



**GIG**  
CYMRU  
**NHS**  
WALES

Iechyd Cyhoeddus  
Cymru  
Public Health  
Wales

**Reference Number:** PHW 69  
**Version Number:** 2  
**Date of next review:** 27 November  
2021

# Medical Devices and Equipment Management Policy

## Policy Statement

It is the policy of Public Health Wales that all practicable steps should be taken to ensure all risks associated with the acquisition, management and use of medical devices are minimised to protect the public health and safeguard the interest of service users, carers and staff.

The term "medical devices" covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. The range of products is very wide, it includes airways and equipment used in life support, aids to daily living eg wheelchairs, syringes, needles, thermometers, mattresses, beds, examination gloves, urine testing strips, specimen collection tubes and any of thousands of other items used every day by healthcare providers and users.

Public Health Wales must ensure that the medical devices and equipment meet appropriate standards of safety, quality and performance, complying with all the relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA).

It is the responsibility of the organisation and all employees to contribute to the provision of safe and secure use of all medical devices for service users, carers and staff.

The aim is to ensure whenever a medical device is used, it should be:

- (a) Suitable for its intended purpose;
- (b) Properly understood by the user;
- (c) Maintained in a safe and reliable condition;
- (d) Stored and disposed of appropriately;
- (e) Decontaminated in accordance to manufacturers guidance.

## Policy Commitment

To provide a clear understanding of the organisation's principles regarding the management and decontamination of medical devices and to set out standards and guidance to ensure systems are in place to provide assurances for the safe use and storage of equipment in Public Health Wales.

This policy aims to prevent and control the spread of infection by the provision of robust decontamination principles, for the safety of patients and staff.

The aim of this policy is to support staff in understanding their responsibilities in relation to the management of medical devices. The knowledge and skills of staff, carers and services users have major implications for safety. Instructions must be clear, concise and readily available. Training should be timely and effective, and include procedures for the routine maintenance of medical devices by staff, carers and service users.

This policy is based on statutory requirements produced by the Health and Safety Commission, Department of Health, Medicines and Healthcare Products Regulatory Agency and the Welsh Government including the:

- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2008 and 2012
- Health and Safety at Work etc. Act 1974
- Electricity at Work Regulations 1989
- Management of Health and Safety at Work Regulations 1999
- Provision and Use of Work Equipment Regulations 1998
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

## **Supporting Procedures and Written Control Documents**

### **Other related documents are:**

- [Health and Safety Policy](#)
- [Incident Reporting Policy](#)
- [Radiation Safety Policy](#)
- [Risk Management Policy](#)
- [Waste Management Policy](#)
- [Infection Control Policy](#)
- [Decontamination Policy](#)
- [Disposal of Obsolete and Surplus Equipment Policy](#)

## **Scope**

This policy applies to all medical devices used in Public Health Wales, associated establishments or supplied to service users for use in their own homes irrespective of whether the equipment has been purchased, loaned or received as a gift. The purpose of medical device management is to ensure that the right equipment is available when required, in a safe and serviceable condition and at a reasonable cost.

This policy applies to all staff (employed or contracted) who use, repair or procure medical devices in the course of their work.

All staff are required to ensure that they work within the boundaries set out by this policy.

|  |  |
|--|--|
| <b>Equality and Health Impact Assessment</b>                 | Integrated Screening Tool completed.   |
| <b>Approved by</b>   | Quality, Safety and Improvement Committee  |
| <b>Approval Date</b>   | 27 November 2018   |
| <b>Review Date</b>   | 27 November 2021   |
| <b>Date of Publication:</b>                                  | 05 December 2018   |
| <b>Group with authority to approve supporting procedures</b> | Quality, Safety and Improvement Committee  |
| <b>Accountable Executive Director</b>                        | Dr Quentin Sandifer, Executive Director of Public Health Services and Medical Director |
| <b>Author</b>  | Cara Tingle, Compliance Manager, Public Health Services                                |

**Disclaimer**

**If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or [Corporate Governance](#).**

**Summary of reviews/amendments**

| <b>Version number</b> | <b>Date of Review</b> | <b>Date of Approval</b> | <b>Date published</b> | <b>Summary of Amendments</b>   |
|-----------------------|-----------------------|-------------------------|-----------------------|--|
| 1                     | 1/4/15                | 1/10/09                 | 1/10/09               | First version of policy.   |
| 2                     | 01/02/18              | 27/11/18                | 05/12/18              | Review undertaken in February/March 2018. Changes made as a result of legislative changes. Documentation currently subject to internal approval processes. |