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Policy for the Decontamination of Reusable Medical Devices and Equipment used for Service User/Patient Care

Policy Statement

Preventing avoidable Healthcare Associated Infections (HCAIs) requires the proactive involvement of every member of staff across all healthcare settings. All employees must be clear as to their role and responsibilities in relation to the decontamination of reusable medical devices and equipment used in the provision of care to the service user/patient within PHW services.

The recommendations set out in the [Decontamination of Medical Devices: a Development Plan for Healthcare Organisations \(Development Plan\)](#) (2016) sets out the standards Welsh Government expects for the management, development and planning for the decontamination of medical devices. They embed zero tolerance approach to preventable HCAIs that every service user/patient rightfully expects.

This policy provides clear information to staff at all levels of the organisation on the requirements for the safe and effective decontamination of reusable medical devices and care equipment. Public Health Wales staff use a variety of medical devices and equipment to deliver a wide range of services to the public. It is essential that all staff involved in the use of or management of single use and non-invasive re-usable medical devices and care equipment are: competently trained, utilise best practice, adhere to current standards and evidence-based technical guidance relating to effective decontamination. There must be clear lines of accountability and responsibility in managing services using medical devices to ensure robust decontamination policy, procedures and processes are utilised in the prevention of avoidable HCAI's and associated harms.

This document policy reflects the required standard and recommendations contained in the Welsh Government (WG) Welsh Health Circular (WHC) '[Decontamination of Medical Devices: A Development Plan for Healthcare Organisations \(2016\)](#)'. It also aligns to the standard for decontamination detailed in the HCAI code of practice (2014).

This policy aligns with Public Health Wales Long term Strategy; [Working Together for a Healthier Wales](#) : Strategic Priority 5 objective: Delivering *Excellent Services to protect the public and maximise population outcomes.*,

Policy Commitment

Decontamination is a combination of a hierarchy of one or more processes: cleaning, disinfection and sterilization. The statutory requirements in the management of Medical Devices (Medical Device Regulations (2002)) and how to manage medical devices ([Managing Medical Devices Guidance](#) (Medicines and Healthcare Products Regulatory Agency (MHRA)) (2021)) are detailed in PHW **Medical Devices and Equipment Management Policy** (PHW 69).

There is also robust evidence based national and UK technical guidance for the decontamination of reusable medical devices and care equipment. Welsh Health technical Memoranda (WHTM) provide technical guidance for the decontamination of reusable surgical instruments, endoscopes and critical/semi critical devices as well as the decontamination of linen. Guidance for decontamination of reusable care equipment is detailed in the [Chapter 1.5](#) of the National Infection Prevention and Control Manual (NIPCM) for Wales. All organisations including PHW need to have clear and up to date policy and procedures that adhere to the current statutory, technical and IPC guidance for decontamination of medical devices. These should be reviewed every 3 years as a minimum or as new evidence or technical guidance emerges.

In conforming to the principles of [The Duty of Quality statutory guidance \(2023\)](#), healthcare organisations and individuals involved in providing services utilising reusable devices and equipment are legally responsible to provide safe effective care and continue to improve standards. This applies to the prevention of cross infection and reduction of transmission risks through safe decontamination processes. The [all Wales Code of Practice for the Prevention and Control of Healthcare Associated Infections \(HCAI\) \(2014\)](#) (Standard 2) also states: *'there are effective arrangements for the appropriate decontamination of instruments and other equipment'*.

Public Health Wales commits to:

- Protecting the service user, staff or visitors from harm or the risk of infection in the use or decontamination of medical devices or care equipment.
- Meeting the standards within the statutory, technical and IPC guidance.
- Meeting a standard for decontamination and use of medical devices that aligns to safe effective care described by the Duty of Quality
- Utilising best practices in managing and decontaminating medical devices and care equipment.
- Providing a clear understanding of the organisational structures for the management and the levels of responsibilities for decontamination in PHW in accordance with the HCAI code of practice and as described by

the WHO [`Decontamination of Medical Devices: A Development Plan for Healthcare Organisations \(2016\)](#).

- Ensuring systems are in place to provide assurances to the Executive lead that safe decontamination processes are in place, are monitored and any decontamination failure or serious incident is reported and managed efficiently, and any lessons learnt are translated into actions.
- Applying the principles for safe use, suitable environment and appropriate storage of medical devices and care equipment within Public Health Wales services.
- Providing the required training and knowledge for staff involved in decontamination processes and assessing their ongoing competency.
- Assessing and reporting compliance with this policy and the PHW decontamination procedure.
- Sustainability and zero carbon emissions in managing decontamination where it does not compromise patient safety.

This Policy states the commitment of the organisation to ensure that all decontamination processes of medical devices and care equipment undertaken within and on behalf of Public Health Wales are in accordance with current recommended standards and guidance. Decontamination is a science in its own right and best undertaken by staff specifically trained and competent for this task

Linked Policies, Procedures, National guidance and Written Control Documents

Policies and procedures available on the [Clinical Governance and Infection Control Policies - Public Health Wales \(nhs.wales\)](#) intranet page:

- Policy for the Decontamination of Reusable Medical Devices and Equipment used for Service User/Patient Care (PHW policy 28 TP01)
- Medical Devices and Equipment Management Policy (PHW 69)
- Medical Devices and Equipment Procedure PHW 69/TP01
- Infection Prevention and Control Policy (PHW 27)

Available from the [Risk Management, Health and Safety and Estates Policies - Public Health Wales \(nhs.wales\)](#) intranet pages:

- Health and Safety policy (PHW 10)
- Waste management procedure (PHW 63-TP01)
- Procedure for the disposal of obsolete and surplus equipment, vehicles, furniture and consumables (PHW63-TP02)

Other documents:

- [British Safety \(BS\)/European Union \(EU\) testing and HSE biocide regulations](#)
- [UK 5-year action plan for antimicrobial resistance 2024 to 2029 - GOV.UK \(www.gov.uk\)](#)

- [Decontamination of Medical Devices: a Development Plan for Healthcare Organisations \(Development Plan\)](#)
- [National Infection Prevention and Control Manual for Wales](#), in particular section 1.5.
- [National Action Plan \(NAP\) for the prevention Of Antimicrobial Resistance](#) – add new link when available
- PHW decontamination of medical devices development plan
- [The Duty of Quality Statutory Guidance 2023 and Quality Standards 2023](#)
- Waste electrical and electronic equipment (WEEE) regulations (2013)
- Welsh Health Technical Memoranda (WHTM):
- 01-01 Decontamination of surgical instruments (medical devices) used in acute care (for laboratory autoclave management & validation):
 - [Part A: Management and Provision](#)
 - [Part C: Steam sterilization and steam for sterilization](#)
- 01-06 Decontamination of flexible endoscopes:
 - [Part F: Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes](#)
- 07-01 [Safe Management of Healthcare waste](#)

Scope	
This policy applies to all staff who are responsible for and/ or involved with any elements of the decontamination process for reusable medical devices/patient care equipment within PHW services. It is also applicable to staff who are involved with decontamination of healthcare equipment prior to inspection, service, maintenance or repair.	
Equality and Health Impact Assessment	An Equality Health Impact Assessment has been completed and can be viewed on the policy webpage.
Approved by	Quality, Safety and Improvement Committee
Approval Date	
Review Date	
Date of Publication:	
Group with authority to approve supporting procedures	Quality, Safety and Improvement Committee
Accountable Executive Director/Director	Claire Birchall, Director of Quality, Nursing and Allied Health Professionals.
Author	Gail Lusardi Consultant Nurse for HCAI, HARP

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Summary of reviews/amendments

Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
V2	Jan 2015	31 Jan 2013	31 Jan 2013	The previous policy has been separated into two distinct Policy and Procedure documents in order to align with Public Health Wales policy requirements. Links to on-line documents have been embedded.
V3	Dec 2018			Document re-formatted further to align with Public Health Wales policy requirements.
V4	April 2024			Contents reviewed and updated where necessary, including the inclusion of information around High Level Disinfection. Links to documents updated.