoring and review of training records requirements.</p> <p>The guidance will be tabled at the Medical Device Committee for approval and linked as a supporting document to the Medical Device Policy.</p>	December 2026



Detailed Findings

Risk: Failure to establish and maintain robust governance frameworks for medical device management could lead to confusion, non-compliance, and ineffective oversight, ultimately increasing the risk of patient harm, financial penalties, and reputational damage for NHS Lothian.

Finding 6 - Policy Review			Type
<p>It is important that policies and guidance are reviewed on time to keep responsibilities current, align with law and standards, and provide staff with clear, up-to-date instructions.</p> <p>We found that the Medical Devices Policy and the LMERG Guidance were both overdue for review. The Medical Devices Policy was approved in June 2022 with a review date of June 2025, making it 6 months overdue for review at the time of the audit. The LMERG Guidance was due for review in August 2025, making it 4 months overdue for review at the time of the audit.</p>			<p>Effectiveness</p> 
<p>Implication</p> <p>There is a risk, if policies and procedures are not regularly reviewed and updated, that staff rely on out-of-date direction which can drive inconsistent practice, weaken compliance with current regulations and procurement rules, and slow responses to adverse events.</p>			<p>Significance</p> <p>Low</p>
Recommendations	Action owner	Management response	Completion date
<p>We recommend that the Medical Devices Policy and LMERG Guidance document are reviewed and updated (if necessary) as soon as possible to align with the current NHS Lothian and legislative environment.</p>	<p>Medical Device Committee</p> <p>LMERG</p>	<p>The Medical Devices Policy and LMERG Guidance document will be reviewed and updated. Both documents will be tabled at their respective meeting for governance and approval.</p>	<p>June 2026</p>



Detailed Findings

Risk: Failure to establish and maintain robust governance frameworks for medical device management could lead to confusion, non-compliance, and ineffective oversight, ultimately increasing the risk of patient harm, financial penalties, and reputational damage for NHS Lothian.

Finding 7 - Competency Level Matrix			Type
<p>It is important that guidance documents are complete and include comprehensive information to ensure staff have a clear understanding of their roles and responsibilities, and tasks are carried out by the appropriate member of staff.</p> <p>The Medical Equipment Management (MEM) competency level matrix defines the competency level of staff by band level in relation to medical equipment, defining tasks staff can perform by band.</p> <p>We found that the electrical safety section in the matrix had all band levels left blank. Management advised that this was due to electrical safety being an assumed pre-requisite for other areas covered in the matrix.</p>			<p>Effectiveness</p> 
Implication			Significance
<p>There is a risk that, if the competency matrix is not comprehensively completed, staff may incorrectly assume electrical safety tasks can be performed without the adequate competencies resulting in misuse of devices, device damages or faults, and risks to staff members health and safety.</p>			Low
Recommendations	Action owner	Management response	Completion date
<p>We recommend that the MEM competency level matrix is updated to clearly define staff member competency by band for electrical safety, or make clear where this is a pre-requisite for other competencies already captured.</p>	<p>Department of Medical Physics</p>	<p>The MEM competency level training documents will be updated to clearly indicate electrical safety training and sign off is a pre-requisite to performing any maintenance and/or repairs on medical devices.</p>	<p>April 2026</p>

Observations



Observations - all noted

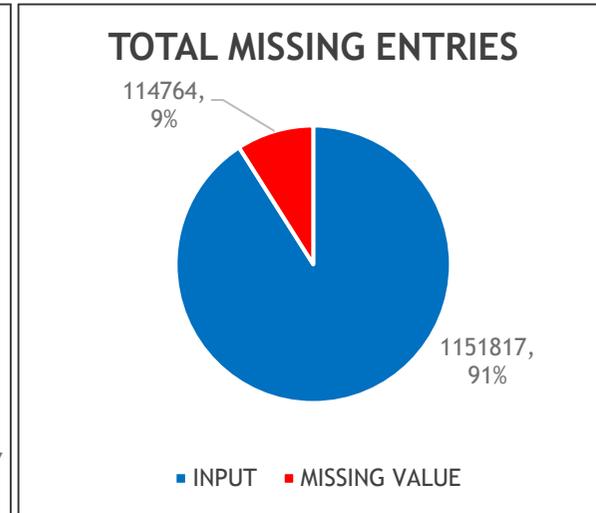
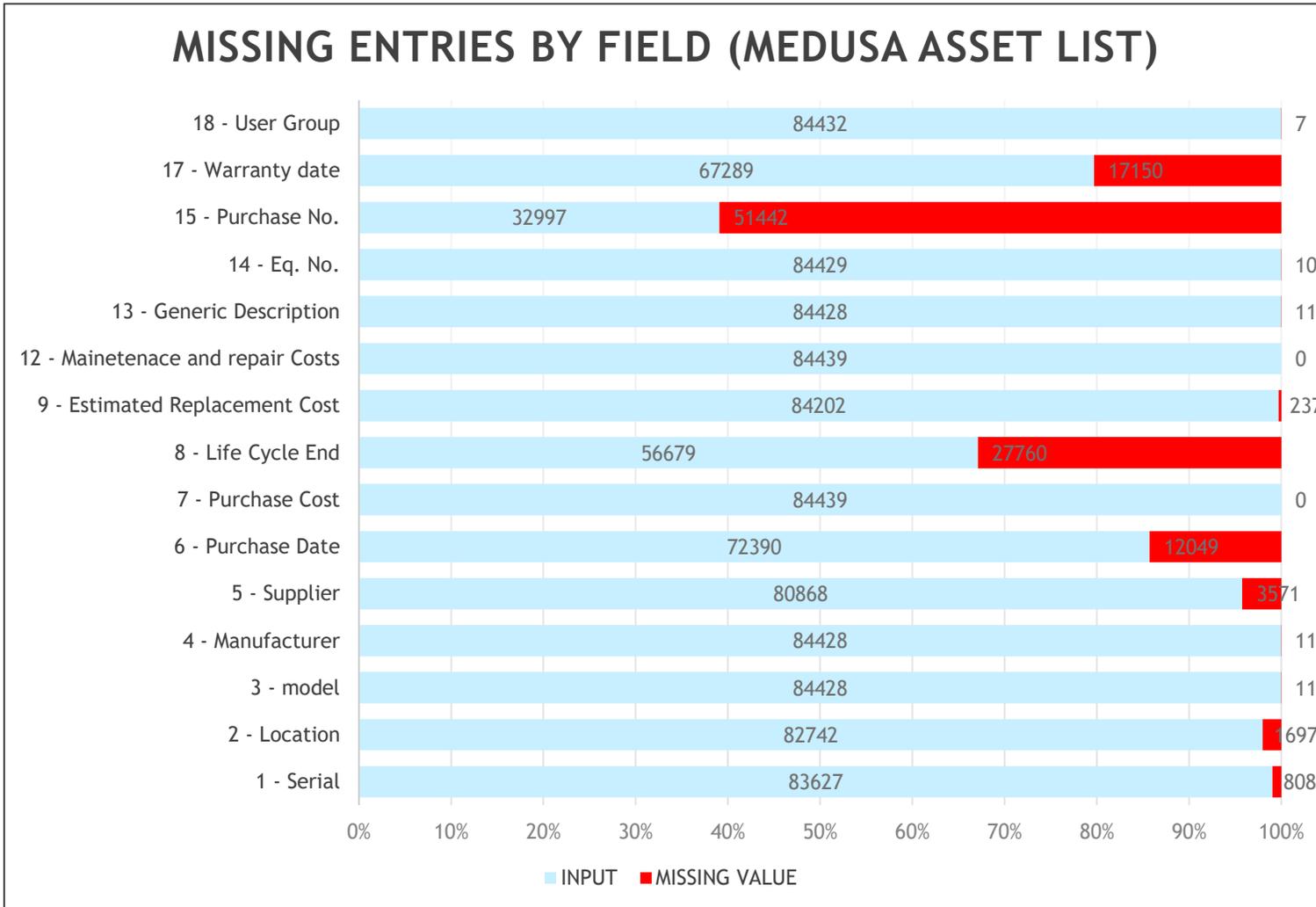
Observation 1 - Sample verification

During the sample testing on the verification of medical devices two samples could not be verified as they could not be physically accessed. Eq no 180014 was missing, which NHS Lothian was aware of, and hence could not be verified. Additionally, eq no 66450 was decommissioned during the audit and hence could not be verified.

Appendices



Appendix I: Medusa data analysis

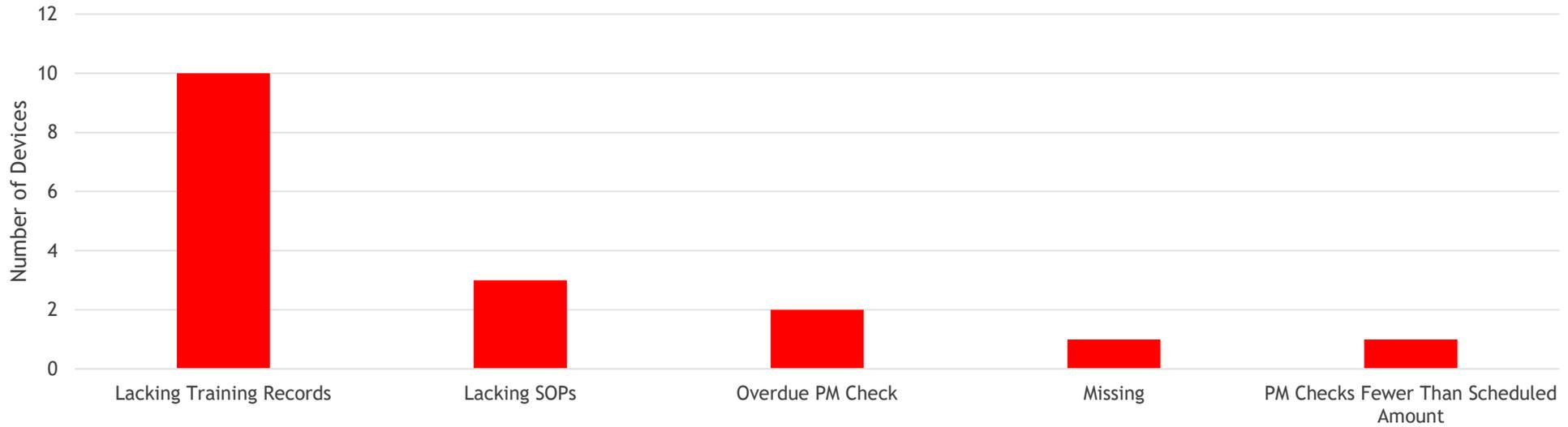


It is noted that some of these missing entries are as a result of changes in minimum data set requirements following introduction of Medusa, at which point historical data was unavailable.



Appendix II: Testing data

MAINTAINANCE DEVICES SAMPLED BY ISSUE



Issue by equipment no.	Issue				
	Lacking Training Records	Lacking SOPs	Overdue PM Check	Stolen	PM checks fewer than scheduled amount
	92020390	92020390	92033678	1800014	92038618
	66450	66450	92058643		
	92007586	92007586			
	RAD0032				
	RAD0034				
	92061215				
	92061169				
	92104003				
	92033678				
	92058643				
Sample eq no.					



Appendix III: Background

It was agreed as part of the 2025-26 Internal Audit Plan that Internal Audit would review the arrangements for Medical Devices at NHS Lothian. Effective medical device management supports patient safety, efficient care, compliance with relevant standards and good use of resources. The Department of Medical Physics supports a service-led approach to device governance and maintains a central asset register via Medusa where all Medical Physics medical devices are recorded. Devices are maintained in house or by third-party suppliers under contract, with service level agreements in place for some contracts.

Governance and oversight: The Medical Devices Committee provides governance on Medical Devices, developing and reviewing policies and procedures, promoting standardisation, supporting competence across services and monitoring incident themes alongside the Quality Improvement Support Team. The Lothian Medical Equipment Review Group (LMERG) manages capital planning and replacement, balanced clinical and financial risk, develops ten-year rolling replacement plans aligned to the capital plan and ensures governance for funded replacements. The Lothian Radiation Protection Committee oversees compliance for ionising and non-ionising radiation devices. The Renal Technical Managers met quarterly under Medical Physics to share best practice across NHS Scotland.

Policies and procedures: There is a Medical Devices Policy in place that covers a consistent Board-wide approach to the management of medical devices. The policy defines devices and key lifecycle terms, sets out roles for senior leadership, managers and clinical leads, and confirmed responsibilities for training, release of equipment for maintenance, handling of safety alerts and risk register entries. There is a Standing Financial Instructions policy in place that covered procurement governance including legal compliance, thresholds for competitive quotes and tenders, approvals, segregation of duties, receipt checks and payment controls. The Policy was reviewed to a Board timetable with the next review due April 2026. There is an Adverse Event Management Policy and Procedure in place which cover the reporting, review, learning and improvement from adverse events and near misses. Policies, guidance and device user manuals were available on the intranet Policy Hub, which included a four-week consultation zone for policies before their implementation.

Controls: Procurement follows the Standing Financial Instructions and, where available, NSS National Procurement frameworks. For non-framework purchases, a pre-purchase questionnaire addresses standards, warranty, installation, decontamination and radiation requirements. The PECOS system supports purchase-to-pay with an auditable trail of orders, receipts, approvals and stored documents (as uploaded). Devices over £5,000 require a Capital Equipment Form that captures specification, sustainability, maintenance and support, training, revenue costs and IT/digital needs, with approvals from scientific and technical services, procurement, budget holders, local and, where applicable, strategic governance and Capital Finance sign-off; always requiring LMERG approval. Budget holders anticipate procurement needs and work with Procurement to secure appropriate contracting.

Asset Management: Asset management and maintenance are supported by Medusa as the device register and maintenance management system in Medical Physics. Medusa holds unique identifiers, locations, ownership, warranty and lifecycle fields, preventative maintenance schedules, work orders and associated documents; with a minimum data set defining core fields. System administration SOPs ensure process requirements are clear in the administrator's absence. Assets carry RFID tags where safe tag reads updated locations automatically, with manual confirmation for fixed or non-tagable equipment. Monthly preventative maintenance analyses exported from Medusa are issued to workshop managers showing completed, scheduled and overdue work and trend charts. Devices are maintained by in-house teams or by third parties under contract, with planned maintenance schedules and service level requirements recorded where used. Action alert sheets are issued to Site and Service Directors to address device risks with defined actions, owners and deadlines.

Training: Training and competence requirements are defined in the policy and supporting guidance. The Executive Medical Director, Medical Directors and Clinical Directors are responsible for ensuring medical leadership, training and record-keeping for doctors, and release of equipment for maintenance. Clinical Nurse Managers, Charge/Lead Nurses, AHP, and Clinical Physiology leads are responsible for ensuring training for their team. Service and Locality Managers ensure equipment provision, local assessment of safety alerts, risk management and funded maintenance and replacement plans. Dependent on contract, 'train the trainer' programs are rolled-out for new equipment. A competency framework sets device and task levels by Agenda for Change band from first-line support through specialised repair, full lifecycle support and lifecycle management.

Incident reporting: Incident reporting and learning is operated through DATIX as the primary system of record. The Adverse Event Management Procedure sets a five-stage process from immediate actions and initial reporting through analysis, proportionate review, improvement planning and monitoring, embedded Duty of Candour and defined roles, tools and templates. The DATIX Actions module tracks owners, timescales and review dates, with Quality Improvement Support Team oversight and six-monthly reporting to the Healthcare Governance Committee. The Quality Improvement Support Team holds the responsibility in delivering any medical device alerts from supplier to the relevant clinical services or departments.

Decommissioning: Decommissioning and disposal are guided by a Medical Physics SOP and flowchart using Medusa work orders and three disposal routes—WEEE bin, trade-in or sale/auction—with authorisation aligned to role banding. A Data Processing Agreement with British Medical Auctions set secure handling and erasure of data on certain decommissioned devices, with a defined wiping protocol and certification.



Appendix IV: Definitions

Level of assurance	Design of internal control framework		Operational effectiveness of controls	
	Findings from review	Design opinion	Findings from review	Effectiveness opinion
Substantial	Appropriate procedures and controls in place to mitigate the key risks.	There is a sound system of internal control designed to achieve system objectives.	No, or only minor, exceptions found in testing of the procedures and controls.	The controls that are in place are being consistently applied.
Moderate	In the main there are appropriate procedures and controls in place to mitigate the key risks reviewed albeit with some that are not fully effective.	Generally a sound system of internal control designed to achieve system objectives with some exceptions.	A small number of exceptions found in testing of the procedures and controls.	Evidence of non compliance with some controls, that may put some of the system objectives at risk.
Limited	A number of significant gaps identified in the procedures and controls in key areas. Where practical, efforts should be made to address in-year.	System of internal controls is weakened with system objectives at risk of not being achieved.	A number of reoccurring exceptions found in testing of the procedures and controls. Where practical, efforts should be made to address in-year.	Non-compliance with key procedures and controls places the system objectives at risk.
No	For all risk areas there are significant gaps in the procedures and controls. Failure to address in-year affects the quality of the organisation's overall internal control framework.	Poor system of internal control.	Due to absence of effective controls and procedures, no reliance can be placed on their operation. Failure to address in-year affects the quality of the organisation's overall internal control framework.	Non compliance and/or compliance with inadequate controls.

Recommendation significance

High	A weakness where there is substantial risk of loss, fraud, impropriety, poor value for money, or failure to achieve organisational objectives. Such risk could lead to an adverse impact on the business. Remedial action must be taken urgently.
Medium	A weakness in control which, although not fundamental, relates to shortcomings which expose individual business systems to a less immediate level of threatening risk or poor value for money. Such a risk could impact on operational objectives and should be of concern to senior management and requires prompt specific action.
Low	Areas that individually have no significant impact, but where management would benefit from improved controls and/or have the opportunity to achieve greater effectiveness and/or efficiency.



Appendix V: Terms of reference

Extract from terms of reference

Purpose

The Medical Devices Internal Audit aims to provide assurance to management and the Audit and Risk Committee that the controls around medical devices are suitably designed and operating effectively. This review will consider the following areas:

- Governance Framework
- Procurement Processes
- Maintenance, Repair and Calibration
- Training and Usage Protocols
- Device Suitability, Certification and Decommissioning
- Continuous Improvement

Key risks

1. Failure to establish and maintain robust governance frameworks for medical device management could lead to confusion, non-compliance, and ineffective oversight, ultimately increasing the risk of patient harm, financial penalties, and reputational damage for NHS Lothian.
2. Failure to implement robust procurement processes for medical devices could lead to inappropriate or unsafe equipment acquisitions, increased financial and compliance risks, and compromised patient safety.
3. Failure to maintain accurate device inventories, perform timely maintenance and calibration, and enforce robust service-level agreements with third-party providers increases the risk of equipment failure, patient harm, regulatory non-compliance, and financial inefficiency for NHS Lothian.
4. Failure to ensure adequate staff training, updated usage protocols, and comprehensive incident reporting for medical devices could lead to improper operation, patient harm, regulatory non-compliance, and reputational damage for NHS Lothian.
5. Failure to ensure medical devices are certified, remain fit for purpose, and are properly decommissioned (including managing data security risks) could result in non-compliance, financial and reputational damage, and compromised patient safety for NHS Lothian.

Exclusions/limitations of scope

The scope of the review is limited to the areas documented under the scope and approach. All other areas are considered outside of the scope of this review. Our review will not provide assurance over all aspects of medical devices.

This review will focus on larger medical devices used in an Acute setting.

Where sample testing is undertaken, our findings and conclusions will be limited to the sample tested only. Please note that there is a risk that our findings and conclusions based on the sample may differ from the findings and conclusions we would reach if we tested the entire population from which the sample is taken.



Appendix VI: Staff interviewed

BDO LLP appreciates the time provided by all the individuals involved in this review and would like to thank them for their assistance and cooperation.

Andrew Davie	Healthcare Science Professional Lead	Key contact
Caoimhe McIntyre	Head Of Medical Physics	Key contact
Iain Gorman	Service Director - Diagnostics, Anaesthetics, Theatre And Critical Care	Key contact
Kenny Pake	Systems Administrator - Medical Physics	Interviewee
Alistair Gibson	Consultant In Intensive Care And Anaesthetics	Interviewee
Andy Hay	Deputy Head Of Procurement	Interviewee
Aris Tyrothoulakis	Site Director Rhcyp And LMERG Chair	Interviewee
Carol Stewart	Radiology Manager	Interviewee
Catherine Bakkers	Medical Equipment Asset Manager	Interviewee
Debbie Harries	Principal Physicist	Interviewee
Lee Hampson	Principal Physicist	Interviewee
Emma Cochrane	Policy Hub Programme Manager/Policy Advisor	Interviewee
James Foster	Technical Project Manager	Interviewee
Lesley Dickson	Advanced Nurse Specialist	Interviewee
Nadine Wilkinson	Healthcare Science Manager	Interviewee
Colin Hand	Team Leader	Interviewee
Robert Wilkinson	Quality And Assurance Manager	Interviewee
Steve Kersterton	West Sector Manager	Interviewee
Chris Mcleod	Clinical Technologist Team Lead	Interviewee
John Ramsay	Renal Technical Manager	Interviewee



Appendix VII: Responsibilities, limitations and conformance with the Global Internal Audit Standards

Management responsibilities

The Board is responsible for determining the scope of internal audit work, and for deciding the action to be taken on the outcome of our findings from our work.

The Board is responsible for ensuring the internal audit function has:

- The support of the Company's management team.
- Direct access and freedom to report to senior management, including the Chair of the Audit Committee.
- The Board is responsible for the establishment and proper operation of a system of internal control, including proper accounting records and other management information suitable for running the Company.

Internal controls covers the whole system of controls, financial and otherwise, established by the Board in order to carry on the business of the Company in an orderly and efficient manner, ensure adherence to management policies, safeguard the assets and secure as far as possible the completeness and accuracy of the records. The individual components of an internal control system are known as 'controls' or 'internal controls'.

The Board is responsible for risk management in the organisation, and for deciding the action to be taken on the outcome of any findings from our work. The identification of risks and the strategies put in place to deal with identified risks remain the sole responsibility of the Board.

Limitations

The scope of the review is limited to the areas documented under Appendix II - Terms of reference. All other areas are considered outside of the scope of this review.

Our work is inherently limited by the honest representation of those interviewed as part of colleagues interviewed as part of the review. Our work and conclusion is subject to sampling risk, which means that our work may not be representative of the full population.

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Our assessment of controls is for the period specified only. Historic evaluation of effectiveness may not be relevant to future periods due to the risk that: the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or the degree of compliance with policies and procedures may deteriorate.

Conformance with the Global Internal Audit Standards

This engagement has been conducted in accordance with the Institute of Internal Auditors' Global Internal Audit Standards.

FOR MORE INFORMATION:

CLAIRE ROBERTSON, DIRECTOR AND HEAD
OF RISK ADVISORY SERVICES - SCOTLAND

+44 (0)7583 237 579
claire.robertson@bdo.co.uk

This publication has been carefully prepared, but it has been written in general terms and should be seen as containing broad statements only. This publication should not be used or relied upon to cover specific situations and you should not act, or refrain from acting, upon the information contained in this publication without obtaining specific professional advice. Please contact BDO LLP to discuss these matters in the context of your particular circumstances. BDO LLP, its partners, employees and agents do not accept or assume any responsibility or duty of care in respect of any use of or reliance on this publication, and will deny any liability for any loss arising from any action taken or not taken or decision made by anyone in reliance on this publication or any part of it. Any use of this publication or reliance on it for any purpose or in any context is therefore at your own risk, without any right of recourse against BDO LLP or any of its partners, employees or agents.

BDO LLP, a UK limited liability partnership registered in England and Wales under number OC305127, is a member of BDO International Limited, a UK company limited by guarantee, and forms part of the international BDO network of independent member firms. A list of members' names is open to inspection at our registered office, 55 Baker Street, London W1U 7EU. BDO LLP is authorised and regulated by the Financial Conduct Authority to conduct investment business.

BDO is the brand name of the BDO network and for each of the BDO member firms.

BDO Northern Ireland, a partnership formed in and under the laws of Northern Ireland, is licensed to operate within the international BDO network of independent member firms.

Copyright © 2026 BDO LLP. All rights reserved. Published in the UK.

www.bdo.co.uk