Medical Equipment and Devices

Final Internal Audit Report

2025/26

Cardiff & Vale University Health Board

Reasonable Assurance

Contents

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Executive Sign Off	8 December 2025
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Executive Summary

Purpose

The overall objective of the audit was to evaluate and determine the adequacy of the systems and controls in place within the Health Board for the management of Medical Equipment and Devices including implants.

The term 'medical equipment or device' includes all products, excluding medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. The range of products is wide and includes dressings, tubing, syringes, infusion pumps, heart valves, surgical instruments, resuscitators, radiotherapy machines, wheelchairs, walking frames or other assistive technology products.

A systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices aligned with appropriate staff training and quality assurance arrangements will ensure that the use of medical devices is done safely, competently and effectively for the best care of patients and complies with all relevant legislation and guidance.

Testing of medical equipment and devices has been undertaken within Radiology at University Hospital of Wales (UHW) and University Hospital Llandough (UHL), Hospital Sterilisation and Decontamination Unit (HSDU) at UHW and Sterile Services Unit (SSU) in UHL.

This area was last reviewed during 2022/23 and was assessed as Reasonable Assurance.

Overview

We have concluded **Reasonable** assurance on this area. The significant matters requiring management attention include:

- Review of the policy and procedure is significantly overdue.
- Radiology medical equipment and devices are not accurately recorded on Medusa.
- A significant number of medical equipment and devices have overdue planned maintenance.
- Lack of Clinical Engineering oversight of Radiology and HSDU / SSU.

Full details of matters arising are detailed within the Findings & Agreed Action Plan. The following issue represents an opportunity for enhancement that does not impact the overall opinion and is highlighted for management information:

- Commissioning paperwork could not be provided for one Radiology asset tested.

Scope & Assurance Summary

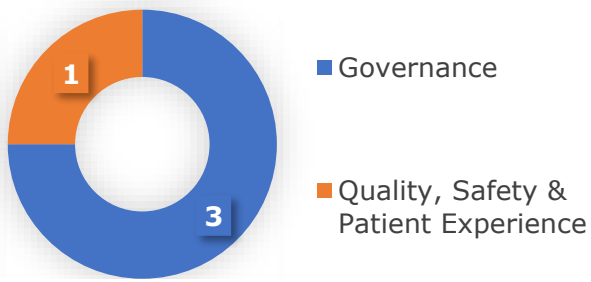
Objectives (The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.)		Related Findings	Assurance
1	The Health Board has appropriate policies and procedures in place for the management of Medical Equipment & Devices, which are reviewed and maintained by the Medical Equipment Group. Staff are made aware of their responsibilities or any revisions to responsibilities following a review	1	**Reasonable**
2	There is a medical equipment inventory database that accurately records the purchase, transfer, loan and disposal of medical equipment and devices, with all equipment being disposed of appropriately	2, 3	**Limited**
3	Medical equipment and devices are cleaned and maintained and kept in an appropriate state of repair	4	**Reasonable**
4	Medical equipment and devices are suitably decontaminated after each patient use	-	**Substantial**
5	Medical equipment and devices are stored in a safe and secure location when not in use	-	**Substantial**
6	Risk assessments are completed on devices and equipment which may pose a significant risk to patients or staff and any incidents are recorded on Datix	-	**Substantial**
7	Staff receive appropriate training before using medical equipment and devices	-	**Substantial**

Management Actions

2 High Priority

2 Medium Priority

Themes



Risk Types

Quality or Safety Issues

Findings & Agreed Action Plan

Objective 1: The Health Board has appropriate policies and procedures in place for the management of Medical Equipment & Devices, which are reviewed and maintained by the Medical Equipment Group. Staff are made aware of their responsibilities or any revisions to responsibilities following a review	**Reasonable**

Overview / Summary of Observations

The Health Board has a policy and procedure in place which covers the management of Medical Equipment and Devices (Reference Number: UHB 082) which are available to all staff on the Health Board's intranet. Both documents were scheduled for review by 31 March 2023, making them now considerably overdue. The policy and procedure are unchanged since our previous review of the management of Medical Equipment and Devices which was issued in October 2022 (CVU-2223-25).

Whilst overdue for review, we note that the policy and procedure still reflect the current standards and processes in place for Medical Equipment and Devices.

	Key Findings	Risk & Impact	Agreed Management Action
1	**Review of the policy and procedure is significantly overdue** The Health Board's policy and procedure in place covering the management of Medical Equipment and Devices were last reviewed on 2 March 2022, with the next review date due by 31 March 2023, which has now passed.	Inappropriate procedures resulting in harm and possible death.	**Agreed Action:** The Health Board policy and procedure which cover the management of Medical Equipment and Devices will be reviewed to ensure that they accurately reflect required actions and any changes will be communicated to relevant staff.
			Expected Evidence of Implementation: Copy of the reviewed and approved Health Board policy and procedure have been reviewed and approved. Copy of communication of reviewed and approved Health Board policy and procedure to relevant staff.
		Medium Priority	**Officer: Edward Chapman** **Target Implementation Date: August 2026**
	Theme: Governance	Control Operation	

Objective 2: There is a medical equipment inventory database that accurately records the purchase, transfer, loan and disposal of medical equipment and devices, with all equipment being disposed of appropriately	**Limited**

Overview / Summary of Observations

The Medical Equipment Management Policy states that records of Medical Equipment will be kept on a database held and maintained by the Health Board's Clinical Engineering Department. The database utilised within the Health Board is the Medusa system.

Radiology

We tested a sample of Radiology medical equipment and devices from Medusa, however, a significant proportion could not be verified as they had either been decommissioned, replaced or were no longer in situ. Furthermore, other assets could not be verified as the required serial numbers were not recorded on Medusa.

Additionally, when we selected a sample of medical equipment and devices located at UHW and UHL, the majority were not recorded on Medusa.

The Head of Clinical Engineering informed us that the original intention was that directorates would notify asset changes via the Finance Department's annual asset verification exercise, which would then inform the Clinical Engineering department to update the Medusa system. However, this process has not been followed. Furthermore, we were informed by Radiology staff that they do not have any involvement with Medusa, although they do notify asset changes via the Finance Department's annual asset verification exercise.

Follow up of our previous audit's Agreed Management Actions

One of the Agreed Management Actions following our previous audit was that Clinical Engineering would perform an audit of equipment not seen for over 10 years. However, while a Medusa online dashboard has since been developed to help facilitate this, we note that it lists a significant number of medical equipment and devices with overdue 'Next Planned Maintenance' dates.

	Key Findings	Risk & Impact	Agreed Management Action
2	**Radiology medical equipment and devices are not accurately recorded on Medusa** We selected 22 Radiology medical equipment and devices at UHW and eight Radiology medical equipment and devices at UHL for verification from the Medusa system: • 11 of the medical equipment and devices at UHW had been decommissioned, replaced or were not still in situ. Furthermore, three of the medical equipment and devices could not be verified as the required serial numbers were not recorded on Medusa. • Five of the medical equipment and devices selected at UHL had been replaced, four in 2023 and one in 2025, and a further medical equipment and device was incomplete on	Inadequate management of Medical Equipment and Devices.	**Agreed Action:** The Medical Equipment Policy and Procedure will be amended to correctly reflect the arrangements for federated equipment management and the distinction between capital asset records. Clinical Boards and services have responsibility for managing medical equipment and devices used in their areas. They may use their own systems for this activity as appropriate. Access to Medusa can be granted if required. The Policy and Procedure will incorporate the requirement to record financial assets in Medusa for capital management purposes and mandate that updates from the Finance Dept are notified on a regular basis. **Expected Evidence of Implementation:**

	Medusa as it only included the workstation not the radiology equipment. In addition, we selected 10 medical equipment and devices on site at UHW and four medical equipment and devices on site at UHL and checked whether they were recorded in Medusa. Only one of the assets selected at UHW and only one of the assets selected at UHL were recorded in Medusa. We were informed that the original intention was that directorates would notify asset changes via the Finance Department's annual asset verification exercise who would subsequently notify Clinical Engineering to update Medusa. However, this has not occurred. Furthermore, we were informed by Radiology staff at both UHW and UHL that they do not have any involvement with Medusa, although they do notify asset changes via the Finance Department's annual asset verification exercise.	**High Priority**	An updated Medical Equipment Policy and Procedure **Officer: Edward Chapman** **Target Implementation Date: Tied to the Policy rewrite, August 2026**
	Theme: Governance	Control Operation	
3	**Overdue planned maintenance dates** One of the Agreed Management Actions in our previous audit was that Clinical Engineering would perform an audit of items not seen for over 10 years. However, while a Medusa online dashboard has since been developed to help facilitate this, we note that it lists a significant number of assets with overdue planned maintenance dates. It was identified that: • four were due in 2016; • two were due in 2018; • four were due in 2019; • six were due in 2020;	Inadequate management of Medical Equipment and Devices.	**Agreed Action:** An SBAR was submitted in 2023 with a plan to increase the headcount in CE to resolve the backlog of maintenance created during the pandemic. Planned maintenance is prioritised according to risk, and a plan to mitigate risks will be drafted should recruitment not succeed. The workforce challenges in Clinical Engineering have been acknowledged at EDAHPHCS and work is continuing with HEIW and professional groups to consider options to the improve recruitment pipelines.

	• 58 were due in 2021; • 240 were due in 2022; • 320 were due in 2023; and • 798 were due in 2024. Some were marked maintenance in progress, but the vast majority did not indicate maintenance had occurred. This was also evidenced during our sample testing of two assets.	**High Priority**	**Expected Evidence of Implementation:** Successful recruitment and filling of posts, or cessation of services to maintain core high risk device maintenance. **Officer: Edward Chapman** **Target Implementation Date: 01/01/2027**
	Theme: Quality, Safety & Patient Experience	Control Operation	

Objective 3: Medical equipment and devices are cleaned and maintained and kept in an appropriate state of repair	**Reasonable**

Overview / Summary of Observations

Radiology

From our testing of a sample of medical equipment and devices at UHW and UHL, we confirmed that the items were clean at the time of our visit and appropriate cleaning arrangements are in place. These vary according to the nature and purpose of the equipment but typically comprise wiping all contact surfaces at the start of each day's activity and prior to the treatment of each patient.

For the sample of medical equipment and devices, we reviewed the adequacy of the documentation held in relation to commissioning, service and fault correction. While no issues were identified in relation to the service and fault correction paperwork, commissioning paperwork could not be provided for one Radiology asset tested.

HSDU / SSU

HESSDA (Health Edge Sterile Services Department Application), tracks the theatre equipment through the cleaning and sterilisation process.

We tested the cleaning of 12 items of equipment through HSDU's cleaning process and 10 items of equipment through SSU's cleaning process including checking consistency with the printout records from the washer machines and no issues were identified.

General cleaning of the HSDU and SSU rooms is undertaken daily before the cleaning process commences which includes wiping down all surfaces which are part of the process.

An appropriate washer machine maintenance process is in place to ensure that the washer machines are operating correctly, and fault repairs are undertaken when necessary.

General

Clinical Engineering's involvement with the above areas is limited and largely relates to providing support if requested. It does not maintain operational oversight of them. Therefore, the vast majority of audit testing was undertaken with staff in Radiology and HSDU / SSU rather than in Clinical Engineering.

	Key Findings	Risk & Impact	Agreed Management Action
4	**Lack of Clinical Engineering oversight of Radiology and HSDU / SSU.** The vast majority of audit testing was undertaken with staff in Radiology and HSDU and SSU as Clinical Engineering's involvement with these areas is limited and largely relates to providing support if requested. It does not maintain operational oversight of them. The significant number of issues identified under Objective 2 highlight that an increased level of oversight is required to	Inadequate management of Medical Equipment and Devices.	**Agreed Action:** As stated above, CE involvement with areas without significant amounts of CE maintained equipment is limited. It is the service user and owner of the equipment that is responsible for operational oversight and compliance with the policy and procedure. **Expected Evidence of Implementation:** Appropriate governance and assurance arrangements are in place in relation to Radiology and HSDU and SSU.

	ensure the appropriate recording and management of medical equipment and devices.	**Medium Priority**	**Officer: Relevant Heads of Service** **Target Implementation Date: August 2026**
	Theme: Governance	Control Design	

Objective 4: Medical equipment and devices are suitably decontaminated after each patient use	**Substantial**

Overview / Summary of Observations

Radiology

We confirmed that appropriate disinfection arrangements are in place which, while they vary according to the nature and purpose of the equipment, typically comprise wiping all contact surfaces at the start of each day's activity and prior to the treatment of each patient using disposable clinical grade disinfection wipes.

HSDU / SSU

We tested the disinfection of 12 items of equipment through HSDU's sterilisation process and 10 items of equipment through SSU's sterilisation process including checking consistency with the printout records from the sterilisation machines and no issues were identified.

In addition, we confirmed that industry test sheets are put through each sterilisation machine daily before being used which change colour confirming that they are sterilising correctly.

Objective 5: Medical equipment and devices are stored in a safe and secure location when not in use	**Substantial**

Overview / Summary of Observations

Radiology

From our testing of a sample of assets held by Radiology in UHW and UHL, we confirmed that all were being stored securely.

HSDU / SSU

We confirmed that equipment coming into HSDU / SSU, held by HSDU / SSU and ready for return by HSDU / SSU was being stored securely.

Objective 6: Risk assessments are completed on devices and equipment which may pose a significant risk to patients or staff and any incidents are recorded on Datix	**Substantial**

Overview / Summary of Observations

Risk assessments

Both UHW / UHL Radiology and HSDU / SSU maintain a wide range of detailed risk assessments which cover all aspects of their operation.

Datix

We have been informed by management responsible for the sample areas of Radiology and HSDU / SSU tested that there have been no medical equipment incidents which required reporting on Datix. Furthermore, we have been informed that if an incident occurred involving equipment, then it would be removed from use, corrective action would be taken, and lessons would be shared with staff.

We have also been informed that Clinical Engineering will provide support / guidance to directorates when requested and undertakes a light touch review of medical equipment incidents on Datix. However, this does not extend further as it is the directorates who are responsible for investigating incidents.

Objective 7: Staff receive appropriate training before using medical equipment and devices	**Substantial**

Overview / Summary of Observations

UHW Radiology

We confirmed that staff training records for a sample of key medical equipment and devices at UHW Radiology were detailed and covered a wide range of required competencies.

UHL Radiology

Core users receive extensive training by the manufacturer on new equipment, and a training file is maintained for each radiographer which sets out the detailed competencies for each device which is completed by the radiographer and signed off by their supervisor. Furthermore, an annual summary is completed by each radiographer which confirms their continued competency on each device which is again signed off by their supervisor.

HSDU / SSU

Detailed training logs are maintained for all new staff which record undertaking each of the required competencies for working in HSDU / SSU. Furthermore, detailed procedures files are maintained which set out step by step instructions for the various tasks in HSDU / SSU and staff are monitored to ensure that work is undertaken appropriately.

Appendix A

Assurance Opinion

 **Substantial**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
 **Reasonable**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
 **Limited**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
 **Unsatisfactory**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
 **Advisory**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Findings

Priority	Explanation
High	Significant risk to achievement of a system objective OR evidence present of material loss, error, or misstatement. Poor system design OR widespread non-compliance.
Medium	Some risk to achievement of a system objective. Minor weakness in system design OR limited non-compliance.

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Audit work undertaken by NHS Wales Audit and Assurance Services conforms with the International Standards for the Professional Practice of Internal Auditing and associated Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Chartered Institute of Public Finance & Accountancy in April 2023.

Website: [Audit & Assurance Services - NHS Wales Shared Services Partnership]