Medical Devices Regulations

Final Internal Audit Report

2025/26

Hywel Dda University Health Board

Substantial Assurance

Contents

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Executive Sign Off	01/12/25
Audit Committee	December 2025
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Executive Summary

Purpose

The objective of this audit is to provide assurance that effective governance, operational controls, and monitoring arrangements are in place to ensure compliance with the UK Medical Devices Regulations 2002 and the MHRA[1] Managing Medical Devices guidance in relation to the management of reusable medical devices.

Overview

The Health Board has in place appropriate governance arrangements for medical devices that is underpinned by policies and procedures, a centralised asset management system for the recording and monitoring of devices, distribution and communication channels for safety notices and alerts, appropriately trained staff and the monitoring and the scrutiny of incidents reported on the Datix system.

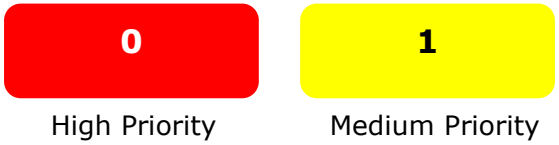
One matter requiring management attention surrounded the expired training of employees for one manufacturer for devices that have not changed since the received training to ensure the Health Board is not impacted from a legal and patient safety aspect by this situation.

We have concluded **Substantial** assurance on this area. Full details of matters arising are detailed within the Findings & Agreed Action Plan.

Scope & Assurance Summary

Objectives[2]		Related Findings	Assurance
1	Appropriate governance arrangements are in place for the management of medical devices.	-	**Substantial**
2	A comprehensive inventory listing of medical devices is maintained. Devices are properly maintained, kept in an appropriate state of repair and decontaminated.	-	**Substantial**
3	Training programmes ensure that staff are trained and competent in the use of medical devices.	1	**Reasonable**
4	Device faults, alerts or warning notices issued by appropriate agencies are promptly addressed and reported. Incidents relating to medical devices are reported via Datix and escalated where appropriate.	-	**Substantial**

Management Actions



Themes

Risk Types

Legal & Regulatory Non-Compliance

Public Perception & Reputational Risk

1 Medicines and Healthcare Products Regulatory Agency

2 The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

Findings & Agreed Action Plan

Objective 1: Appropriate governance arrangements are in place for the management of medical devices	**Substantial**

Overview / Summary of Observations

The Health Board's Scheme of Delegation formally outlines the strategic and operational governance responsibilities for medical devices to the Director of Allied Health Professions & Health Science and Chief Operating Officer respectively.

A Medical Devices Group has been established with a terms of reference (ToR) in place outlining key elements including duties, operational responsibilities, membership, frequency of meetings and reporting arrangements. The Head of Clinical Engineering and Deputy Director of Health Care Sciences are the Chair and Vice Chair respectively.

The reporting arrangements in the ToR was recently updated and submitted to the Medical Devices Group in October 2025 following the changes made to the operational governance arrangements within Hywel Dda, with the updated ToR to be submitted for ratification and approval at the next Quality Safety Intelligence Group (QSIG) meeting.

A *Medical Devices Management Policy* is in place, and available to staff on the organisation's intranet site, that sets out the Health Board's approach and commitment to achieving a safe and assured system for medical devices management. A review of the *Medical Devices Management Policy* confirmed its alignment and completeness against the MHRA *Managing Medical Devices Guidance* document and other NHS Wales organisation policies. In addition, a 'Strategic Medical Devices Replacement' paper outlining current status, recent investments and future planning for medical devices across the Hywel Dda University Health Board was submitted to the Capital Sub-Committee in July 2025

A review of the governance reporting arrangements during 2025 confirmed the Medical Devices Group reports through to the Health Board via QSIG. Prior to the changes in the governance reporting structure, we can also confirm that the Medical Devices Group reported through to the Quality, Safety & Experience Sub-Committee (QSESC) and Committee (QSEC).

Objective 2: A comprehensive inventory listing of medical devices is maintained. Devices are properly maintained, kept in an appropriate state of repair and decontaminated	**Substantial**

Overview / Summary of Observations

The Clinical Engineering Department has a centralised asset management system (e-Quip) in place that maintains an inventory record of medical devices received into the organisation. A review of the e-Quip system confirmed that content of the system aligned with the requirements of the MHRA.

A sample of 20 medical devices categorised as 'in use' was reviewed on the e-Quip system and confirmed that required risk assessments (known as Acceptance Testing) had been completed before first use, whilst other key documentation such as delivery notes and service history was also evident.

In September 2025, the British Standards Institute (BSI) undertook an audit to determine the effectiveness of implementation of the of the Clinical Engineering Department management system including a review of decontamination compliance. The observed compliance and consistency in the booking-in, checking and completion of paperwork for medical devices requiring decontamination.

Objective 3: Training programmes ensure that staff are trained and competent in the use of medical devices	**Reasonable**

Overview / Summary of Observations

The Health Board has a *Medical Devices Training, Safe Use & Operation Procedure* in place that was approved by the Medical Devices Group in February 2025 and aligns with MHRA guidance. The procedure is available to employees on the organisation's intranet site.

The BSI audit undertaken in September 2025 also reviewed training record compliance. The report confirmed training records and certificates were compliant and up to date.

A sample of employees training records tested during this internal audit review corroborated the findings in the BSI report. Employees are issued a certificate from the manufacturers per medical device following training, in addition to online secure portables on the manufacturers website that contains testing procedures and updates or safety notices on the medical devices.

We noted that for one medical device manufacturer an expiry date is included on their training certificates. Of the sampled certificates reviewed, two employees had certificates that expired in 2023 with no subsequent refresher training having taken place. This finding was raised with the Head of Clinical Engineering who explained that this represented a low risk as the individual employees would have received the appropriate training with notices of any changes or defects to the medical device received via the manufacturers secure online portal. The Health Board should risk assess this finding to ensure that this does not impact the organisation.

	Key Findings	Risk & Impact	Agreed Management Action
1	**Expired Training** Of the sampled certificates reviewed, two employees had certificates that expired in 2023 with no subsequent refresher training having taken place. This finding was raised with the Head of Clinical Engineering who explained that this represented a low risk as the individual employees would have received the appropriate training with notices of any changes or defects to the medical device received via the manufacturers secure online portal. The Health Board should risk assess this finding to ensure that this does not impact the organisation.	The Health Board is exposed to legal and patient safety risks due to expired training of medical devices of staff	**Agreed Action:** The Staff Training Policy (GQP 005) will be updated to reflect the validity of external medical device training certificates, following an expiration date, currently outlined in the training matrix. The only company that provide certificates with an expiry date is Dreager, they have confirmed that refresher training is only advised but this is at the discretion of the Health Board. Their online portal only allows access to the latest documents, and so any changes will be evident from the outset and technicians will be aware and can seek support if needed. Using the online portal will be written into the policy for these devices and mitigates the risk. **Expected Evidence of Implementation:** 1) Updated Staff Training Policy 2) Evidence to show access to the portal is available to all trained technicians
		Medium Priority	**Officer:** Jan Bojanowski, Head of Clinical Engineering
	Theme: Training & Development	Control Operation	**Target Implementation Date:** 28 November 2025

Objective 4: Device faults, alerts or warning notices issued by appropriate agencies are promptly addressed and reported. Incidents relating to medical devices are reported via Datix and escalated where appropriate	**Substantial**

Overview / Summary of Observations

The Health Board has in place an *Incident, Near Miss and Hazard Reporting Management Procedure* to ensure that all staff can identify incidents, take appropriate actions and reduce risks to service users and employees. The procedure document also outlines the Head of Clinical Engineering as the Health Board's Medical Devices Safety Officer (MDSO) in line with MHRA requirements.

Arrangements to distribute medical devices safety information to appropriate Clinical Engineering individuals was evident through direct manufacturer notifications, MHRA alerts and safety notices communicated via the ECRI[3] system. We also noted that medical devices regulation updates and changes were submitted and discussed at the Medical Devices Group meeting during 2025.

Incidents and never events involving medical devices for the period January to October 2025 identified only five entries. Of the two incidents that were closed, a review of the Datix confirm their entries as complete, whilst three were currently under 'management review'. MHRA guidance states that any incident deemed serious must be reported, with defined criteria outlined for what constitutes a 'serious incident'. A review of the five incidents confirmed that none were reported to the MHRA, as they were correctly assessed as not meeting the criteria for seriousness threshold.

A review of the Medical Devices Group for the period January to October 2025 also confirmed that medical devices incidents are regularly reported for discussion.

[3] Emergency Care Research Institute

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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Public Sector Internal Audit Standards

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]

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