Reference Number: UHB 282 **Version Number:** 2	**Date of Next Review:** 18.02.2028 **Previous Trust/LHB Reference Number:**

CARDIFF AND VALE UHB REUSABLE MEDICAL DEVICE DECONTAMINATION POLICY AND PROCEDURES

Policy Statement

Every patient has the right to expect that medical devices used in their care will be clean and safe.

Reliable, consistent and fit for purpose decontamination processes and procedures based on contemporary evidence for multi-use medical devices are a fundamental tenet for the provision of good health care. Decontamination of non-sterile reusable medical devices is pivotal to maintaining a high standard of infection prevention and protection for patients, staff and visitors within Cardiff and Vale UHB's diverse healthcare settings.

Therefore, effective decontamination of reusable medical devices needs to be everybody's business and must be part of everyday healthcare practice and based on the best available evidence so that people are protected from preventable Healthcare Associated Infections (HCAIs). Improving, adapting and sustaining reusable medical device decontamination services forms an important part of the UHB's overarching HCAI prevention framework.

Decontamination covers all aspects of cleaning, disinfection and sterilisation of reusable medical devices. Therefore, there is a critical clinical safety need to comply with decontamination procedures by all staff who are required to use, maintain or store reusable medical devices and equipment. Medical devices should be decontaminated and stored in accordance with available legislation, evidence based best practice guidance and in line with manufacturers' reprocessing instructions.

Cardiff and Vale UHB is required to provide safe decontamination systems which generate a clean, disinfected or sterile product as appropriate for its intended clinical use. This must be embedded as part of the UHB's culture in support of successful clinical outcomes and the associated safety, health and well-being of patients and staff. This policy describes the requirements for the UHB's overarching decontamination framework to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed.

The UHB has historically tended to focus major decontamination improvement policies on acute (secondary and tertiary) services as this is where the perceived major risks of infection transmission by reusable medical devices and in particular surgical instruments exist. However, the risk of encountering HCAI exists in primary care as well as the secondary and tertiary care sectors. The UHB owes the same duty of care to patients and staff across all sectors where is provides healthcare including primary and community services.

Therefore, UHB healthcare services delivered in community settings (General Practitioner surgeries, dental practices and community clinics, pharmacies etc.) must have in place fit for purpose processes and facilities to ensure decontamination is in accordance with current national policy including Welsh Health Technical Memoranda (WHTM), EU Directives and Welsh Government's "Health and Care Standards).

Policy Commitment

- Cardiff and Vale UHB's Board acknowledge that decontamination procedures for reusable medical devices play an essential part in the prevention and control of Healthcare Associated Infections (HCAI). As such decontamination will be prioritised accordingly by the Executive team, recognising that is critical to safety and therefore a core business for the UHB.
- Wherever reasonably practicable Cardiff and Vale UHB healthcare services will use single use medical devices to reduce the risks of avoidable HCAI. Where this is not reasonably practicable Cardiff and Vale UHB will adopt the best available evidence-based decontamination practices. Patient safety must take primary in the decision-making process.
- The UHB will ensure decontamination procedures and facilities across the UHB's healthcare services are fit-for-purpose and meet the WHTM 01-01 (Parts A to E), WHTM 01-05, WHTM 01-06 (Parts A to F) and HBN 13 (2004) (for refurbished decontamination facilities and new builds). This will ensure statutory regulatory compliance, ISO standard compliance and a move to achieving fully Joint Advisory Group (JAG) on Gastro-intestinal Endoscopy Accreditation of relevant services.
- All reusable medical devices used in acute healthcare settings requiring sterilisation will be reprocessed in an ISO compliant accredited facility.
- Local reprocessing will only be carried out in community dental settings which meet the requirements of WHTM 01-05 where it is not reasonably practicable to send the medical devices to an ISO Accredited facility.
- All reusable medical devices will be covered by suitable tracking and traceability systems to ensure full tracking and traceability records are available covering all episodes of use. This requirement extends to reusable medical devices which are loaned ("on demo" or as part of business continuity plans) or "ex demo" purchased items.
- The choice of decontamination methodology must be proportionate to the level of risk of infection.
- All re-usable medical devices must be reprocessed using a validated automated process.
- Only chemicals approved by the UHB's Infection Prevention and Control (IP&C) team will be used in UHB decontamination procedures.
- Disinfectants must be used at the correct concentrations as recommended by relevant IP&C Standard Operating Procedures (SOPs) following manufacturers guidelines.

- There must be sufficient stock of medical devices including surgical instrument sets and endoscopes to allow for effective decontamination cycle times. The efficacy of decontamination processes, and therefore patient safety, must never be compromised to achieve desired levels of operational performance.
- All sterile good must be stored in clean dry conditions.
- Items returned to sterile service units must not expose staff to an avoidable infection risk / sharps injury.
- All staff that are required to decontaminate reusable medical devices must be trained and competence assessment.
- Personal protective equipment must be work to undertake decontamination practices where indicated by risk assessment.
- All novel an emergent decontamination technology (equipment, processes, chemistries etc.) must comply with the essential requirements of the MDR and must be CE marked. They must be authorised by the Director of Infection, Prevention and Control, NHS Wales Shared Services Partnership / Facilities Services (NWSSP-FS) Authorising Engineer (Decontamination) (AE(D)) and be formally signed off by the UHB's IP&C committee and Decontamination Group. This may be done in conjunction with the UHB's Medical Equipment Group for decontamination equipment.
- All decontamination facilities and processes used in clinical practice will be routinely audited with findings reported to the UHB's Decontamination group.
- Local self-audit tools will be available to clinical areas where decontamination of reusable medical devices is required.
- All decontamination processes must be subject to continuous quality improvement programmes to ensure that they meet or exceed evolving standards for decontamination and provide the greatest level of protection to patients, visitors and staff.
- All equipment used in decontamination processes must be validated for its intending use and regularly checked and inspected locally to ensure its continued fitness-for-purpose and be on an approved planned preventative maintenance contract.
- A permit to work must be completed every time decontamination equipment is taken out of service for routine testing, repair and maintenance.
- An accurate declaration of contamination status form must be completed prior to inspection, service, repair or transport of medical, dental or laboratory equipment, either on hospital premises or elsewhere.
- Decontamination services must develop robust local business continuity plans to cover scheduled and unplanned disruption to service.
- The UHB is committed to deploy and utilise all available decontamination resources to maximum effect to optimise outcomes for patients and to protect staff and visitors regardless of which Department, Directorate or Clinical Board they are held within. It will manage the life cycle risks of all decontamination equipment in accordance with the Cardiff and Vale UHB's "Management of Medical Equipment Policy". It will ensure that all Health and Safety risks associated with the use of equipment and chemicals are managed in accordance with Cardiff and Vale UHB's "Health and Safety Policy".

- The UHB is committed to the overarching principles of standardisation and centralisation where patient focused benefits are evident. This will ensure that prudent healthcare principles of reducing waste, variation and harm are adhered to through the adoption of evidence-based decision making, rather than user preference. This will be done in partnership with NHS Wales Shared Services Partnership – Facilities Services (NWSSP-FS).
- The UHB is committed to building organisational resilience, capacity and capability to effectively decontaminate reusable medical devices to ensure the safety of service users and staff and to safeguard its reputation and stakeholder confidence.
- The UHB will establish and maintain the necessary functional requirements and infrastructure to ensure that it meets its statutory obligation to, as far as reasonably practicable, ensure that all reusable medical devices are properly decontaminated prior to use. This will ensure that the risks associated with decontamination facilities and processes are adequately managed.
- The Decontamination Lead is organisationally responsible for the effective and technically compliant provision of decontamination services. The Decontamination Lead is responsible for the implementation of an operational policy for decontamination. The Decontamination Lead is also responsible for monitoring the implementation of the policy.
- The Decontamination Lead delegates specific responsibilities to key personnel and the UHB's Decontamination Group. The Decontamination Group's primary role is to provide assurance to Cardiff and Vale UHB that decontamination procedures and facilities across the UHB's healthcare services are fit-for-purpose and meet the requirements of WHTM 01-01 (Parts A to E), WHTM 01-05 and HBN 13, (2004) (for refurbished decontamination facilities and new builds).
- Ultimately it is the clinician's responsibility to satisfy themselves that any medical device they are about to use is safe and this includes being satisfied that the device is appropriately decontaminated before use.

Supporting Procedures and Written Control Documents

This Policy and the Decontamination of Reusable Medical Devices Procedure describe the UHB will discharge its duties in respect of statutory legislation and its obligations to meet external quality standards set out by health service accreditation bodies.

Other supporting documents

- *Cardiff and Vale UHB Policies and Procedures:*

- *UHB Decontamination Procedure*
- *Medical Equipment Management Policy and Procedure*
- *Infection Control Standard Precaution Procedure for Cardiff and Vale University Health Board*
  Waste Disposal Policy
- *Decontamination of Ultrasound Transducers – Standard Operating Procedure*

- *COSSH Policy*
- *Health and Safety Policy*
- *Management of CJD / VCJ Protocols*
- *National Guidance Documents*
- *WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part A: Management and Environment*
- *WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part B: Common Elements*
- *WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part C: Steam Sterilisation and Steam for Sterilisation*
- *WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part D: Washer Disinfectors*
- *WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part E: Alternatives to Steam for the Sterilisation of Reusable Medical Devices*
- *WHTM 01-05 Decontamination in Primary Care Dental Practices and Community Dental Services*
- *WHTM 01-06 Parts A-F Decontamination of Flexible Endoscopes*
- *British Society of Gastroenterology (BSG) Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy*
- *Health Building Note 13: Sterile Services Department, NHS Estates, Department of Health (2004).*
- *Medical Device Regulations (MDR)*
- *ISO 13485*

Scope

This policy applies to all of Cardiff and Vale UHB staff in all locations including those with honorary contracts. It applies to the decontamination of all reusable Medical Devices or Equipment used by Cardiff and Vale UHB services irrespective of whether the Medical Device or Equipment is owned, loaned, leased or used by commissioned external service providers.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has / has been completed and this found there to be a positive impact.

Health Impact Assessment	A Health Impact Assessment (HIA) is not required for this policy.
Policy Approved by	Quality Committee.
Group with authority to approve procedures written to explain how	Decontamination Group.

this policy will be implemented	
Accountable Executive or Clinical Board Director	Chief Operating Officer UHB.

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 the Governance Directorate.

Summary of reviews/amendments

Version Number	Date Review Approved	Date Published	Summary of Amendments
1	*23/02/2016*	08/03/2016	UHB Decontamination of Reusable Medical Devices Policy reviewed and updated to reflect new organisational structures and WHTM guidance on the Decontamination of Reusable Medical Devices. This is in response to the rapidly evolving scientific evidence base establishing the HCAI risks associated with the use of reusable medical devices, and to keep pace with innovative, novel and emergent decontamination technologies. The Policy and Procedure are now contained in separate documents. Updated Document
2	*18/02/2025*	25/02/2025	Full re write of old policy

CARDIFF AND VALE UNIVERSITY HEALTH BOARD
DECONTAMINATION OF REUSABLE MEDICAL DEVICES PROCEDURE

CONTENTS

1. Summary

1.1 Decontamination procedures for reusable medical devices play an essential part in the prevention and control of Health Care Associated Infections (HCAI).

1.2 Single use devices should be considered if reasonably practicable, cost effective and support the sustainability targets of Cardiff and Vale UHB.

1.3 CVUHB will work towards reprocessing reusable medical devices used in acute healthcare settings, in a Medical Device Regulations (MDR amended part II) accredited facility.

1.4 The choice of decontamination methodology must be proportionate to the level of risk of infection.

1.5 Only chemicals approved by the Infection Prevention and Control Committee (IPC) and Decontamination Group are to be used for disinfection in the UHB.

1.6 Disinfectants and detergents must be used at the correct concentrations as recommended by the Infection Prevention and Control Committee and in line with manufacturers instructions for use (IFU).

1.7 There must be sufficient stock of medical devices including surgical instrument sets and endoscopes to allow for effective decontamination cycle times. The efficacy of decontamination processes, and therefore patient safety, must never be compromised to achieve desired levels of operational performance.

1.8 All sterile goods must be stored in designated clean areas, in accordance with NHS Estates Health Building Note 13, controlled environments (humidity / temp monitoring) and designated racking to ensure goods are protected.

1.9 Items returned to sterile service units must not expose staff to an avoidable infection risk / sharps injury.

1.10All staff that are required to decontaminate reusable medical devices must be trained and competent to do so. Training must be completed by appropriate persons suitable qualified to train and the training must be undertaken at routine periods, to include refresher packages. They must have supporting evidence of a competence assessment.

1.10 Personal protective equipment must be worn to undertake decontamination practices where indicated by risk / COSHH assessments. Management must ensure where PPE is provided, staff wear the appropriate protection at all times.

1.12 All novel decontamination technologies (equipment, processes, chemistries etc.) must comply with the essential requirements of the MDD, have CE marking in place and have to be authorised by the UHB's IPC Committee, Decontamination Group, Authorising Engineer for Decontamination (AED).

1.13 All decontamination facilities and processes, must operate in accordance with relevant WHTM/WHBN and minimise potential for environmental recontamination. All departments will be routinely audited with findings reported to the UHB's Decontamination Group.

1.14 All decontamination processes must be subject to continuous quality improvement programmes to ensure that they meet or exceed evolving standards for decontamination and provide the greatest level of protection to patients, visitors and staff.

1.15 All equipment used in decontamination processes must be regularly inspected locally to ensure its continued fitness-for-purpose, be on an approved maintenance contract and validation reports authorised by the AED.

1.16 Local self-assessment audit tools will be available to clinical areas where decontamination of reusable medical equipment is required.

1.17 The UHB has established the functional requirements and infrastructure to ensure that it meets its statutory obligation to, as far as reasonably practicable, ensure that all reusable medical devices are decontaminated effectively prior to use. This will ensure that the risks associated with decontamination facilities and processes are adequately managed. This function is delegated by the Head of Decontamination through the UHB's Decontamination Lead to the UHB's Decontamination Group. The Decontamination Groups primary role is to provide assurance to Cardiff and Vale UHB that decontamination and sterilisation procedures and facilities across the UHB's healthcare services are fit-for-purpose and meet the requirements of WHTM 01-01 (Parts A to E), WHTM 01-05 and HBN 13.

2. *Introduction*

Reliable, consistent and fit for purposed decontamination processes and procedures based on contemporary evidence for multi-use medical equipment and devices are a fundamental tenant of good health care. Decontamination of non-sterile reusable equipment is pivotal to maintaining a high standard of infection prevention and protection for patients, staff and visitors within Cardiff and Vale UHB's diverse healthcare settings.

Cardiff and Vale UHB are required to provide a safe decontamination service that generates a clean and sterile product and is embedded as part of the service culture in support of successful clinical outcomes and the associated well-being of patient and staff.

Decontamination covers all aspects of cleaning, disinfection and sterilisation of reusable medical equipment. There-fore there is a critical clinical safety need to comply with decontamination procedures by all staff who are required to use, maintain or store reusable medical devices and equipment.

Medical devices should be decontaminated and stored in accordance with legislation, guidance and in line with the manufacturers reprocessing instructions.

This document describes the UHB's systems which ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed.

The UHB has historically tended to focus major decontamination improvement policies on acute (secondary and tertiary) services as this is where the perceived major risks of infection transmission by reusable medical devices and surgical instruments exist. However, all sectors of healthcare delivered by the UHB including primary and community services owe the same duty of care to patients and staff.

The risk of encountering HCAI exists in primary care as well as the secondary and tertiary care sectors. UHB healthcare services delivered in community settings (General Practitioners surgeries, dental practices, pharmacies etc), must have in place fit for purpose processes and facilities to ensure decontamination is achieved in accordance with current, national policy including Welsh Government "Health and Care Standards", Welsh Health Technical Memoranda (WHTM) and EU Directives.

3. *STATEMENT OF INTENT*

3.1 Where reasonably practicable Cardiff and Vale UHB healthcare services will use single use medical devices to reduce the risks of avoidable HCAI.

3.2 Where his is not reasonably practicable Cardiff and Vale UHB will adopt the best available evidence-based decontamination practices. The UHB will ensure decontamination procedures and facilities across the UHB's healthcare services are fit-for-purpose and meet the WHTM 01-01 (Parts A to E), WHTM 01-05, WHTM 01-06 (Parts A to F) and HBN 13 (for refurbished decontamination facilities and new builds). This will ensure statutory regulatory compliance, ISO standard compliance and a move to achieving Joint Advisory Group (JAG) accreditation of relevant services.

3.3 Cardiff and Vale UHB is committed to deploy and utilise all available decontamination resources to maximum effect to optimise outcomes for patients and to protect staff and visitors regardless of which Department, Directorate or Clinical Board they are held within. It will manage the life cycle risks of all decontamination equipment in accordance with the Cardiff and Vale UHB's "Medical Equipment Policy". It will ensure that all Health and Safety risks associated with the use of equipment and chemicals are managed in accordance with Cardiff and Vale UHB's "Health and Safety Policy".

3.4 The UHB is committed to the overarching principle of standardisation and centralisation where patient focused benefits are evident. This will ensure that prudent healthcare principles of reducing waste, variation and harm are adhered to through the adoption of evidenced based decision making, rather than user preference. This will be done in partnership with NHS Wales Shared Services Partnership – Specialist estates Services (NWSSP-SESS).

4. Aims of Policy

4.1 To deliver a system-wide, consistent and robust decontamination infrastructure to provide appropriate advice to staff so that effective decontamination is achieved at all UHB locations which complies with national standards.
4.2 To provide advice on the approved materials and equipment for their use for effective decontamination.
4.3 To provide advice on the approved methods for standard and effective decontamination.

5. *OBJECTIVES*

5.1 To prevent and control transmission of infection through medical devices – with specific reference to surgical instruments and the risk of human prion disease or Transmissible Spongiform Encephalopathies (TSEs) transmission.

5.2 To adopt a comprehensive and consistent approach to infection risk control and reduction across instrument management and decontamination.

5.3 To provide assurance to the UHB's Executive Board regarding the management and decontamination of medical devices including surgical instruments, in terms of availability, quality and suitability.

5.4 To ensure the continuous improvement of high-quality engineering through the adoption of European Norms (ENs), quality systems and standards.

5.5 To universally adopt best practice guidance for optimisation of the environment, equipment and facilities used in decontamination.

5.6 To develop an effective quality management system to cover all aspects of the decontamination life cycle.

5.7 To ensure that documented robust and comprehensive policies and procedures are available to clinical services to ensure that decontamination processes are undertaken in a controlled manner to protect the health and safety of patients, service users, visitors and staff.

5.8 To ensure UHB procurement practices are organisationally "joined up" and have oversight by Cardiff and Vale UHB's Decontamination Group and Medical Equipment Group so that all purchased instruments are compatible with decontamination processes available within the UHB and all stakeholders are consulted prior to device procurement.

5.9 To ensure that manual cleaning of devices is restricted to those items or those components of an overall decontamination process deemed incompatible with automated / validated processes by the device's manufacturer.

5.10 To ensure that reprocessing of reusable medical devices will be undertaken in dedicated facilities and outside the clinical / patient environment, in facilities accredited to the Medical Device Regulations amended Part 2 (MDR).

5.11 To ensure that any local reprocessing will only be undertaken in community settings where is not reasonably practicable to send the equipment to an MDR accredited facility. This decision must be supported by a comprehensive and robust risk assessment signed by the Primary, Community and Intermediate Care (PCIC) Clinical Board Director, Director of Infection Prevention and Control, the UHB Decontamination Lead and User's. However, CVUHB strives to centralise all decontamination into accredited units where practically possible.

5.12 To ensure that equipment used to decontaminate medical devices and associated equipment (for example, washer-disinfector's) must be fit for purpose, validated, tested and maintained in accordance with national guidelines and manufacturers recommendations.

5.13 To develop comprehensive service wide systems to track instruments trays and endoscopes through decontamination processes, from clinical area, to the reprocessing centre to the patient.

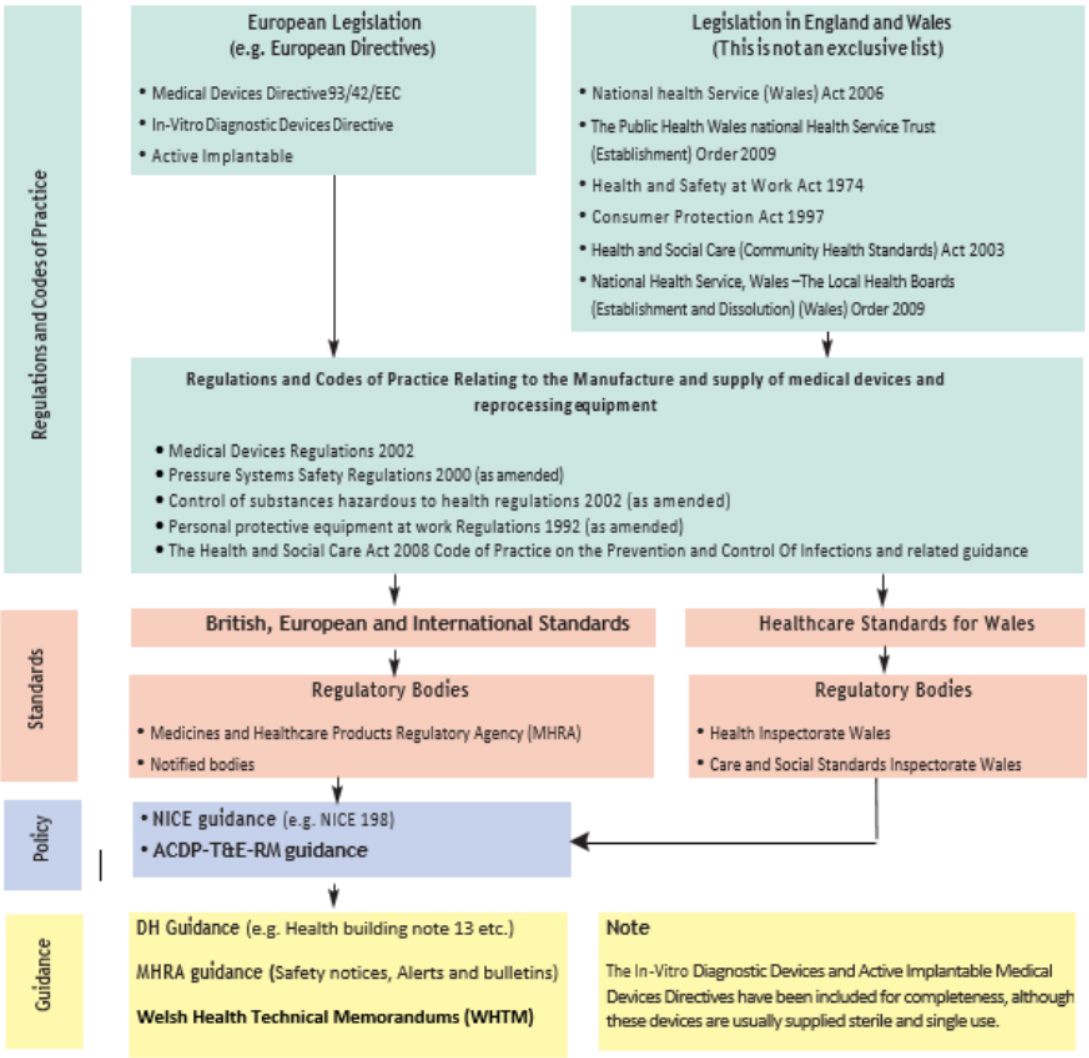
5.14 To ensure that robust documented training schemes are available for all staff who are required to decontaminate medical devices.

5.15 Electronic tracking systems should be in place in the acute reprocessing facilities where possible. The tracking system must be capable of identifying what equipment has been used on what patient, track the following patients who the equipment was used on, identify location of equipment within the Hospital, track limited use devices and facilitate individual instrument marking systems if in use.

6.0 Legislation and Standards

This section sets out the duty of care for Decontamination across Wales and the Local Health Boards.

6.1 The following regulatory framework applies to all sites that operate a decontamination service



NHS Wales Shared Service Partnership (2017) "WHTM 01-01: Decontamination of surgical instruments (medical devices) used in acute care, Part A: Management and Provision".

.

European Legislation

6.2 There are three EU Directives relating to the manufacture and supply of medical devices:

- Medical Device Regulations (MDR) 2002 as amended part 2
- In-vitro Diagnostic Devices Directive 98/79/EEC as amended by Directive 2007/47/EC
- Active implantable Medical Devices Directive 90/385/EEC as amended by Directive 2007/47/EC

Regulations

6.3 There are a number of regulations relating to the manufacture and supply of medical devices and reprocessing equipment. The primary regulations are:

- The Medical Device Regulations 2002 (as amended)
- The Pressure Systems Safety Regulations 2000 (as amended)
- The Control of Substances Hazardous to Health Regulations 2002 (as amended)
- The Personal Protective Equipment at Work Regulations 1992 (as amended)
- The Electromagnetic Compatibility Regulations (the EMC Regulations)
- UK Government (2000) “Pressure Systems Safety Regulations 2000”.

Standards Relevant to Decontamination Equipment

6.4 Standards relevant to decontamination equipment:

- BS EN ISO 17665-1: Sterilisation of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilisation process for medical devices (this includes porous loan and fluid sterilisers (except where used for medicinal products), and sterilisers for unwrapped instruments and utensils).
- BS EN 285: Sterilisation. Steam sterilisers. Large sterilisers.
- BS EN 13060: Small sterilisers, Large sterilisers.
- BS EN ISO 15883-1: Washer disinfectors. General requirements, terms and definitions and tests.

- BS EN ISO 15883-2: Washer disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- BS EN ISO 15883-3: Washer disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers.
- BS EN ISO 15883-4: Washer disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscope.

Standards for Health

6.5 The Welsh Government document “Doing Well, Doing Better: Standards for Health Services in Wales (2010) sets out the core and developmental standards that all healthcare organisations in Wales which treat NHS patients.

6.6 Users should comply with the Welsh Government guidance document “Decontamination of Medical Devices (WHC/2015/050).

6.7 All Healthcare organisations in Wales will be expected to assure themselves and the communities they serve that they are achieving or working towards these standards of care. Healthcare Inspectorate Wales will carry out external, independent assessments of organisations to ensure compliance with, or progress towards meeting Standards.

6.8 Decontamination standards in Doing Well, Doing Better: Standards for Health Services in Wales and in the National Minimum Standards require decontamination to be properly carried out in facilities that comply with guidance issues by the MHRA and are subject to external audit by a designated body approved by the MHRA.

Guidance

6.9 For guidance refer to the following:

- Department of Health Building Note 13 – Sterile Services Department.
- WHTM 01-01 Part A-E: Management and Decontamination of Surgical Instruments (medical devices) used in Acute Care.

- WHTM 01-06 Part A–F: Decontamination of Flexible Endoscopes
- WHTM 01-05: Decontamination in Primary Care Dental Practices and Community Dental Services
- WHTM 07-01: Safe Management of Healthcare Waste
- WHTM 03-01: Specialised Ventilation for Healthcare Premises
- WHTM 04-01: Safe Water in Healthcare Premises.

7.0 Definitions

- **Contamination –** the soiling or pollution of inanimate objects or living material with potentially infection substances. In the clinical situation this is most likely to be organic matter (e.g. blood, faeces, proteins etc.) but may also include inorganic substances such as dust. Such contamination may be transferred to susceptible host (person).

- **Decontamination –** a process, which removes or nullifies contamination by biomass reduction and thereby prevents microorganisms reaching a susceptible (body) site in sufficient quantities to cause infection. Differing levels of decontamination are available. They are:

  Cleaning followed by high level of disinfection; or cleaning followed by sterilization, depending on the procedure and chemicals used

  Or

  Decontamination, the combination of processes (including cleaning, disinfection and sterilisation) used to render a reusable item safe for further use on patients and handling by staff. – "*A guide to the decontamination of reusable surgical instruments – NHS Estates 2003".*

- **Cleaning –** a process that physically removes contamination but does not necessarily destroy microorganisms. Cleaning is a necessary prerequisite to ensure effective disinfection or sterilization.

- **Disinfection –** is a process following cleaning that reduces the number of viable micro-organisms but may not inactivate some microbes such as certain viruses and bacterial spores. There are 2 main methods of disinfection; thermal and chemical.

Thermal disinfection is governed by the A0 scale of above 600 to effectively disinfect or A0 3000. In a washer disinfector this is normally achieved by holding a temperature (normally using RO water) for a min of 1 min.

In decontamination, chemical disinfection is predominately used to disinfect thermally restricted devices (i.e. flexible endoscopes) and is achieved by the appropriate dosing process and contact times.

- **Sterilisation –** a process used to render the object completely free from viable microorganisms, including viruses. This process is required for high-risk equipment. Within UHB, sterilisation is predominately achieved using steam sterilisation, which subjects the devices to temperatures of 134-137°C for 3-3.5 mins / 121°C for 15mins. For heat sensitive equipment the UHB has the capability to use hydrogen peroxide for low temperature sterilisation.

- **Detergent –** An agent whose action in combination with cleaning removes visible contamination and the majority of micro-organisms.

- **Disinfectant –** An agent that destroys micro-organisms including bacteria, viruses and parasites but not necessarily bacterial spores.

- **Single Patient-Use:** A device that can be used more than once on a single patient, and can be decontaminated between users on that patient only.

- **Single-use** A device that is used once, on a single patient, and then disposed of. Devices that are labelled by the manufacturer for “single-use only” must not be re-used. The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk. Such devices are required to be identified by the single-use symbol on either the instrument or its packaging as shown in Fig 1:

Figure 1 – Symbol for single-use devices

These devices must be disposed of safely after use and it is important that the single-use instruments are not allowed to enter reusable instrument sets. This statement also applies to single use implantable devices.

- **Medical Device or Medial Equipment.** In the context of this policy this includes any instrument, apparatus, appliance, or other article, whether used alone or in combination, together with any accessories, to be used specifically for diagnostic and / or therapeutic purposes. This will include:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,

- Diagnosis, monitoring, treatment, alleviation of a compensation for an injury or handicap,

- Investigation, replacement or modification of the anatomy or of a physiological process,

8.0 General Principles of Decontamination

8.1 Spaulding Classification: The level of decontamination required depends on the risk of the item transmitting micro-organisms, and the process the device will tolerate. Therefore, devices can be categorised into one of three levels of risk. Fig 2 Spaulding Classification:

Spaulding Classification- adapted.

Classification	Indication	Level of decontamination	Method
High Risk ***(Critical)***	Items that come into contact with normally sterile body tissues.	Single use Sterilise	Autoclave Low temperature steriliser
Medium Risk ***(Semi- Critical)***	Items that come into contact with mucous membranes or non-intact skin.	Single use Sterilise Disinfection	Autoclave Low temperature steriliser Automated high level disinfection
Low Risk ***(Non- Critical)***	Items that come into contact with intact skin	Clean +/- disinfect	Detergent wipes/ solution Combined detergent & disinfection wipes

Spaulding, E.H. (1957) "Chemical disinfection and antisepsis in the hospital". *JHospRes*. 9: pp 5–31.

Only low-risk devices should be decontaminated in the ward environment. Manufacturers' instructions must be followed unless otherwise authorised by the Infection Prevention & Control (IP&C) team and a risk assessment completed. All medium and high-risk items must be decontaminated in designated areas by fully trained and competent staff who are trained on the products and equipment in use.

8.2 Decontamination Cycle for reusable medical devices.

Regardless of the location of decontamination (for example, primary, community or acute sectors), the same standards apply, Figure 3 highlights each stage of the decontamination process through which medical devices pass before every use:

Figure 3: The reusable surgical instrument cycle

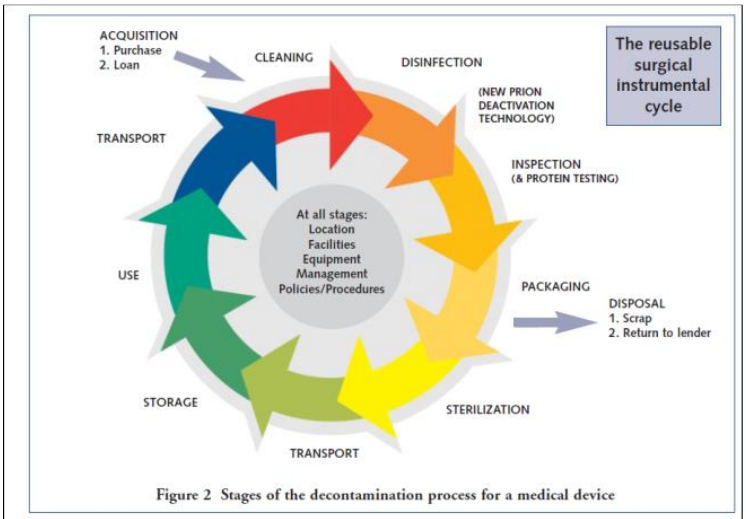


Figure 2 Stages of the decontamination process for a medical device

At all stages of reprocessing reusable medical devices, the following issues need to be considered:

1. The existence of effective management arrangements;

2. The existence of policies, procedures and effective competence-based training programmes for all aspects of decontamination work;

3. The location and activities where decontamination takes place;

4. Fit for purpose facilities and equipment available to each clinical service which utilises reusable medical devices to ensure effective and verifiable decontamination;

5. Ensuring the equipment used is validated, maintained and tested in accordance with manufacturer's guidelines and legislation.

6. The equipment is fully tacked through all aspects of the decontamination life cycle.

8.3 Reducing the Time from Close of Procedure to Reprocessing

Prions are easier to remove if they have not dried on the surface of an instrument. To enable efficient prion removal,

theatre and HSDU staff should ensure that instruments are transported to the HSDU immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible.

- This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved by the HSDU. In Cardiff and Vale this can be a moist bag or a pre-spray of an enzymatic solution.

  For further guidance on keeping instruments moist, Users can refer to WHTM 01-01 Part A: Management and Decontamination of Surgical Instruments (medical devices) used in Acute Care.

8.4 Tracking and Traceability of Medical Devices

It is important to be able to trace products through the decontamination processes to which they have been subjected and to the patient on whom they have been used. Whether individual or part of an instrument set, such items must be fully traceable. All processing information must be documented in accordance with the manufacturer's guidance. This should include the number of times an item has been processed as there will be a finite reprocessing life of the product.

Traceability information should be kept as stated within the Quality Management System (QMS) of the processing unit (in Cardiff and Vale UHB this is predominantly 15 years). Any of the related information, which may include the number processed, graphical information or any other processing records, should be accessible if required in circumstances such as product recall or investigations due to unexpected failure of an item. These records need to link directly to patients where they were used. The risk management option to move to the use of pre-sterile single use implantable items (where possible) offers a simple solution to these challenges.

The ability to track and trace medical devices and equipment enables corrective action to be taken when necessary.

Records should be maintained for all trays cleaned, identifying:

a. The cleaning and sterilisation method used;
b. The name of the person undertaking the decontamination;
c. Details of the actual tray processed;
d. Which patients have been treated with the tray;
e. The equipment cycles details and numbers;

This information is required so that instrument trays can be traced, if required. In the event of a failure in the decontamination cycle or for infection control reasons.

The use of untracked supplementary instruments should be avoided, where possible, and instruments grouped together into traceable trays.

In Cardiff and Vale UHB, an electronic tracking system is predominantly used in the sterile service departments and endoscopy, however there are still areas with manual systems in place across the Health Board. Where manual decontamination tracking systems are in place, regular audits need to be performed to ensure accuracy of systems.

8.5 Loan Sets

Reusable medical devices acquired on loan are subject to the same decontamination requirements as set out in this policy. All surgical instruments and associated equipment entering the organisation, regardless of the source, should be cleaned and sterilised before and after use in accordance with the manufacturers' instructions.

Only reusable medical devices that are compatible with the Health Board's decontamination methods and policy should be acquired on loan. Records must be kept for traceability purposes and in line with the requirements of the Health Board's policy.

Departments should develop their own procedure in relation to loan of specialist equipment that covers initial inspection, check of inventory is complete, documentation, and traceability records.

The master indemnity register must be checked prior to accepting the loan agree to ensure the company have appropriate indemnity cover for the loan of surgical devices.

Prior to return of the equipment to the supplier, the equipment must be reprocessed and sterilised unwrapped prior to return. For traceability purposes and proof of process performed prior to return a decontamination certificate must be provided with the equipment.

8.6 Human Prion Disease (including variant Creutzfeldt-Jakob disease ((CJD)) and other forms of CJD).

The human prion diseases are a group of rare fatal neurological disorders that occur in sporadic, genetic and acquired forms, the latter occurring by transmission from one individual (species) to another. These conditions are all associated with the conversion of a normal protein in the body, the prion protein, to an abnormal disease-associated form that accumulates in the brain and results in neuronal degeneration and death. The abnormal prion protein is thought to be the major component of transmissible prion agents.

The most common human prion disease is the sporadic form of Creutzfeldt-Jakob disease (sCJD), with an annual incidence worldwide of one-to-two cases per million of the population. In the UK, there are between 50 and 90 cases annually, with a peak incidence in the 60-70-year age group. This disease presents with rapidly progressive dementia and a range of other neurological sins and symptoms, with death occurring in around three-to-six months of disease onset. The genetic forms of human prion disease account for around 10% of total cases, while acquired cases account for around 1%, including iatrogenic CJD (iCJD) in human growth hormone and dura mater graft recipients, and variant CJD (vCJD). Incubation periods in acquired human prion diseases can vary from two to over 40 years, depending on the route of exposure. vCJD was first reported as a novel human prion disease in 1996, acquired from infection by the bovine spongiform encephalopathy (BSE) agent, most likely via the oral route.

Patient with sCJD and vCJD have differences in the distribution of prion infectivity around the body. In sCJD (and also in some cases of genetic prion diseases and iCJD),

abnormal prion protein appears to be restricted to the central nervous system (CNS), whereas in vCJD it has also been detected in lymphoid tissues, including tonsils, spleen and gastrointestinal lymphoid tissue. Abnormal prion protein has been detected in the lymphoid tissues of a few individuals infected with vCJD before the onset of clinical signs and symptoms of the illness, indicating asymptomatic vCJD infection.

vCJD is distinguishable from non-vCJD in a number of ways:

- It tends to affect younger people with an average (median) age of onset of around 26 years (median age at death 28 years).
- The predominant initial clinical symptom is of psychiatric or sensory problems, with coordination problems, dementia and muscle-twitching occurring later.
- The illness usually lasts about 14 months (range 6-84 months) before death.

A definitive diagnosis of vCJD can only be confirmed by examining brain tissue, usually at post-mortem, and requires the exclusion of other forms of human prion disease, particularly sCJD. In the UK. As of 2016, there have been 177 deaths from definitive or probable cases of vCJD, three of which appear to have been acquired by packed red blood cell transfusion from infected donors. The peak year of deaths was 2000, since when numbers of cases have fallen progressively with no new cases reported since 2012. However, given the long incubation periods previously seen for acquired CJD, and with evidence from tissue-based prevalence studies in the general population, the potential for further cases to emerge or for potential asymptomatic abnormal prion carriage within the general population has yet to be ruled out.

While three vCJD cases may have been transmitted by blood transfusion, there are no known cases of vCJD being transmitted by surgical instruments or endoscopes. However, it may be possible because:

- sCJD has been transmitted by neurosurgical instruments used on the brain;

- abnormal prion protein binds avidly to steel surfaces and can be very difficult to remove from surgical instruments;

- prion infectivity has been found in a range of tissues (brain, spleen, tonsils etc) of patients developing symptomatic vCJD

8.7 Improvements to processes to reduce risk of vCJD

Because of the risks of prion transmission, there is a need to optimise the whole of the decontamination pathway of surgical instruments. Further guidance of this can be found in the: *Guidance from the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup, formerly the TSE Working Group.*

Reducing the time from close of procedure to reprocessing

Prions are easier to remove if they have not dried on the surface of an instrument, prion adhesion can occur as little as 20 mins from onset to a surgical instrument. To enable efficient prion removal, theatre and HSDU staff should ensure that instruments are transported to the HSDU immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible and keeping them in a moist environment when possible (moist bags / enzymatic spray).

This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods, which within the Health Board are moist bags or neutral enzymatic preparation spray immediately post op.

Cleaning validation and continuous monitoring

Traditionally, cleaning validation has been about removing visible soiling. Now the emphasis is on removing proteins to very low levels. To be able to have a greater chance of removing these proteins, there needs to be an efficient a cleaning process as possible – the HSDU work with NWSSP Shared Services at time of validations, to ensure the cleaning efficacy process is as effective as possible. This could mean considering alternative chemistries and additional wash phases to improve the cleaning efficacy process.

With any change in chemistry Users must ensure compatibility with the medical devices, reprocessing equipment and water quality within the locality.

Results should be recorded and monitored in accordance with WHTM 01/01-part D. Appropriate actions should be taken based on these results. HSDU's should undertake:

- Daily testing using process challenge devices (PCD's)
- A schedule of weekly residual protein testing (quantifiable protein measurement / residual swab method).

- Priority for cleaning validation and continuous monitoring should be given to instruments that have been in contact with high – prion – risk tissues as defined by ACDP – TSE's:

Table A1 – Distribution of TSE infectivity in human tissues and body fluids

Key: **+ve** = tested positive **-ve** = tested negative
NT = not tested **P** = infectivity proven in experimental transmission studies

Tissue	Presence of abnormal prion protein and level of infectivity			
	CJD other than vCJD		vCJD	
	PrP^{TSE} detected	Assumed level of infectivity	PrP^{TSE} detected	Assumed level of infectivity
Brain	+ve	High P	+ve	High P
Spinal cord	+ve	High P	+ve	High P

Cranial nerves, specifically the entire optic nerve and only the intracranial components of the other cranial nerves	+ve	High	+ve	High
Cranial ganglia	+ve	High	+ve	High P
Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid, optic nerve	+ve	High P	+ve	High
Pituitary gland	+ve	High (?)	+ve	High (?)
Spinal ganglia[1]	+ve	Medium	+ve	Medium P
Olfactory epithelium	+ve	Medium	NT	Medium
Dura mater[2]	-ve	Low	+ve[4]	Low
Tonsil	-ve	Low	+ve	Medium P
Lymph nodes and other organised lymphoid tissues containing follicular structures	-ve	Low P	+ve	Medium P
Gut-associated lymphoid tissue	-ve	Low	+ve	Medium
Appendix	-ve	Low	+ve	Medium
Spleen	+ve	Low P	+ve	Medium P
Thymus	-ve	Low	+ve	Medium
Anterior eye and cornea	-ve	Low	-ve	Low
Peripheral nerve	+ve	Low	+ve	Low
Skeletal muscle	+ve	Low	+ve	Low
Dental Pulp	-ve	Low	-ve	Low
Gingival Tissue	NT	Low	-ve	Low
Blood and bone marrow	NT	Low	-ve	Low
CSF[3]	-ve	Low P	-ve	Low
Placenta	-ve	Low	-ve	Low
Urine	-ve	Low	-ve	Low
Other tissues	-ve	Low P	+ve[4]	Low

[1]Spinal ganglia have a high assumed level of infectivity in the WHO Guidelines. However, unpublished results on the infectivity of spinal ganglia indicate that this tissue is of medium infectivity.

Methods for detecting residual protein

Any method used to detect residual protein, should be validated as being able to detect protein equivalent to <5 µg of BSA in situ on the surface of an instrument. Methods that do not have protein as their target, such as ATP assays (Ninhydrin), cannot be used as a substitute for residual protein detection.

Within the Health Board we have adopted the “in-situ” protein

detection technology and perform daily tests on high risk and low risk instrumentation.

Continuous improvement plans

Sterile service departments should have in place a plan of continuous process improvement. This plan is part of the risk assessment plan (BS EN ISO 14971) and is reviewed as part of the department's management review meetings.

9.0 Roles and Responsibilities

This chapter describes the roles and responsibilities of key personnel involved in the operation, maintenance and use of decontamination processes. Fig 4 is the Decontamination Management Structure for Wales:

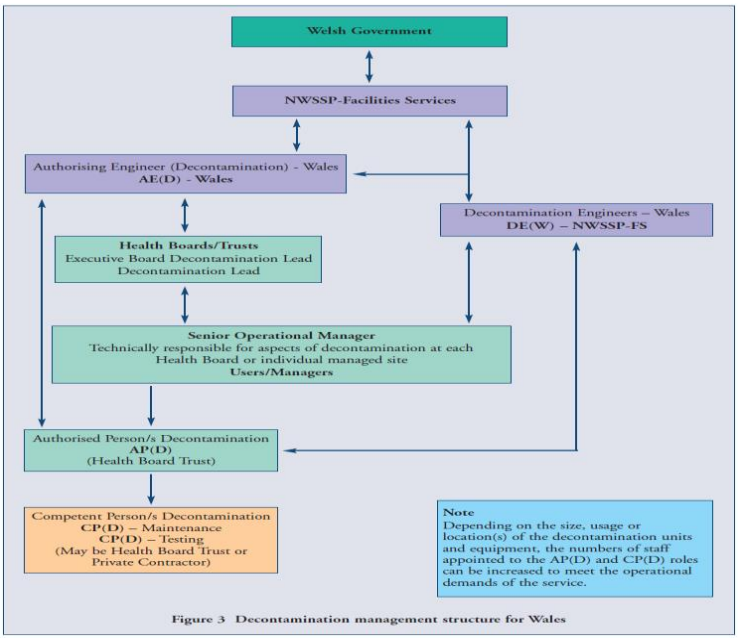


Figure 3 Decontamination management structure for Wales

The following persons are considered key personnel who have a specific responsibility within decontamination:

a. Executive Board Lead (for example, Chief Executive)

b. Decontamination Lead

c. Senior Operational Manager (for example, Estates Manager)

d. User (for example, Sterile Service Manager)

e. Authorising Engineer (Decontamination)

f. Decontamination Engineers (Wales) at NWSSP-SES

g. Authorised Person (Decontamination)

h. Competent Person (Decontamination)

i. Lead for Infection, Prevention and Control

j. Microbiologist (Decontamination)

k. Operator

l. Manufacturer

m. Contractor

n. Purchaser

o. Competent Person (Pressure Systems)

9.1 Executive Board Lead

Has ultimate responsibility, including allocation of resources and the appointment of personnel for the organisation. Within the Health Board this post is nominated to the Chief Operating Officer for the Organisation.

9.2 Decontamination Lead

The Health Board has a nominated Decontamination Lead with responsibility for decontamination. The Decontamination Lead reports directly to the Executive Board Lead via the Decontamination Group.

The Decontamination Lead is organisationally responsible for the effective and technically compliant provision of decontamination services.

The Decontamination Lead is responsible for the implementation of the operational policy for decontamination. They must ensure the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of

decontamination equipment across the Health Board. The Decontamination Lead is also responsible for monitoring the implementation of the policy.

The Decontamination Lead should have received formal training, specific for management of medical device decontamination on undertaking the role.

9.3 Senior Operational Manager

The Senior Operational Manager is technically, professionally and managerially responsible for the engineering aspects of decontamination (for example, decontamination equipment and environment). Within the Health Board this role is designated to the Head of Estates for the UHB.

9.4 User

Within the Health Board the user is the designated sterile service manager for the organisation.

The principal responsibilities of the user are as follows:

a. to certify that the decontamination equipment is fit for use;

b. to hold all documentation relating to the decontamination equipment

c. to ensure that decontamination equipment is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records;

f. to establish procedures for product release in line with the quality management system;

g. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice. The user may seek the advice of infection prevention and control team;

h. to ensure the surgical instrument management is carried out.

Specifically, the responsibility of the user will cover the following,

a. make judgements on the suitability of reusable instruments in consultation with surgical teams and those responsible for decontamination. This work is assisted in the Health Board via the Sterile Service User Group and the Endoscopy User Group.

b. Determine appropriate instrument-set structures designed to assist in the prevention of leakage on of instruments between sets (including preventing the movement of supplementary instruments between sets) in consultation with clinical specialists and decontamination teams; ensure that guidance on tracking and traceability is appropriately applied to all instruments (this includes loan sets and implantable items including screws and plates) and collaborate with those responsible for patient records to ensure any patient with whom they are used can be identified and linked to the sets or individual instruments used;

c. Ensure that missing or damaged surgical instruments are replaced preserving the appropriate set structure;

d. oversee the monitoring of condition and suitability for surgical instruments;

e. oversee the audit process for instrument sets from procurement through to use, decontamination and final disposal;

f. ensure instrument sets never used are reviewed and / or disposed of;

g. oversee actions to provide a mechanism for routinely revalidating instrument – set content (for example, annual sign off of the tray checklist by surgical teams);

h. mange the loaning of instrument sets to and from external suppliers

i. purchase new instrument and sets (including, as a minimum, the documented approval of the theatre team, decontamination specialists and Control of Infection Lead);

j. ensure repaired instruments are returned to the original instrument set;

k. oversee a standardised approach to instrument recognition throughout the organisation.

l. ensure all instrument sets have an accurate version-controlled checklist validated by the surgical team

m. determine that all instrument stores are audited on a regular basis, and all redundant items removed from circulation;

n. ensure a mechanism is in place for addressing instrument set usage non-conformities such as wet pack, wrong inventory, holes in tray wrap etc.

o. provide and oversee mechanisms to ensure all instruments in the health board's inventory are fit for purpose;

p. ensure the health board hold an accurate database of its instrument-set inventory including tray type, location of use and stock level;

q. ensure all instrument sets which are critical in stock levels are risk assessed, to maximise patient safety and inform instrument set investment;

r. ensure compliance with all manufacturers' reprocessing instructions of any implantable items;

9.5 Authoring Engineer (Decontamination (AE(D)

The AE(D) is defined as a person designated by management to provide independent auditing and advice on washer-disinfectors, sterilisers and sterilisation and to review and witness documentation on validation.

The AE(D) is required to liaise closely with other professionals in various disciplines and consequently, the

appointment should be known in writing to all interested parties.

Role of AE (D)

This role should be fully independent of the Health Boards 'and healthcare facilities' structure for maintenance, testing and management of the decontamination equipment.

The AE (D) at NWSSP-SES has a reporting route to the Decontamination Lead via the Health Boards Decontamination Group and reports directly to Welsh Government via the All Wales Welsh Assembly Government Decontamination Committee.

The AE(D) provides technical advice to AP(D)s, CP(D)s and users involved in the control of decontamination processes in healthcare facilities.

Responsibilities of the AE(D)

The principal responsibilities of the AE (D) are as follows:

a. to provide Management and others, general and impartial advice on all matters concerned with decontamination;

b. to provide Management and others, on programmes of validation;

c. to audit reports on validation, revalidation and yearly tests submitted by the AP(D);

d. to advise Management and others on programmes of periodic tests and periodic maintenance;

e. to advise Management and others on operational procedures for routine production;

f. to advise Management on the appointment of the AP(D);

g. to provide technical advice on the relevant guidance for wales on decontamination equipment for the users;

h. to provide technical advice on the relevant guidance for Wales on decontamination equipment and procedures;

i. NWSSP-SES undertakes the role of Authorising Engineer for the NHS in Wales.

j. The Institute of Healthcare Engineering and Estate Management (IHEEM) supports and operates the DTP (Decontamination technology Platform) which is made up of IHEEM-registered AE(D)s.

9.6 Decontamination Engineers (Wales) at NWSSP-SES

The Decontamination Engineers (DE(W)) in Wales support the AE (D) and undertake the testing programme of decontamination equipment on behalf of the Welsh Government.

The DE(W) will also be responsible for:

a. the engineering technical advice of decontamination equipment to all users;

b. the safe and effective systems of work for all installed decontamination equipment within his / her area of responsibility;

c. participate and undertake technical audits of decontamination facilities and equipment on behalf of welsh Government and NWSSP-SES;

d. close liaison with the AE(D), AP(D), Decontamination Led, users and other interested professionals to enable them to discharge their responsibilities for management of decontamination effectively;

e. ensuring the continued support of a liaison with site CP(D)s, as appropriate.

9.7 Authorised Person (Decontamination (AP(D))

The AP(D) will be an individual representing a health care organisation possessing adequate technical knowledge and having received appropriate training, appointed in writing by the health care organisation (in conjunction with the advice provided by the AE(D)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of decontamination equipment.

The AP(D) should be able to undertake the safe and effective management of the engineering aspects of the service.

The role of AP(D) is intended to provide the organisation with an individual who, as part of the management infrastructure, will provide day-to-day operational management responsibility for the safety of the system. This should be an internal appointment within the organisation. It is however, recognised that in some organisations there are so few items of decontamination equipment in use that a service provided by a third party may be adequate. In most organisations the role of AP(D) would only be one of a number of areas of similar responsibility for the individual(s) concerned. However, any additional responsibilities should not reduce the importance of the role nor impair the ability of the AP(D) to carry out his/her duties effectively.
When the scope and range of services dictates, healthcare organisations may wish to consider the appointment of more than one AP(D) to ensure that appropriate cover is provided. In these circumstances the organisation should appoint a senior AP(D). In any event, organisations will need to ensure that cover is available during the absence of the AP(D). Larger organisations may be able to warrant the appointment of an AP(D) dedicated full-time to the role.

If the estates roles are contracted out, it is recommended that the AP(D) function remains the responsibility of the healthcare organisation.

The healthcare organisation has a responsibility to ensure that the AP(D) reporting structure has a line of professional accountability.

The AP(D) will also be responsible for:

a. the engineering management of decontamination equipment – site specific only;

b. the management and / or appointment of the CP(D)s on each site for the organisation;

c. safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility;

d. the acceptance criteria for operational and performance testing as decided with the relevant users and AE(D) of all installed decontamination equipment;

e. liaison with the AE(D) and/or DE(W) at NWSSP-SES, Decontamination Lead and other interested professionals;

f. authorising the use of decontamination equipment after repair or refurbishment and after quarterly tests;

g. operation of the permit system in line with guidance specified in this document;

h. ensuring the continued local registration of the CP(D)s, as appropriate;

i. liaising with the user, and other technical support personnel, to enable them to discharge their responsibilities for management of decontamination effectively.

The AP(D) must have a knowledge of the specific equipment installed on-site and not simply a generic overview of decontamination equipment.

The AP(D) must have received appropriate training and be conversant with periodic testing. He/she should have completed an accredited course for CP(D)s and successfully passed the examination.

9.8 Competent Person (Decontamination) (CP(D))

The CP(D) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of washer-disinfectors and sterilisers.

The CP(D) may be either directly employed labour or provided as a service to the healthcare organisation from third parties. Healthcare organisations may wish to maintain the sperate functional roles of provision of testing and/or maintenance. The content of this role can be developed at a local level dependant on training and work-based experience. Consultation with the AE(D or DE(W) is recommended.

The CP(D) should report directly to an appropriate member of the estates department prior to commencement of work activity, for example, AP(D) and liaise with the DE(W) / AE(D).

The principal responsibilities of the CP9D) are:

a. to carry out the maintenance tasks outlined in Welsh Health Technical Memorandum 01-01 Parts C and D;

b. to carry out additional maintenance and repair work at the request of the user;

c. to conduct the periodic tests specified in Welsh Health Technical Memorandum 01-01 Parts C and D and to prepare reports as required by the user;

d. to conduct any additional tests at the request of the user, AE(D) or De(W).

The CP(D) should:

a. be able to clearly demonstrate adequate technical competence working with decontamination equipment they work with (e.g. activities such as maintenance):

b. have completed an accredited course for CP(D)s and successfully passed the examination;

c. have a certificate demonstrating satisfactory completion of an accredited course in the validation and periodic testing of at least two decontamination processes/machine types;

d. have at least three year's experience in the validation and periodic testing of porous-load sterilisers and at least one other decontamination process/machine type.

e. Received appropriate training from equipment manufacturers on how to carry out maintenance/service tasks.

f. If the CP(D) does not undertake duties for a prolonged period, the need for refresher training may need to be implemented.

g. External CP(D)'s must work in accordance with the CVUHB Control of Contractors policy, for engineers working on premises

9.9 Infection Prevention and Control Lead

The Lead for Infection Prevention and Control is defined as a person designated by Management to be responsible for advising the user on all infection control aspects.

9.10 Microbiologist

The Microbiologist (Decontamination) is defined as a person designated by Management to be responsible for advising the user on microbiological aspects of disinfecting and sterilising non-medicinal products. He/she should also be defined as the person responsible for advising the user on the microbiological aspects of handling. washing, disinfecting and sterilising used medical devices.

The Microbiologist (Decontamination) should be suitably qualified and nominated by the healthcare organisation.

The principal responsibilities of the Microbiologist (Decontamination) are:

a. To advise the user on the microbiological aspects of decontamination procedures for non-medicinal products;

b. to audit the documentation from all decontamination equipment that has been tested by microbiological methods.

9.11 Operator

The operator is defined as any person with the authority to operate decontamination equipment, including the noting of instrument readings and simple housekeeping duties.

Operators should have their tasks defined in their job description. Operators should also have documented training records to demonstrate that they are competent to undertake their assigned tasks and receive refresher training as and when required.

9.12 Manufacturer

The manufacturer is defined as a person or organisation responsible for the manufacture of a washer-disinfector or steriliser. The manufacturer should ensure that the decontamination equipment if designed, manufactured and tested with a quality system. The manufacturer should also carry out pre-delivery works testing. The extent of testing will depend on whether the product is in serial production or a one-off and, for machines in serial production, whether the manufacturer has obtained a certificate of compliance with the relevant British or European Standards by means of a type test for the particular type and size of decontamination equipment. (See BS EN 15883 Parts 1 and 2 for type-test details for washer disinfectors and BS EN 285 for type-test details for sterilisers).

9.13 Contractor

The contractor (or supplier) is defined as a person or organisation designated by management to be responsible for the supply and installation of the washer-disinfector or steriliser, and for the conduct of the installation checks and tests. The contractor (or supplier) may also be the manufacturer of the machine.

9.14 Purchaser

The purchaser is defined as the person or organisation that orders the washer disinfector or steriliser and is responsible for paying for it.

9.15 Competent Person (Pressure Systems)

The competent person as defined in the Pressure-System Regulations (latest -edition) is not the same person as the Competent Person (Decontamination) defined in the WHTM 01-01. The former is an engineer responsible for drawing up a written scheme of examination for the system. The latter is the person who carries out maintenance, validation and periodic testing of washer-disinfectors and sterilisers.

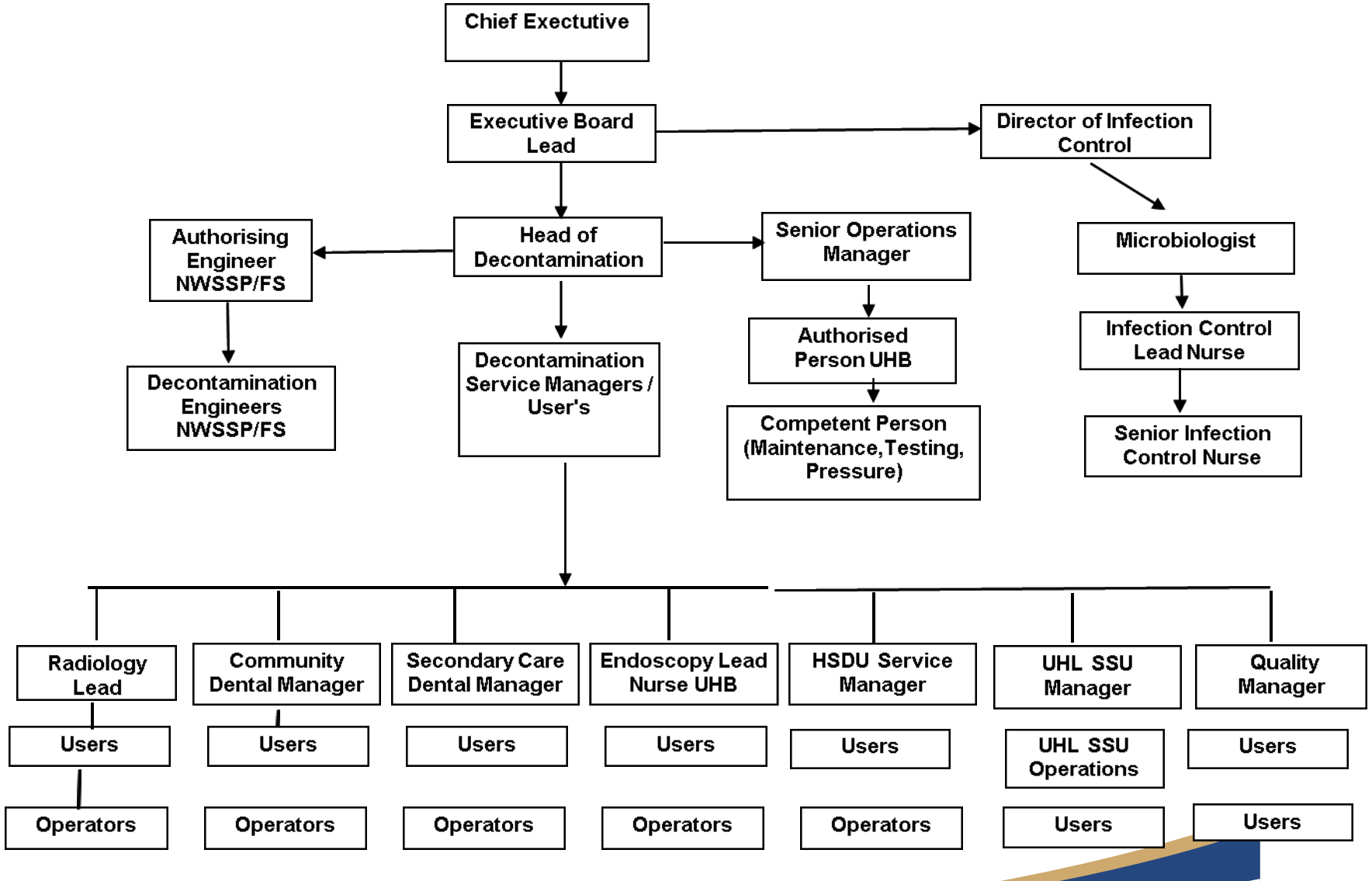
Most insurance companies maintain a technical division able to advise on appointing a CP(PS). The AE(D) should also be able to provide advice.

9.16 Management Structure for the Management of Decontamination at Cardiff and Vale UHB.

Fig 5 confirms the Decontamination Management Structure for Cardiff and Vale. Details of named individuals in the positions identified can be sought from the Head of Decontamination. This structure identifies all positions in line of the requirements of WHTM 01-01 Part A and WHTM 01-05:

Fig 5

Cardiff and Vale UHB Decontamination Management Structure



10.0 Decontamination Training

Decontamination is a science in its own right. Staff undertaking decontamination must be competent and properly trained. Individual training records, detailing the individual's core competencies and any other training, should be maintained and updated regularly. Line managers are responsible for maintaining these records. In the primary care setting, whoever owns or manages the practice is responsible for ensuring that systems are in place for ongoing staff training.

Within the UHB each department has robust training systems in place to ensure all Operators are appropriately trained to perform the act in hand and use decontamination correctly and safely.

Accredited courses are sourced dependant on the departments through appropriate providers such as Eastwood Park or the Institute of Decontamination Sciences. In addition, other providers include internal training courses, mandatory training and specialist training courses through the approved body.

11.0 Permit-to-Work System

To manage decontamination equipment that is required to be taken out of action for service, validation or repair. WHTM 01-01 Part A recommend the use of a robust permit to work system.

The permit to work system reduces the possibility of process failure as a result of the following issues:

- Failure to undertake work activities in a safe manner during validation and maintenance;
- Accidental reconfiguration of the validated process;
- Failure to comply with the work permit system;
- Accidents associated with engineers working within the facility;
- Communication failure associated with engineering activities;

The following process should be completed when managing the permit to work system in line with WHTM 01-01 Part a:

The user should sign the permit to allow the equipment to be taken out of use for routine testing, repair and maintenance by the relevant CP(D).

The CP(D) should sign the permit to allow the equipment back into use after routine maintenance and weekly testing. The user should sign the permit to allow the equipment back into use.

As part of the accountability, three copies of the permit should be produced. The user, the CP(D) and the AP(D) should all retain copies for their records.

Permit to work's should be implemented for any activity which can compromise the safety and configuration of the decontamination equipment, to include maintenance, breakdown, repair, validation and/or software upgrades.

After repairs following a breakdown and after quarterly testing, both AP(D) and the CP(D) should sign the permit to allow the equipment back into use. The DE(W) from NWSSP-SES and the user should sign the permit following the annual testing. The CP(D) carrying out the work should also sign the permit. In the event of work spanning a number of shifts or days, the signatures of all the CP(D)s involved should show continuity.

The AE(D) or the DE(W) under authorised delegation, should sign the initial permit to use the equipment after installation and validation testing (or revalidation testing for existing equipment that has been reinstalled). The user should sign the permit to accept the equipment into use.

The AE(D) should formally audit the permit system records with the AP(D) at periodic intervals.

Fig 6 is the Permit to work template used within the UHB:

DECONTAMINATION EQUIPMENT – PERMIT TO WORK – in accordance with WHTM01-01 Part A

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board

Hospital / Trust - _____ Permit No 01/ 4051

The purpose of this permit is to ensure that other than weekly testing no maintenance or other testing is carried out on decontamination equipment without the approval of the Authorised Person – Decontamination.

Part 1 AP (D): Description of work and authorisation / permission to proceed:

Location / Department of decontamination equipment _____

Manufacturer _____ Asset No _____

Serial No _____ Model No _____

The Following work is to be carried out:

_____

_____

_____

The work will take place between _____ hours on ___/___/___ and _____ hours on ___/___/____

NO OTHER WORK WILL BE CARRIED OUT UNDER THIS PERMIT

User Permission (to be completed by Authorised User / Department Manager / Person in charge)
I hereby give permission for the above equipment to be taken out of use and the above described work can be carried out.
It has not been possible to guarantee that the decontamination equipment is free of contaminants.

Name _____ Signature _____

Date _____ Time _____

Position _____

Authorised Person

I hereby give permission for the work as described to proceed

AP (D) – Name (Print) _____ Sign _____ Date _____ Time _____

Part 2 CP (D): Acceptance of work and conditions

I accept responsibility for the work as described
No other work will be carried out by me or persons working under my control
I am **fully conversant** with the work described and relevant health and safety requirements

CP (D) – Name (Print) _____ Sign _____ Date _____ Time _____

Part 3 CP (D): Detail of work carried out

Work Performed	*(Tick appropriate box)*
Breakdown maintenance / Repair	
Routine Servicing / maintenance	
Quarterly Periodic Testing	
Yearly Periodic Testing	
Installation / PQ/PRQ	

Explanation of work carried out _____

_____

_____

_____

The work on the above decontamination equipment has been *completed / suspended**
The decontamination equipment *may / may not* be returned to service*

**Delete as applicable*

Appropriate tests have been carried out to verify the performance of the equipment in accordance with WHTM. (See Equipment logbook for further details)

CP (D) – Name (Print) _____ Sign _____ Date _____ Time _____

Part 4 AP (D): Authorisation to use Decontamination Equipment

The Decontamination Equipment may be taken into use*
The Decontamination Equipment may not be taken into use, as further work under new permit is now necessary*

**Delete as applicable*

AP (D) – Name (Print) _____ Sign _____ Date _____ Time _____

Part 5 – Acceptance of Decontamination Equipment Status by Authorised User / Department Manager / Person in charge

I declare that all aspect of the work has been explained to me. I hereby accept the decontamination Equipment back into service*

I understand that further work is required and will ensure that the Decontamination Equipment will remain out of use*
**Delete as applicable*

Name _____ Signature _____

Date _____ Time _____

Position _____

Original (White) copy to be retained in book by Authorised Person (D) – Pink copy to Department Manager – Yellow copy to Competent Person (D)

Fig 6

23.0 Reporting of Incidents

All incidents involving decontamination equipment or decontamination processes must be reported following the UHB's incident reporting procedures contained in the UHB's "Risk Management Policy". All incidents must be reported using the RLDatix system within the UHB by the relevant operators and discussed at the UHB Decontamination Group.

Where necessary these incidents may also be subject to the reporting requirements established by the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013) (RIDDOR) and be escalated to the local office of the Health & Safety Executive (HSE). Serious incident requires a full investigation and discussion at a Serious Untoward Incident meeting arranged through the UHB Health and safety Team.

The user / Responsible Person within the Organisation should notify the HSE immediately, normally by telephone, if any of the following occur:

a. Any fatal injuries to employees or other people in an accident connected with the operation of an item of decontamination equipment;

b. Any major injuries to employees or other people in an accident connected with the operation of the steriliser;

c. Any of the dangerous occur

Management responsible within the healthcare organisation should send a written report to the HSE in Wales within seven days of an incident including:

a. Any of the notifiable incidents listed above;

b. Any other injury to an employee which results in their absence from work or being unable to do their normal work for more than three days;

c. Any of the cases of ill-health listed in the Regulations.

A record should be kept of any injury, occurrence or case of disease requiring a report. This should include the date, time

and place, personal details of those involved and a brief description of the nature of the event.

Examples of dangerous occurrences applicable to sterilisers include:

a. The explosion, collapse or bursting of any closed vessel;
b. Electrical short-circuit or overload causing fire or explosion;

c. Any explosion or fire resulting in the suspension of normal work for more than 24 hours;

d. An uncontrolled or accidental release or escape of any pathogens or substance from any apparatus or equipment;

e. Any incident where breathing apparatus malfunctions in such a way as to deprive the wearer of oxygen.

Examples of reportable diseases applicable t sterilisers include:

a. Poisoning by steriliant;

b. Any illness caused by a pathogen;

Full details can be found in the HSE guidance: A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations.

Incidents and dangerous occurrences that are reported to the HSE should also be reported either to the MHRA or to the Welsh Government, as appropriate, by telephone as soon as possible and by the latest during the first working day after the incident and then followed by a written report.

13.0 Risk Management

The UHB have an over arching decontamination risk register. This identifies any risks currently being held in the UHB with a risk rating of 15 or above.

In addition to the risk register each directorate captures any decontamination risks of 10 -15 within the Directorate Risk Register.

Any department that is active in performing decontamination processes or managing equipment, is required to risk assess the

activities and if scoring 0-10 captured on the departments risk register.

Any member of staff or management completing risk assessments, must have completed the UHB Risk Management Training and Risk Assessments must be generated using the risk assessment templates found in the UHB Risk Management Policy.

The HSDU, DSDU and SSU Departments that are accredited to ISO 13485, in addition must carry out risk analysis in line with ISO 14971:2019 to identify hazards and estimate risk.

FIG 7 shows the scoring system and management tool used in the UHB:

5.0 Risk Analysis Evaluation

Key:

- C= Consequence
  - 1 – Negligible
  - 2 – Minor
  - 3 – Moderate
  - 4 – Major
  - 5 – Catastrophic
- L = Likelihood
  - 1 – Rare
  - 2 – Unlikely
  - 3 – Possible
  - 4 – Likely
  - 5 – Almost Certain
- Risk =Consequence x Likelihood

Risk Scoring = Consequence x Likelihood (C x L)

Consequence Score	Likelihood Score				
	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost certain
5 - Catastrophic	5	10	15	20	25
4 - Major	4	8	12	16	20
3 - Moderate	3	6	9	12	15
2 - Minor	2	4	6	8	10
1 - Negligible	1	2	3	4	5

1 - 3 = Low Risk	**Quick, easy measures implemented immediately and further action planned for when resources permit**
4 -10 = Moderate Risk	**Actions implemented as soon as possible but no later than a year**
12 -16 = High Risk	**Actions implemented as soon as possible but no later than six months**
20 - 25 = Extreme Risk	**Requires urgent action. The UHB Board is made aware and it implements immediate corrective action**

Red = Extreme Risk
Unacceptable if it is within the scope of responsibility of HSDU. If the risk is outside the scope of responsibility of the HSDU then the users are notified of the risks. A copy is also sent to the Corporate Risk Department.
Orange = High risk
Unacceptable if it is within the scope of responsibility of HSDU. If the risk is outside the scope of responsibility of the HSDU then the users are notified of the risks. A copy is also sent to the Corporate Risk Department.
Yellow = Moderate Risk
Acceptable but risk reduction methods need to be addressed
Green = Low Risk
Risk reduction methods need to be addressed where possible

14.0 Control of Substances Hazardous to Health

Hazardous substances include:

-substances used directly in work activities (e.g. cleaning agents)
-substances generated during work activities (e.g. fumes from welding)
- biological agents such as bacteria and other micro-organisms.

There are many cleaning agents used across departments actively performing decontamination or managing decontamination equipment. In order to comply with the COSHH Regulations the following eight steps are required:

- Assess the risks
- Decide what precautions are needed
- Prevent or adequately control exposure
- Ensure that control measures are used and maintained
- Monitor exposure
- Carry out appropriate health surveillance
- Prepare plans and procedures to deal with accidents, incidents, evacuation and emergencies
- Ensure that employees are properly informed, trained and supervised

Each decontamination department should designate a COSHH Co-ordinator who shall:

-Identify the substances present in their assigned area
- Ensure the facility has appropriate ventilation in accordance with the Material Safety Data Sheet for each product used within the designated area.
-Obtain a manufacturer's safety data sheet for chemicals purchased by the UHB
-Determine if an appropriate generic assessment is available for the substance (check the activity on the assessment is the same as how it is used in practice)
-If an appropriate generic assessment is not available, complete and submit to the Health and Safety Department a COSHH assessment request form (CARQ) for each identified substance which will consider –

a. How much of the substance is in use or produced?

b. Work practises i.e. how the substance is used

c. Existing control measures e.g. engineering controls such as fume cupboards, personal protective equipment (PPE), environmental monitoring within the room and notification of room status outside of the room.

Each departments COSHH Co-ordinator should develop a COSHH file, which is subject to annual review and includes all Safety Data Sheets for the chemistries in use and the relevant safety data sheets.

15.0 Audit / Quality Assurance

Decontamination audits are vital to ensure practices are in line with standard operating procedures set by the User / Department Leads.

Each department that is active in decontamination should have a robust internal audit schedule, developed in line with the standard operating procedures for decontamination practices. The internal auditors must be appropriately trained to perform the audits, with training courses available through the UHB or Approved Bodies.

In addition to internal audits, the departments that are accredited to ISO 13485 / Med Dev Regulations, must be subject to surveillance, re-certification and unannounced audits by the approved body assigned by the MHRA. These audits are required to ensure certification and compliance to ISO 13485 / Med Dev Regulations.

The UHB Infection Control Department can provide environment, uniform and hand hygiene audits on request from the User / Department Manager.

The AED(Decontamination) carries out regular decontamination, process and equipment audits on behalf of Welsh Government, as outlined in the WHTM 01-01 guidance.

The designated storage areas of sterile packs and trays, must be subject to audits completed by the theatre teams on a six-monthly basis. The provider i.e. sterile service departments should also perform random assurance checks using the same audit tool.

16.0 Procurement

Procurement is an essential function when related to decontamination. Advice must be sought from the User / Managers before any of the following take place:

- Purchase of new equipment
- Loan of equipment
- Changes in decontamination processes for existing equipment
- Methods of decontamination, i.e. decontamination products / wipes / consumables.

The UHB has a medical equipment management group which over-see the capital bids of new equipment being brought into the organisation. Included in the Capital Medical Devices Bidding Form is a section on decontamination which must be completed by the designated manager completing the bid. Each capital bid must be reviewed by the Head of Decontamination, to ensure the organisation has the relevant processes and infra-structure to

decontaminate the devices in line with the manufacturer's instructions.

As well as the cost of the equipment, the cost of the decontamination process / equipment should also be assessed and, in some instances, it may be cost effective to opt for single use. However, these should be suitably manufactured and fit for use. When considering the option of single use equipment, the costs associated with its disposal e.g. increased clinical waste, disposal costs, should also be considered.

17.0 Maintenance / Validation

All automated decontamination equipment and ancillary plant servicing, must be used, maintained and validated according to the manufacturers' instructions, regulatory requirements and Welsh Health Technical Memorandum Guidance.

17.1 Validation

Steam steriliser maintenance and validation is governed by WHTM Part C: Steam sterilization and steam for sterilisation and WHTM 01-05 WHTM 01-05 Decontamination in Primary Care Dental Practices and Community Dental Services for bench top autoclaves. The sterilizers require daily test and in addition weekly, quarterly and annual validation. Fig 8, shows the required periodic tests required for porous-load steam sterilisers:

Fig 8

Table 4 Periodic tests for porous-load sterilizers

Daily test – User
Bowie-Dick test for steam penetration
Weekly tests – CP(D)
1. Weekly safety checks 2. Air leakage test 3. Air detector function test 4. Automatic control test 5. Bowie-Dick test for steam penetration*
Quarterly tests – CP(D)
1. Weekly safety checks 2. Air leakage test 3. Air leakage test (temperature and pressure sensors connected) 4. Automatic control test 5. Verification of calibration of sterilizer instruments* 6. Thermometric test for a small load* 7. Air leakage test (sensors removed) 8. Air detector function test 9. Bowie-Dick test for steam penetration
Yearly and revalidation tests – CP(D)
1. Yearly safety checks 2. Non-condensable gas test 3. Steam superheat test 4. Steam dryness test 5. Steam chemical purity tests 6. Air leakage test 7. Air leakage test (temperature and pressure sensors connected) 8. Automatic control test 9. Verification of calibration of sterilizer instruments* 10. Air detector performance test for a small load 11. Air detector performance test for a full load 12. Thermometric test for a small load 13. Thermometric test for a full load 13a. Load dryness test for a metal load (see BS EN 285) 14. Test for PRQ as required by the user 15. Air leakage test (sensors removed) 16. Air detector function test 17. Bowie-Dick test for steam penetration 18. Hollow load test
At a frequency defined by the manufacturer
1. Dynamic pressure test

* May be carried out simultaneously with the preceding test

Alternative systems to steam for sterilisation are governed by WHTM 01-01 Part E. There currently is no standard for the test methods used on these technologies including hydrogen peroxide, gas plasma and Ethelyn oxide systems. Part E contains recommendations however of tests to be considered, including IQ, OQ, PQ, process challenge devices and reference microorganism challenges to present to the system. Currently the tests are developed by the manufacturer of these systems to ensure performance monitoring of the systems are in place and working effectively.

Washer disinfectors used within the sterile service department require daily, weekly, quarterly and annual validation. These tests are governed by WHTM 01-01 Part D: Washer-disinfectors. Fig 9 shows the required periodic tests for sterile service washer disinfectors:

Fig 9

Daily tests – User
1. Check spray arm rotation for free movement
2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages for cannulated instruments)
3. Remove and clean strainers and filters, etc.
4. Ensure sufficient additives available and that dosing system is functioning
Weekly tests – User or CP(D)
1. Weekly safety checks
2. Carry out daily tests
3. Water hardness (all process stages)
4. Water conductivity (final rinse stage)
5. Automatic control test
6. Cleaning efficacy test by residual soil detection
Quarterly tests – CP(D)
1. Weekly safety checks
2. Automatic control test
3. Verification of calibration
4. Thermal disinfection test

32

2 Validation and verification

5. Cleaning efficacy test: – reference load[1] general instruments endoscopic/MAT instruments – test soil
Yearly and revalidation tests – CP(D)
1. Yearly safety checks
2. Automatic control test
3. Verification of calibration of washer-disinfector instruments
4. Water system: – chemical purity – bacterial endotoxins
5. Drainage: – free draining – efficacy of discharge
6. Doors and door interlocks: – Cycle start interlock – In-cycle interlock – Failed cycle interlock
7. Fault indication on sensor failure
8. Water vapour discharge test
9. Chemical additive dosing tests: – reproducibility of volume admitted – low level detection
10. Load carriers
11. Air quality
12. Cleaning efficacy test: – test soil – reference load[1] general instruments endoscopic/MAT instruments
13. Over temperature cut-out test
14. Thermometric test for thermal disinfection – reference load[1]
15. Load dryness test – reference load[1]
16. Process residue test
Notes 1 Additional test loads and alternative test soils may be required for washer-disinfectors that are also intended for use with hollowware and/or anaesthetic accessories. The additional testing should also include tests on the load carriers that will be used with these additional loads. Calibration, limits and function, including fault/alarm, of independent monitoring system should be checked during quarterly and yearly tests.

Table 3 Schedule of periodic tests

Ultrasonic cleaners used within sterile services and dental practices require weekly, quarterly and annual tests, which are governed by WHTM 01-01: Part D Washer Disinfectors. Fig 10 shows the required periodic test required:

Fig 10:

Test	IQ	OQ	PQ	Periodic
Automatic control test	X	X	X	W Q Y
Chamber wall temperature		X	X	Y
Chemical additive(s): low level detection		X	X	
Chemical additive(s): process residue			X	
Chemical: reproducibility		X	X	Y
Cleaning efficacy by residual soil		X	X	W
Cleaning efficacy with test soil		X	X	Q Y
Doors: in-cycle interlock		X	X	Y
Doors: cycle start interlock		X	X	Y
Doors: door-opening force		X	X	Y
Drainage: free drainage		X	X	Y
Fault interlock		X	X	Y
Load carrier temperature test	X	X		
Load carriers				Y
Load dryness test		X	X	Y
Over-temperature cut out test		X	X	Y
Remove and clean strainers or filters				D W
Weekly safety checks		X	X	W Q
Sound pressure test		X	X	Y
Test for ultrasonic activity		X	X	Y
Thermometric test for disinfection		X	X	Y
Verification of calibration	X	X	X	W Q Y
Water: hardness	X			Y
Water: overflow test		X	X	Y
Water supply temperature	X			Y
Volume of water used per stage		X	X	Y
IQ = installation qualification OQ = operational qualification PQ = performance qualification W = weekly Q = quarterly Y = yearly				

Table 4 Schedule of testing for ultrasonic cleaners

Automated endoscope disinfectors used within endoscopy reprocessing departments again require daily, weekly, quarterly and annual validation. These tests are governed by WHTM 01-06 Part D: Decontamination of Flexible Endoscopes Testing Methods. Fig 11 shows the required periodic test for automated endoscope disinfectors:

Fig 11

Table 5 Schedule of periodic tests

Daily tests – User or operator
1. Automatic control test (see paragraph 3.1 in HTM 01-06 Part E)
2. Remove and clean strainers and filters
Weekly tests – User or operator, CP(D) or contractor
1. Weekly safety checks
2. Carry out daily tests
3. Process challenge device cleaning efficacy test*
4. Water hardness (all process stages)
5. Water conductivity (final rinse stage if appropriate)
6. Final rinse-water supply – total viable count

Quarterly tests – CP(D) or contractor
1. Weekly safety checks
2. Weekly tests including automatic control test
3. Verification of calibration
4. Final rinse-water tests:
• appearance
• TOC
• total viable count
• environmental mycobacteria
• electrical conductivity
• water hardness
5. Leak and patency testing:
• leak test
• lumen patency detection test
• lumen disconnection detection test
6. Thermometric tests:
• chamber wall temperature for the self-disinfection cycle (if used)
• temperature during routine cycle
7. Cleaning efficacy test
8. Residual protein detection test
Yearly and revalidation tests – CP(D) or contractor
1. Weekly safety checks
2. All quarterly tests including automatic control test
3. Verification of instruments
4. Final rinse-water system:
• TOC
• total viable count
• environmental mycobacteria
• volume of water used per stage
5. Drainage:
• blocked drain protection
• free draining
• efficacy of discharge through the trap
• estimation of dead volume of pipework
6. Venting system:
• load contamination from ductwork
• droplet emissions
• chemical vapour emission
7. Doors and door interlocks:
• cycle start interlock
• in-cycle interlock
• double-ended EWDs

• on sensor failure
• door opening force
• failed cycle interlock
• fault indication on sensor failure
8. Chemical dosing:
• reproducibility of volume admitted
• indication of insufficient chemical additives
9. Load carriers
10. Chamber wall temperature for the self-disinfection cycle
11. Load carrier temperature during self-decontamination
12. Over-temperature cut-out test
13. Temperature during routine cycle
14. Verification of calibration
15. Air quality
16. Sound pressure
Note * The use of a process challenge device, as listed in the weekly tests, is recommended to balance the overall testing of routine performance of both the cleaning procedures/washing machines and the consistent washing performance against the verification of the process. Process challenge devices are available to prove that the wash process is operating at the optimum performance as set up and reported by validation testing. Some devices can be used both for the cleaning efficacy test with the relevant test pieces and with a restricted device to impede the water flows under the tests.

Validation of High-Level Disinfectors is governed by WHTM 01-06 Part F. Weekly, quarterly and annual validations as prescribed by the manufacturer must be performed on a periodic basis.

17.2 Servicing

The servicing requirements of decontamination equipment is set out by the manufacturer of the device. The frequency can vary dependant on the type of

equipment, from quarterly, six monthly or annual. When the decontamination equipment is being serviced, it is paramount that all routine replacement parts are replaced and authorised service kits are used for the service.

17.3 Test Schedule

All departments that manage the validation, servicing and breakdown call outs of decontamination, must develop a test schedule to track the frequency and completion of the works performed. The test schedule must be reviewed on a regular basis to ensure works are carried out at the appropriate times. If department carry out a management review meeting, the test schedule should be on the agenda of those meetings for review.

17.4 Water Testing

Sterile Services

A continuous supply of water of the specified chemical and microbial quality is essential to the correct functioning of all washer disinfectors, including endoscope disinfectors.

Water that is too hard or has too high a concentration of dissolved solids can impair the activity of detergents, or require the use of increased quantities of chemical additives, and cause deposits, scaling or corrosion of the washer / disinfector.

Water containing high numbers of micro-organisms may re-contaminate disinfected items.

The water quality requirements for sterile service washers, is set out by WHTM 01-01 Part D: Washer-disinfectors. Fig 12 shows the requirements for water quality, final rinse and process water:

Fig 12:

Parameter	Guidance on recommended values	Note
pH	5.5 to 8	Same
Conductivity uS/cm	300	Conductivity is a simple test that can be carried out regularly and can be helpful in identifying unusual trends. Unexpected results indicate that other parameters should be investigated.
Hardness CaCO3(mg/L)	<210	To be assessed locally both through test results and visual assessment of washer-disinfector chamber/devices reprocessed.
Chloride mg/L	50	
TVC cfu/100 ml	5000	Level determined as a result of terminal sterilization process undergone by these instruments reprocessed within the washer-disinfector's.
Endotoxin Units EU/device	<20 EU	Limit based upon risk to patient safety of endotoxins on device rather than in rinse water.

Table 5 Requirements for water quality: final rinse and process water
(See Appendix 1 for additional tests that may be necessary in certain circumstances)

Endoscopy

The final rinse water quality in endoscopy is more critical than sterile services as there is no terminal kill process during a standard endoscopy decontamination processes (not scopes for sterilisation). The final rinse water quality requirements for endoscopy are governed by WHTM 01-06 Part D. Fig 13 sets out the periodic final rinse water tests required:

Fig 13:

4 Water system:
- appearance
- pH
- final rinse-water conductivity (if pure water used)
- total viable count
- volume of water used per stage
- TOC (Nc)
- environmental mycobacteria

Table 2 Total viable count results guide

Aerobic colony count in 100 mL	Interpretation/action	Colour grade
Less than 1	Satisfactory	Green
1–9 on a regular basis	Acceptable – indicates that bacterial numbers are under a reasonable level of control	Yellow
10–100	Risk assessment required to investigate potential problems and super-chlorinate or repeat EWD self-disinfect	Orange
Over 100	Risk assessment required to consider taking EWD out of service until water quality improved	Red

Notes:

Microbiological results from weekly tests should be plotted on a graph to give a trend. This will allow the "normal" and "unusual" results to be distinguished for a particular situation. Investigation of unusual or unsatisfactory results can then be undertaken if results demand (for example, if routine results are below 10 cfu/100 mL, occasionally some of the results may be above 10 cfu/100 mL).

If a bacterial count above 10 cfu/100 mL is obtained from test water, identification of the species is advised. If a significant proportion of the microbes appear the same species from their colonial morphology, carry out an oxidase test to presumptively identify *Pseudomonas* spp. Then if the test is positive, further investigations are required to determine whether *Pseudomonas aeruginosa* is present.

Adapted from: Willis, C. (2006). "Bacteria-free endoscopy rinse water – a realistic aim?" *Epidemiology and Infection*. Vol. 134 No. 2, pp. 279–284.

18.0 The Built Environment

The design and requirements for sterile service departments is set out and governed by *HBN 13 Sterile Services Department – NHS Estates.*

HBN 13 provides guidance to help health planners, estates and facilities managers, sterile services managers and capital planning and design teams to plan and design a sterile services department. In particular the *HBN* focuses on:

- Raising standards in decontamination services by optimising the built environment.
- Service Requirements strategy.
- Calculating the optimum capacity of an SSD to eradicate bottlenecks.
- Determining the most appropriate location of and SSD.

For guidance on design and requirement's for endoscopy decontamination facilities, *WHTM 01-06 Decontamination of Flexible Endoscopes Part A: Policy and Management.*

19.0 Storage

The sterile storage areas are traditionally managed by the theatre users; however, governance and responsibility of the areas remains under the remit of the decontamination service provider. The provider should perform regular surveillance audits of the areas, ensuring storage conditions are optimised for the sterile products.

The sterile storage areas should be controlled with restricted access and environmentally controlled with temperature and humidity control the optimum storage conditions for sterile products, are between 18°C – 25°C and between 40%-60% humidity, the temperature and humidity should be monitored continuously and a daily recording chart should be completed.

The shelving and capacity of the storage area is critical to maintain the integrity of the sterile product. The shelving should be able to accommodate all sterile trays / consumables, with a maximum stacking of 2 high on tray sets dependant on weights of the trays. Sterile and non-sterile products should be segregated in the area and clean and dirty segregation is paramount.

There should be no direct sunlight into the storage area, as this can affect the integrity of the product.

The storage area must have a daily / weekly cleaning schedule and periodically the shelving should be emptied of its contents and wipe down with multi-purpose wipes.

20.0 Transportation

All used medical devices represent a risk of cross-contamination, which may lead to infection. To minimise this risk, any device that needs to be transported for decontamination to take place, must be placed in closed, secure containers (identified as clean and dirty) and transported to the decontamination area as soon as possible following use. All relevant documentation should be fully completed and be transported with the device. These should be kept in the relevant departments and be easily accessible.

To protect the device and handler, transport containers must be:

- Leak proof
- Easy to clean
- Rigid
- Capable of being securely closed
- Labelled to identify the user and contents
- Robust enough to protect the device in transit

Transport containers must be easily identifiable as carrying clean or dirty items I.e. green or red liners for Endoscopes and clean and dirty signs on surgical instrument trolleys / containers

-Subject to a regular cleaning schedule.

Transport containers must be decontaminated with an approved product following use and before subsequent reuse. The cleaning procedure performed must be documented on an appropriate cleaning schedule document.

Staff handling contaminated equipment must wear appropriate PPE in accordance with relevant IPC Policy and be up to date with any vaccinations required for their role e.g. Hepatitis B.

Transportation of medical devices must be in accordance with *"The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009".* Members of staff are not permitted to transport medical devices in their own vehicles.

All medical devices that are decontaminated locally must be decontaminated prior to transportation between wards and departments. This is the case also when requesting maintenance from the estates / clinical engineering departments or third-party contractor / provider.

A decontamination certificate must be completed and accompany each piece of equipment if transferred between wards/departments or when requesting maintenance.

21.0 Business Continuity Plans (BCP)

Service delivery of the sterile service departments in the UHB is essential to ensure surgical activity is sustained and operations are unaffected by the unavailability of surgical instruments and medical devices. The aim of the BCP is to ensure service delivery is maintained and patient cancellations are minimised.

The BCP will come into operation should there be nay equipment failures, major works / installations in the department and in extreme circumstances the whole department being taken out of commission.

The plan aims to:

- Assist Sterile Services to continue services and assist recovery in the event of a disruption.
- Maintain service delivery to the customers of the sterile service departments.

- Categorise the level of escalation required dependant on the type of failure
- Identify department contacts should escalation be required
- Confirm required actions to manage the type of failure

The level of failures is dependent on the percentage lose of services requirements. Fig 14 identifies this:

Priority		Definition
Red	Level 3 Failure losing 100% of service requirements	Critical service needing to be restored within 0-1 hour (Cepod, Major Trauma, Maternity Services). Full capacity to be restored within 5 days.
Yellow	Level 2 Failure – Facility losing 50% of service requirements	Essential service needing to be restored within 1-12 hours.
Amber	Level 1 Failure – Facility losing 50% of service requirements	Essential service needing to be restored within12-24 hours
Green	No failures – Normal service provided	No Action

21.1 Plan Activation

The level of escalation will be based on the impact of the failure:

Level One

- Machine failure 1-3 Units
- Supplier stock failure
- Staff sickness

Action:

- Manage In house if possible, contact competent person and APD
- Source alternative suppliers or stock from other health boards
- Source overtime or bank usage in house
- Inform directorate manager of potential service disruption

Level Two

- Machine failure i.e. all washers / sterilisers
- Critical Supplier Stock Failure
- Major staff sickness

Action:

- Source washer / steriliser capacity in UHB Departments, inform competent person
- Consider temporary implementation of alternative supplier i.e. wrap / chemistry
- Source agency staff, request staff support from other UHB Departments
- Escalate to Directorate Manager and Decontamination Lead, reduce service

21.2

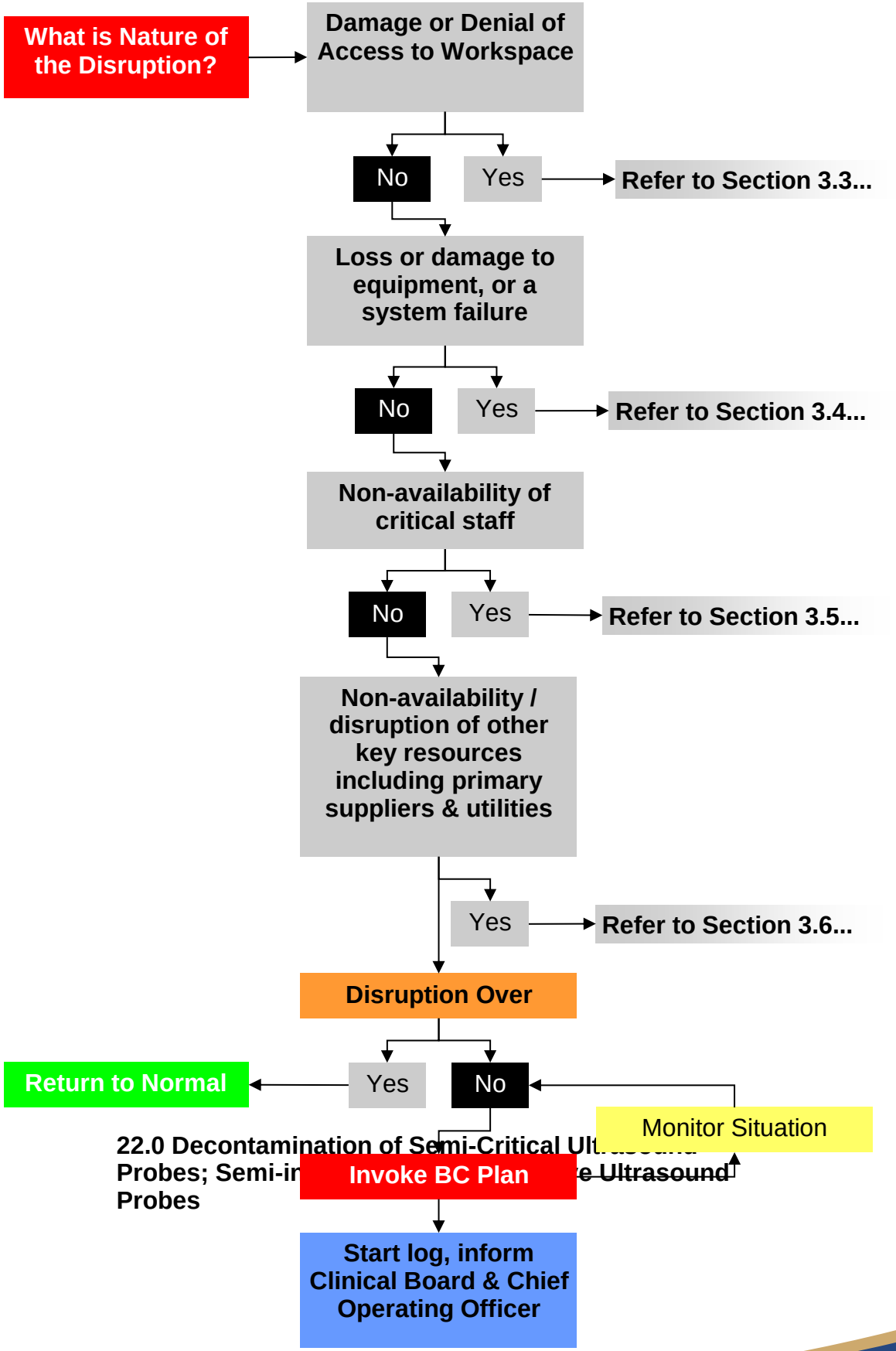
Level Three

- Critical supply major failure: steam, water, electric
- Clean room compromised
- Industrial action
- Major incident

Action:

- Source local capacity and escalate to other Health Boards for assistance
- Reduce service delivery to theatres, consider emergency surgery only
- Escalate to Decontamination Lead and Executive Lead

Process


What is Nature of the Disruption?
Damage or Denial of Access to Workspace
No
Yes
Refer to Section 3.3...
Loss or damage to equipment, or a system failure
No
Yes
Refer to Section 3.4...
Non-availability of critical staff
No
Yes
Refer to Section 3.5...
Non-availability / disruption of other key resources including primary suppliers & utilities
Yes
Refer to Section 3.6...
Disruption Over
Return to Normal
Yes
No
Monitor Situation
22.0 Decontamination of Semi-Critical Ult
Probes; Semi-in
e Ultrasound
Probes
Invoke BC Plan
Start log, inform Clinical Board & Chief Operating Officer

The decontamination of semi-critical ultrasound probes, both semi-invasive (SIUPs) and non-invasive, is governed by *WHTM 01-06 Part F.*

SIUPs cover:

- Transoesophageal Echocardiography (TOE).
- Transvaginal (TV)
- Transrectal (TR) Ultrasound Probes

Non-invasive probes used on broken skin include:

- For vascular access
- Cannulation
- Wound assessment

Vascular access includes:

- Venepuncture/cannulation
- Fine needle aspirations/guided biopsy
- Drainage procedures
- Wound cavity assessments

Ultrasound probes are increasingly becoming a cornerstone in the diagnosis and treatment of patients in healthcare settings. Despite the beneficial impact on patient care, infection control concerns exist over the use of probes and their role as a vector for pathogen transmission. Under the Spaulding Classification Ultrasound Probes that come into contact with broken skin or intact mucous membrane are considered semi-critical devices and should undergo manual cleaning followed by High Level Disinfection (HLD) between each patient use. This decontamination process significantly reduces microbial contamination (i.e. mycobacteria, fungi, viruses and bacteria) and renders if safe for reuse, although small numbers of bacteria spores may still be present.

Cleaning and Disinfection

Cleaning is essential and the most important step in the reprocessing life cycle. UK guidelines mandate the manual cleaning of visible soil from the device, to include probe and cable.

The preferred method of cleaning is using an immersion method within dedicated wash/rinse sinks, using cleaning agents designed for purpose and concentrated to validated levels. However, it is acknowledged that immersion methods are not always possible with Ultrasound probes, so secondary systems must be confirmed.

The removal of visible soil from probe and cable as per the Instructions for Use (IFU) is an essential pre-requisite prior to further decontamination stage and the activity must be, followed by a robust visual inspection of cleanliness prior to disinfection or sterilisation.

Removal of chemical residues form the probes is essential after the cleaning phase, prior to HLD, remaining chemical residues may interact with the probe material causing damage and also may interact with any subsequent high-level disinfection process. Rinsing maybe necessary where pre-clean wipe compatibility is not confirmed with device or HLD process.

HLD using the manual multi-wipe system is the least preferred option for disinfecting Semi-critical Ultrasound Probes. Internationally it is recognised that the use of an automated validated process for decontaminating SIUPs will provide enhanced risk reduction of infection transmission.

Where manual cleaning systems are used in isolation and are not followed by an automated/validated procedure., it is essential that all activities are documented, can be traced and operators who complete tasks are trained and competency assessed routinely by appropriate personnel. Systems should also be audited routinely by the organisations Decontamination Lead or IPC representative.

Medical devices must always be compatible with all detergents and decontamination methods that are used. Compatibility statements from suppliers of probe manufacturer and wipe manufacturer must be confirmed in writing prior to use for decontamination activities.

When choosing a wipe for pre-cleaning/disinfection of a probe following removal of the probe cover, User's must consider the following:

- Choose an appropriate wipe or a pH neutral detergent wipe for pre-cleaning the probe
- The chosen wipe should be recommended & approved by the probe manufacturer s being compatible with the ultrasound probe; review Instructions for Use (IFU).

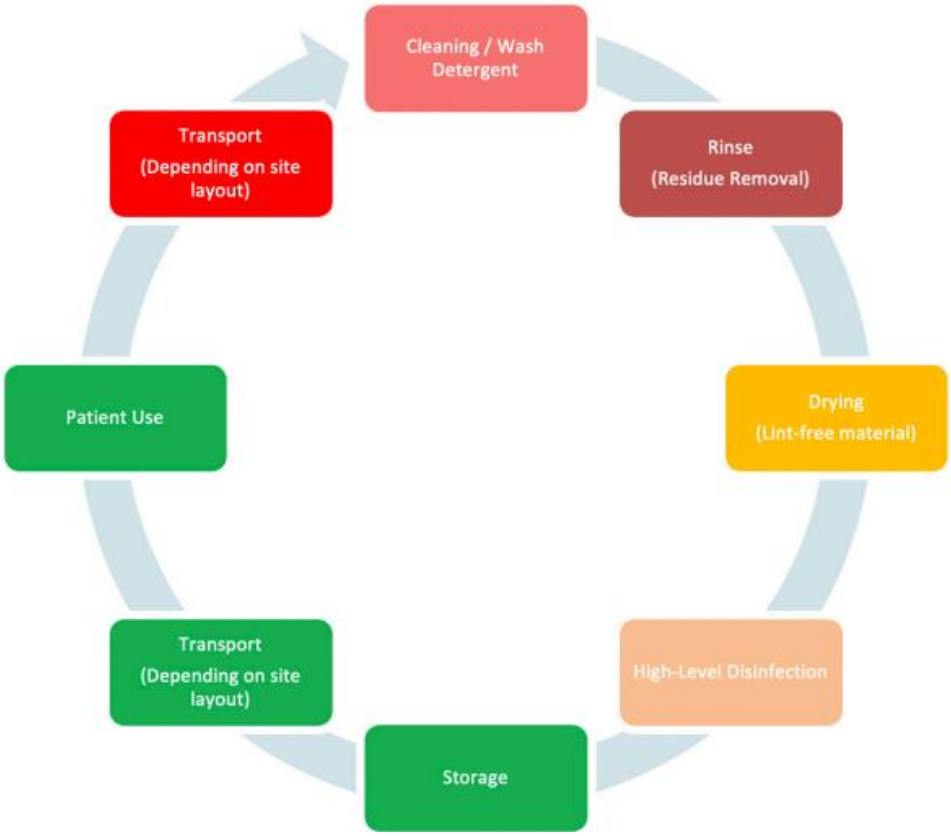
The IFU of the chosen wipe should be consulted to determine:

- Chosen wipe should be classified under UKCA as a medical device (with a CE mark & accompanying number).
- Chosen wipe should not contain any type of alcohol
- Do not use wipes where the IFU states “do not mix with other chemicals”, this indicates the chemistry may not be compatible with other HLD chemistries

The recommended steps for probe reprocessing are:

- Patient Use
- Bedside Clean (If delays are presented prior to return transport)
- Transport
- Cleaning
- Rinsing (Where compatibility uncertainties remain)
- Drying (Essential where moisture would interact with subsequent processes)
- High Level Disinfection
- Transport / Storage
- Preparation for Use (Gel selection / cover)
- Patient Use

Fig 15 – Decontamination Life Cycle Diagram – Semi Critical Probes (No Sterilization)



The information in each of these steps need to be linked through formal traceability systems and responsibilities at each stage must be confirmed.

Device inspection should be taken when cleaning probes, paying extra attention to indentations or complex surfaces. The probe IFU should always be consulted for cleaning instructions and lists of compatible products. Typical cleaning solutions indicated for use with ultrasound probes include detergent – based cleaning wipes, combined cleaning and disinfection wipes or appropriate liquid detergents diluted as per instructions.

Types of HLD methods available:

Compatible Ultraviolet Light Systems

Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure

Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of such UV light HLD systems. Where such systems are used there must be a robust validation procedure to determine optimal values of equipment performance and performance qualification tests to determine whether the efficacy of the installed equipment achieves HLD, with no shadowing present.

In Cardiff and Vale UHB, this technology is adopted for high level disinfection of TOE Probes within the cardiology department.

Using Hydrogen Peroxide Systems:

Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure

Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of such HLD systems.

Hydrogen Peroxide Systems are used for the majority of semi-invasive systems across the UHB in areas performing ultrasound procedures.

Using Manual Multi-wipes:

Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure. This is the least preferred option for decontaminating SIUP's as the process cannot be validated and is subject to operator variation and process drift over time, not least when there are clinical pressures within a department.

Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of individual manual multistage wiping systems.

Additionally, there must be consideration for alternative systems that have advanced with technology. Evidence of process effectiveness must be determined and agreed prior to acceptance.

Facilities for Ultrasound Decontamination Activities

Best practice identifies that decontamination activities should be performed in a suitable location external to the clinical treatment area. This area should facilitate the separation of clean and dirty activities.

Where decontamination is undertaken in the clinical area, consideration must be given to distance the activity from the patient area.

Fig 16: Example of Single Room Decontamination Area

Example of Single Room Decontamination Area

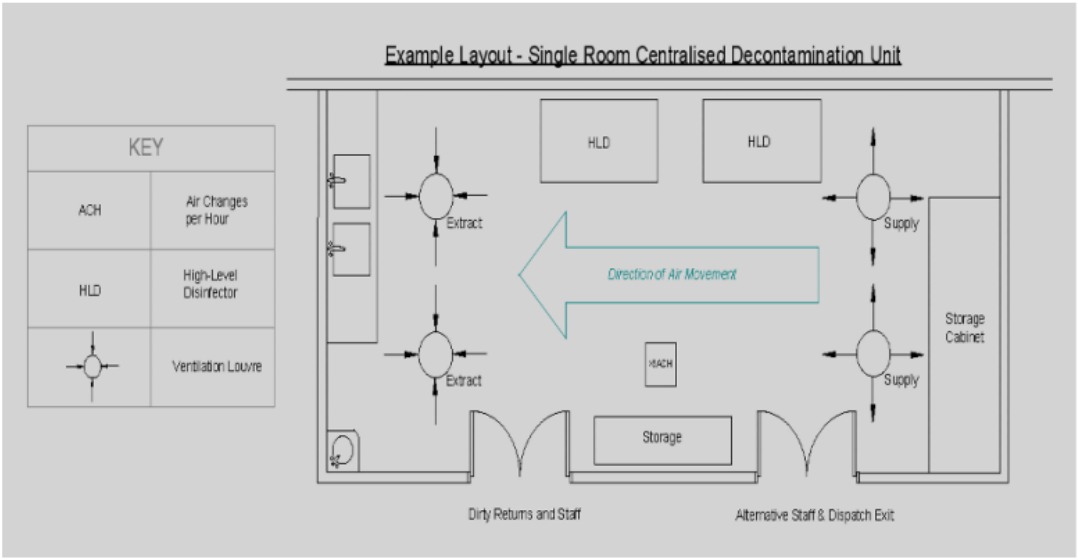
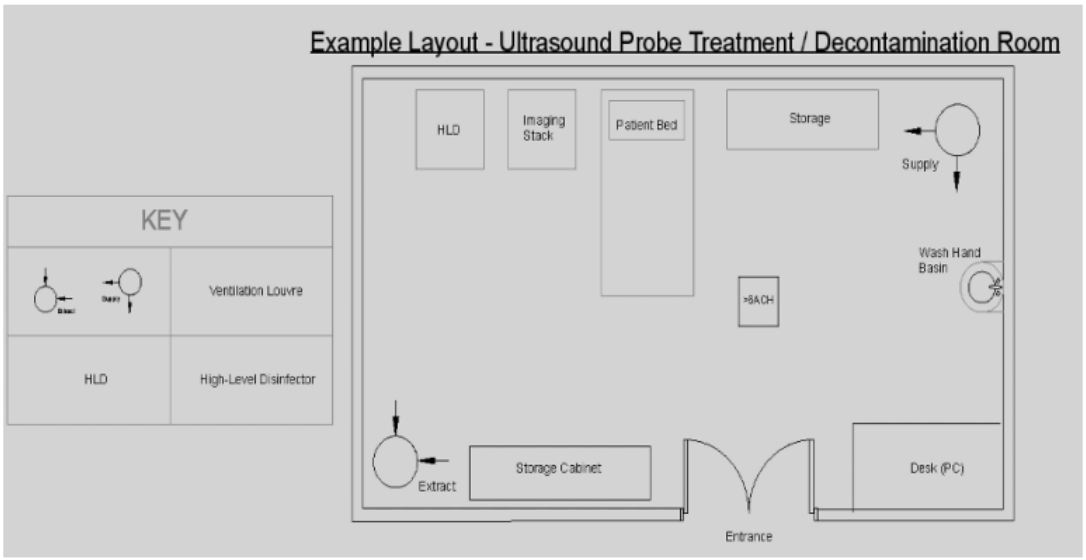


Fig 17: Example of Clinical Room with decontamination activities taking place within.

Example of Clinical Room with decontamination activities taking place within.



Use of a Probe Barrier

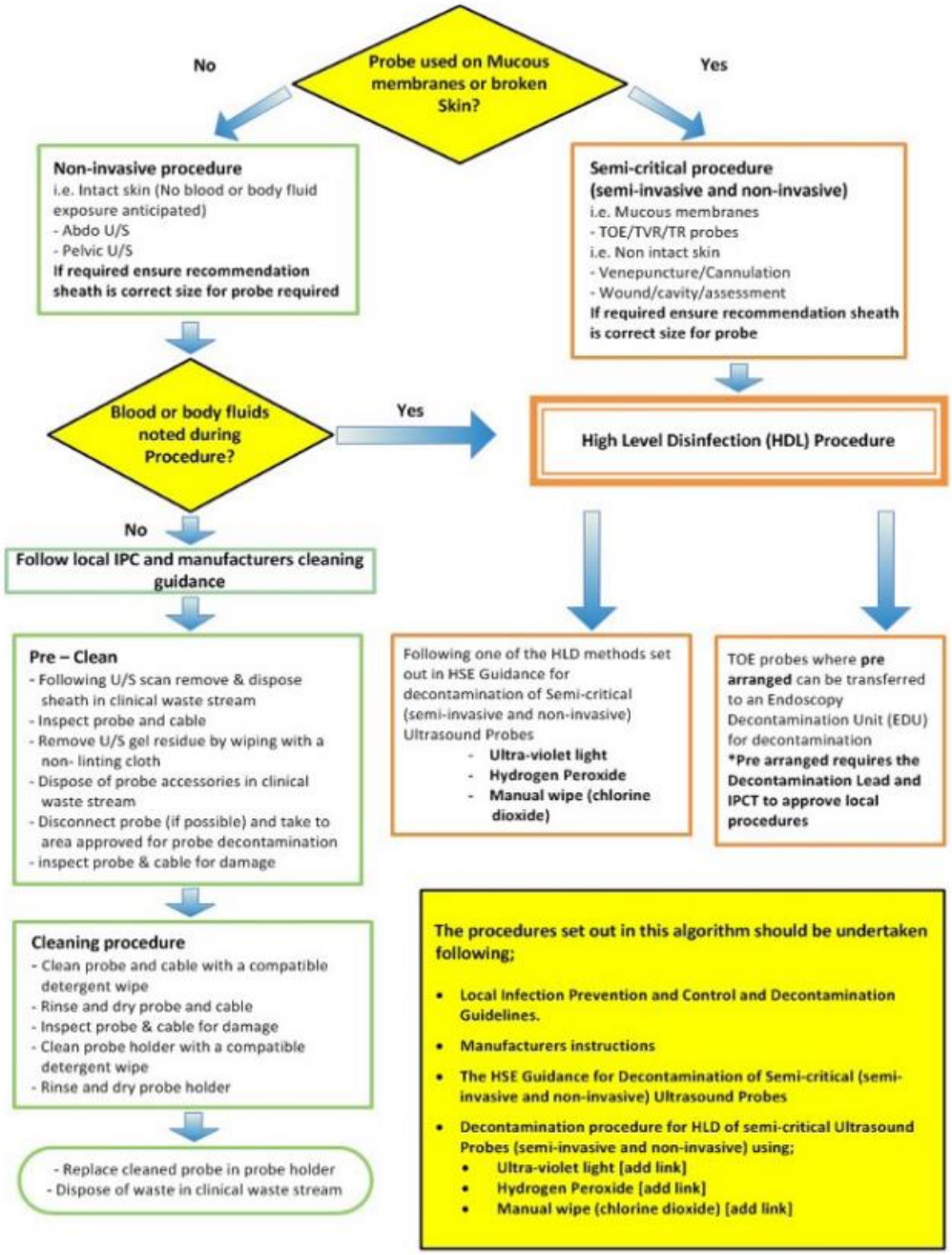
The purpose of probe barriers (sheaths) is to provide an additional layer of protection to prevent gross soiling of the reusable device. Where used, there should be consideration given to periodic bioburden testing as part of quality control, they are usually supplied as unsterile.

Literature evidence and studies are available to demonstrate the high frequency of probe sheath perforation. Use of such barriers does not negate the need for Probes to undergo full decontamination, to include manual cleaning prior and HLD between each patient use.

A sheath, designated for purpose an appropriately certificated in accordance with national standards (UKCA/CE marked) should be used for diagnostic purposes in accordance with manufacturers instructions and should be the correct size for the Probe to be used. The sheath should be visually inspected for damage after use. Where damage is identified it should be recorded in the decontamination records / patients.

Semi-critical Ultrasound Probe (semi-invasive and Non-invasive) Decontamination Algorithm

Decontamination Algorithm (Adopted from NHS Scotland Guidance Document, 2016)



23.0 References and Further reading

Department of Health *"Health Building Note 13: Sterile Service Department- NHS Estates".* Available at: NHS England » Health Building Note 13: Sterile services department

Department of Health ACDP Guidance "*Minimise transmission risk of CJD and vCJD in healthcare settings",* available at: Minimise transmission risk of CJD and vCJD in healthcare settings - GOV.UK (www.gov.uk)

Legislation gov UK "*Council Directive 93/42/EEC concerning medical devices".* Available at: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (legislation.gov.uk)

European Parliament (2002) *"The Medical Device Regulations 2002*". Available at: The Medical Devices Regulations 2002 (legislation.gov.uk)

Health and Safety Executive (1974) "*Health and Safety at Work Act 1974*". Available at: Health and Safety at Work etc Act 1974 – legislation explained (hse.gov.uk)

Health and Safety executive (2013) "*Workplace (Health, Safety and Welfare*). Regulation 1992. Approved Code of Practice and Guidance". Available at: The Workplace (Health, Safety and Welfare) Regulations 1992 (legislation.gov.uk)

Health Protection Scotland (2017*) "National Infection Prevention & Control Manual".* Available at: NHS England » National infection prevention and control

Medicines and *Healthcare* products Regulatory Agency (2021) *"Managing Medical Devices"* Available at: Safeguarding public health (publishing.service.gov.uk)

National Institute for Health and Care Excellence (2020) "*Reducing the risk of transmission of Creutzfeldt-Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues". Available at:* NICE | The National Institute for Health and Care Excellence

NHS Wales Shared Service Partnership (2017) "*Welsh Health Technical Memorandum 01-01 Decontamination of*

Surgical Instruments (medical Devices) used in acute care. Part a: Management and Provision". Available at: nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-01-01-decontamination-of-surgical-instruments-medical-devices-used-in-acute-care-part-a-management-and-provision-pdf/

NHS Wales Shared Service Partnership (2013) "*Welsh Health Technical Memorandum 01-01 Decontamination of Medical Devices within Acute Services. Part B: Common Elements".* Available at*:* https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-01-01-decontamination-of-med

NHS Wales Shared Service Partnership (2013 "*Welsh Health Technical Memorandum 01-01 Decontamination of Medical Devices within Acute Services. Part C: Steam Sterilization and Steam for Sterilization.* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2014) "*Welsh Health Technical Memorandum 01-01 Decontamination of Medical Devices with Acute Services. Part D: Washer Disinfectors".* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2014) *"Welsh Health Technical Memorandum 01-01 Decontamination of Medical Devices with Acute Services Part E: Alternatives to Steam for the Sterilization of Reusable Medical Devices".* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2014) *"Welsh Health Technical Memorandum 01-05: Decontamination in Primary Care Dental Practices and Community Dental Services".*

NHS Wales Shared Service Partnership (2017) "*Welsh Health Technical Memorandum 01-06. Decontamination of*

Flexible Endoscopes. Part A: Policy and Management". Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2014) "*Welsh Health Technical Memorandum 01-06. Decontamination of Flexible Endoscopes. Part B: Design and Installation". Available at:* Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2014) "*Welsh Health Technical Memorandum 01-06. Decontamination of Flexible Endoscopes. Part C: Operational Management".* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2014) "*Welsh Health Technical Memorandum 01-06. Decontamination of Flexible Endoscopes. Part D: Validation and Verification (including storage / drying cabinets)".* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2017) "*Welsh Health Technical Memorandum 01-06. Decontamination of Flexible Endoscopes. Part E: Testing Methods".* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

NHS Wales Shared Service Partnership (2013). "*Welsh Health Technical Memorandum 07-01. Safe Management of Healthcare Waste".* Available at: Welsh Health Technical Memoranda (WHTMs) & Health Technical Memoranda (HTMs) - NHS Wales Shared Services Partnership

UK Government (1987) "*Consumer Protection Act 1987".* Available at: Consumer Protection Act 1987 (legislation.gov.uk)

UK Government (2008) *"Health and Social Care Act 2008".* Available at: Health and Social Care Act 2008 (legislation.gov.uk)

UK Government (2006) *"National Health Service Act 2006".* Available at: National Health Service Act 2006 (legislation.gov.uk)

UK Government (2000) "*Pressure Systems Safety Regulations 2000".* Available at: Pressure Systems Safety Regulations 2000 (PSSR) (hse.gov.uk)

UK Government (2009) *"The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009*". Available at: The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (legislation.gov.uk)

UK Government (2004) "*The Control of Substance Hazardous to Health Regulations 2004".* Available at: Control of Substances Hazardous to Health (COSHH) - HSE

UK Government (2015) "*The Packaging Regulations 2015".* Available at: The Packaging (Essential Requirements) Regulations 2015 (legislation.gov.uk)

UK Government (1992) "*The Personal Protective Equipment at Work Regulations 1992".* Available at: Personal protective equipment (PPE) at work regulations from 6 April 2022 (hse.gov.uk)

Welsh Government (2015) "*Health and Care Standards".* Available at: Health and Care Quality Standards 2023 (WHC/2023/013) | GOV.WALES