GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number:** UHB 282 **Version Number:** 1 **Date of Next Review:** 23 Feb 2019 **Previous LHB Reference Number:** T40

DECONTAMINATION OF REUSABLE MEDICAL DEVICES PROCEDURE

Introduction and Aims.

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

The aim of the Decontamination of Reusable Medical Devices Policy and this associated Procedure is to ensure that Cardiff and Vale UHB provides the most effective decontamination processes to support the delivery of high quality patient care and deliver the best possible health and financial outcomes. The Decontamination of Reusable Medical Devices Policy sets minimum standards which are applicable across all sectors of the UHB's healthcare services and includes reusable Medical Devices which are deployed by partner organisations and contractors to care for UHB patients and service users. It also embeds a strong alignment to the UHB's commitment to principles of prudent healthcare by reducing wastage, variation and avoidable harm.

This Procedure has been developed so as to facilitate the consistent application of the Reusable Medical Devices Policy, as part of an overarching governance framework. It expands on the 31 governance principles established by the Reusable Medical Devices Policy and describes in detail the UHB's Reusable Medical Devices Governance Framework.

Aims:

To deliver a system-wide, consistent and robust decontamination infrastructure to provide appropriate advice to staff to ensure that effective decontamination is achieved at all UHB locations which complies with national standards.

To provide advice on the approved materials and their use for effective decontamination.
To provide advice on the approved methods for standard and effective decontamination.

Objectives

The Decontamination of Reusable Medical Devices Policy establishes a clear framework within which the UHB can;

- Effectively and actively manage the decontamination of reusable medical devices so as to reduce risk,
- Meet its legal obligations to comply with legislation,
- Meet its governance obligations, both clinical and financial,
- Meet the requirements of the relevant Health and Care Standards,
- Demonstrate that it is taking account of Welsh Health Technical Memorandum WHTM guidance,
- Meet external accrediting body quality standards covering decontamination of

reusable medical devices.

This procedure will provide advice and guidance on how to apply the policy in clinical areas which are required to decontaminate reusable medical devices.

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 been completed and this found there to be a positive impact.
Documents to read alongside this Procedure	• Cardiff and Vale UHB Policies and Procedures: ➢ 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 ➢ Health and Safety Policy • 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-D Decontamination of Flexible Endoscopes • British Society of Gastroenterology (BSG) Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy: The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee (2015 Edition)

	• Health Building Note (HBN) 13: Sterile Services Department, NHS Estates, Department of Health (2004). • Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC. • Medical Devices Regulations 2002 • Provision and Use of Work Equipment Regulations (PUWER), 1998 • Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, April 2014.
Approved by	Quality, Safety and Experience Committee
Accountable Executive	Director of Therapies and Health Science.
Author(s)	Decontamination Lead and Decontamination Group.

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 of 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. Significant specific amendments have been made to reflect national guidance: • WHTM 01-01 Decontamination of Medical Devices Within Acute Services Parts A –E • WHTM 01-05 Decontamination in Primary Care Dental Practices and Community Dental Services • WHTM 01-06 Parts A-D Decontamination of Flexible Endoscopes. • The National Institute for Health and Care Excellence (NICE) interventional procedure guidance 196: Patient safety and reduction of risk of transmission of

			Creutzfeldt–Jakob Disease (CJD) via interventional procedures (2006). • Minimise transmission risk of CJD and vCJD in healthcare settings, Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Risk Management Subgroup Department of Health, (October 2015). • British Society of Gastroenterology (BSG) Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy: The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee (2015 Edition). The Policy and Procedure are now contained in separate documents.

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1. POLICY SUMMARY

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

1.2 Wherever reasonably practicable Cardiff and Vale UHB healthcare service 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 primacy in the decision making process.

1.3 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 E) 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.

1.4 All reusable medical devices used in acute healthcare settings requiring sterilisation will be reprocessed in a Medical Device Directive (MDD) accredited facility.

1.5 Local reprocessing will only be carried out in community settings which meet the requirements of WHTM 01-05 where it is not reasonably practicable to send the medical devices to an MDD accredited facility.

1.6 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.

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

1.8 All re-usable medical devices must be decontaminated in accordance with manufacturer's instructions.

1.9 Lumened reusable medical devices must be reprocessed using a validated automated process.

1.10 Only chemicals approved by the UHB’s Infection Prevention and Control (IP&C) team will be used in UHB decontamination procedures.

1.11 Disinfectants must be used at the correct concentrations as recommended by relevant IP&C Standard Operating Procedures (SOPs) following manufacturer’s guidelines.

1.12 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.

1.13 All sterile goods must be stored in clean dry conditions.

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

1.15 All staff that are required to decontaminate reusable medical devices must be trained and competent to do so. They must have supporting evidence of an 'up to date' competence assessment.

1.16 Personal protective equipment must be worn to undertake decontamination practices where indicated by risk assessment.

1.17 All novel and emergent decontamination technologies (equipment, processes, chemistries etc.) must comply with the essential requirements of the MDD, 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 also be done in conjunction with the UHB's Medical Equipment Group for decontamination equipment.

1.18 All decontamination facilities and processes used in clinical practice will be routinely audited with findings reported to the UHB's Decontamination group.

1.19 Local self-audit tools will be available to clinical areas where decontamination of reusable medical devices is required.

1.20 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.

1.21 All equipment used in decontamination processes must be validated for its intended use, and regularly checked and inspected locally to ensure its continued fitness-for-purpose and be on an approved planned preventative maintenance contract.

1.22 A permit to work must be completed every time decontamination equipment is taken out of service for routine testing, repair and maintenance.

1.23 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.

1.24 Decontamination services must develop robust local business continuity plans to cover scheduled and unplanned disruption to service.

1.25 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'.

1.26 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 evidenced based decision making, rather than user preference. This will be done in partnership with NHS Wales Shared Services Partnership - Facilities Services (NWSSP-FS).

1.27 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.

1.28 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. This function is delegated by the Executive Director of Therapies and Health Science to the UHB's Decontamination Lead.

1.29 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.

1.30 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).

1.31 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.

2. INTRODUCTION

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 overarching requirements for UHB decontamination systems 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 it 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'.

3. OBJECTIVES

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

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

3.3 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;

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

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

3.6 To develop an effective quality management system to cover all aspects of the decontamination life-cycle;

3.7 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, staff and students;

3.8 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;

3.9 To ensure that all devices are appropriately manually cleaned using detergents that are specifically designed for the cleaning of instruments prior to high level disinfection or sterilisation. Using a manual clean process as the sole decontamination procedure must be restricted to those devices or device components deemed incompatible with automated processes by the devices' manufacturer;

3.10 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 MDD;

3.11 To ensure that any local reprocessing will only be undertaken in community settings that meet the requirements of WHTM 01-05 where it is not reasonably practicable to send the equipment to an MDD accredited facility. This decision must be supported by a comprehensive and robust documented risk assessment signed by the Primary, Community and Intermediate Care (PCIC) Clinical Board Director or Dental Clinical Board Director, Director of Infection Prevention and Control, the Decontamination Lead and User

3.12 To ensure that equipment used to decontaminate medical devices and associated equipment (for example, heat sealer machines) must be fit for purpose, validated, tested and maintained in accordance with national guidelines and manufacturer's recommendations;

3.13 To develop comprehensive service wide systems to track instrument trays and endoscopes through decontamination processes and to the patient;

3.14 To ensure that robust documented training schemes and competence assessment programmes are available for all staff that are required to decontaminate medical devices to ensure consistent high quality decontamination practices across all clinical areas.

4. DEFINITIONS

Since ambiguity with terms can be a particular problem with decontamination, the definitions used in this document are given below.

- **Contamination** - the soiling or pollution of inanimate objects or living material with potentially infectious 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 a susceptible host (person).

- **Decontamination** - a process, which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response.

Differing levels of decontamination are available. They are:

- Cleaning followed by high level disinfection; or cleaning followed by sterilisation, 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 sterilisation.

- **Disinfection** - a process used to reduce the number of viable organisms but which may not inactivate some viruses and bacterial spores.

- **Sterilisation** - a process used to render the object completely free from viable microorganisms, including viruses.

Medical Device. 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. It also covers equipment defined as medical devices. This will include:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or impairment,
- investigation, replacement or modification of the anatomy or of a physiological process,

Note: this definition includes surgical, medical, laboratory, radiological, dental, out-patient and community medical devices used for interventions or investigations, as well as other devices such as wheelchairs, hoists, beds and decontamination equipment (such as washer-disinfectors and sterilisers) with associated decontamination chemistries.

5. REUSABLE MEDICAL DEVICES

A reusable medical device is a device that is intended for multiple use and requires processing (or 'reprocessing', which may include cleaning, disinfection, packaging and/or sterilisation) to ensure that it is safe for reuse. The processing cycle can include a series of steps such as device preparation, disassembly, inspection, pre-cleaning, cleaning, disinfection (thermal and/or chemical), rinsing, drying, reassembly, packaging, sterilisation (thermal and/or chemical), and storage.

5.1 Decontamination cycle for reusable medical devices.

Regardless of the location of decontamination (for example, primary, community or acute sectors), the same standards apply. The schematic below highlights each stage of the decontamination process through which medical devices pass before every use. Effective decontamination requires the attainment of acceptable standards at all stages of the decontamination cycle for the device in line with WHTM 01-01 and WHTM 01-05. Failure to address issues in any of these stages will result in inadequate decontamination.

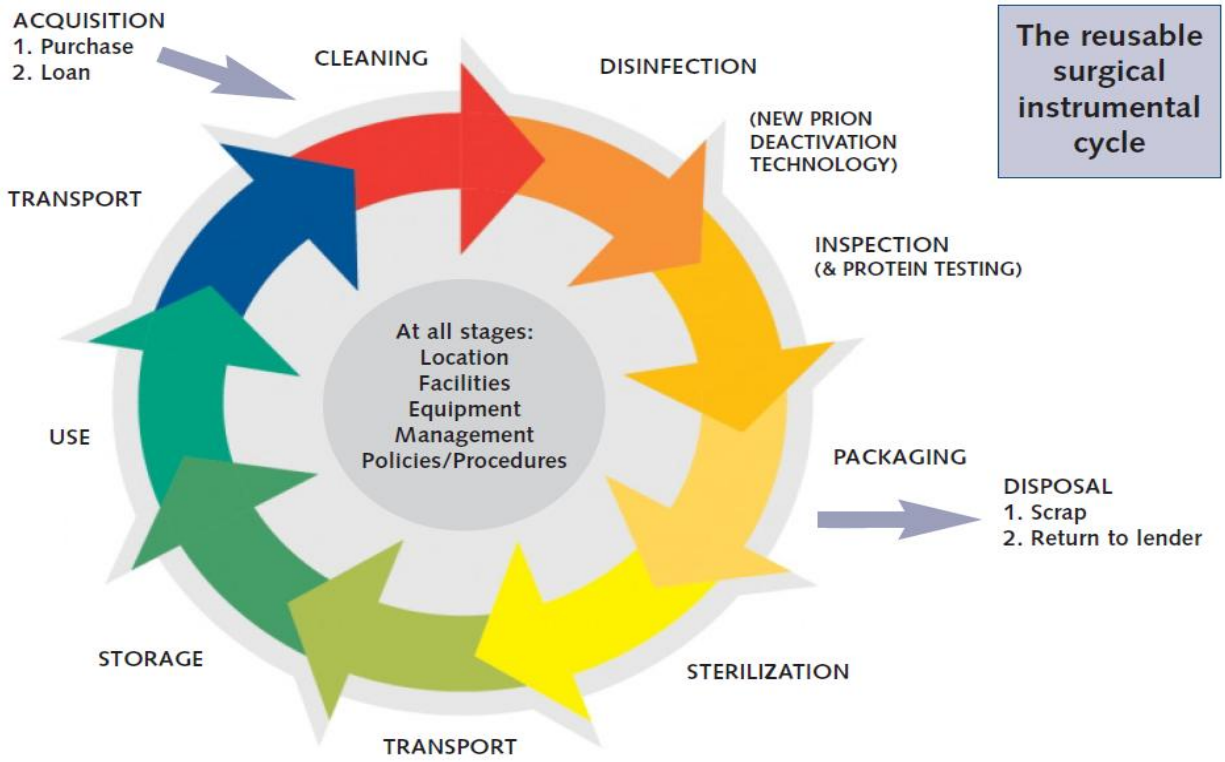


Figure1. Original Figure from WHTM 01-01 Decontamination of Medical Devices within Acute Services. Part A: Management and Environment.

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

5.1.1. The existence of effective management arrangements;

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

5.1.3. The location and activities where decontamination takes place;

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

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

5.2 Procuring reusable medical devices.

Decontamination requirements must be considered before reusable medical devices are acquired (loan or purchase) to ensure they are compatible with the decontamination procedures and equipment available. NHS Wales Shared Service Partnership (NWSSP) Procurement Services utilises a pre-purchase questionnaire prior to procurement to ensure that all medical devices purchased can be effectively decontaminated within the UHB.

It is the responsibility of the device manufacturer to provide detailed instructions to users regarding the safe and effective processing of their devices, when those devices are claimed to be reusable.

Manufacturers guidance for CE marked products must always be followed. If equipment is purchase from outside the EU then the 'User' (see section 5 Table 2 for role definition) will consult with the Authorising Engineer (Decontamination) (AE(D)) (see section 5, Table 2) to ensure fit for purpose decontamination protocols are available to ensure the safety of patients. If the manufacturer's instructions appear inappropriate or incomplete, the organisation should report this to the Medicines and Healthcare Product Regulatory Agency (MHRA) as an adverse incident using it's on line 'Yellow Card' system.

5.3 Choice of decontamination method for reusable medical/surgical devices.

The level of reprocessing required varies according to the specific piece of equipment and its intended use (including an assessment of risk of infection) and in some cases this may only include simple instructions such as cleaning and routine maintenance, while in other more detailed instructions are required. The level of decontamination should be proportional to the overall risk of infection. See Spaulding's Classification below.

Figure 2: Spaulding's Classification

Classification	Definition	Level of processing required
Critical Equipment/Device	Equipment/device that enters sterile tissues, including the vascular system.	Cleaning followed by sterilization.
Semi Critical Equipment/Device	Equipment/device that comes in contact with non intact skin or mucous membranes but does not penetrate them.	Cleaning followed by high level disinfection (HDL) as minimum. Sterilization if preferred.
Non-Critical Equipment/Device	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient.	Cleaning followed by low level disinfection. In some cases, cleaning alone is acceptable.

The choice of decontamination method for medical/surgical equipment, devices and instruments must be proportionate to the risk of infection associated with usage in a given process. For example, for medical devices the following apply

- **High risk** - Items that are in close contact with a break in the skin or mucous membrane or introduced into a sterile body area **require sterilisation** e.g. surgical or other invasive instruments.
- **Intermediate risk** - Items in contact with intact skin, mucous membranes or body fluids, particularly after use on infected patients **require disinfection or sterilisation.** Cleaning may be acceptable in some agreed situations.

- **Low risk** - Items in contact with healthy skin or mucous membranes or not in contact with the patient, **require cleaning.**

Table 1 Risk of Infection

Level of Risk	Definition	Suitable Processes	Examples
Low	Items/surfaces used in contact with intact skin or no contact is involved.	Cleaning.	Hoists, wheel chairs etc.
Intermediate	Items that have contact with mucous membranes or items/surfaces that would normally be low risk but are contaminated by microbes that are easily transmitted/likely to cause infection.	High level disinfection or sterilisation Low level disinfection	Flexible endoscopes, vaginal specula etc. Source isolation room fixtures and fittings
High	Items in close contact with broken skin or broken mucous membranes. Items that penetrate skin/mucous membranes or enter the vascular system or other sterile body areas.	Sterilisation	Surgical Instruments etc.

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.

6. CARDIFF AND VALE UHB'S DECONTMINATION MANAGEMENT INFRASTRUCTURE

Cardiff and Vale UHB has a responsibility for achieving acceptable standards of decontamination which meet statutory regulatory directives. The figure below shows an overview of the interaction between the different structures within the legislative system which provides the regulatory framework in England and Wales.

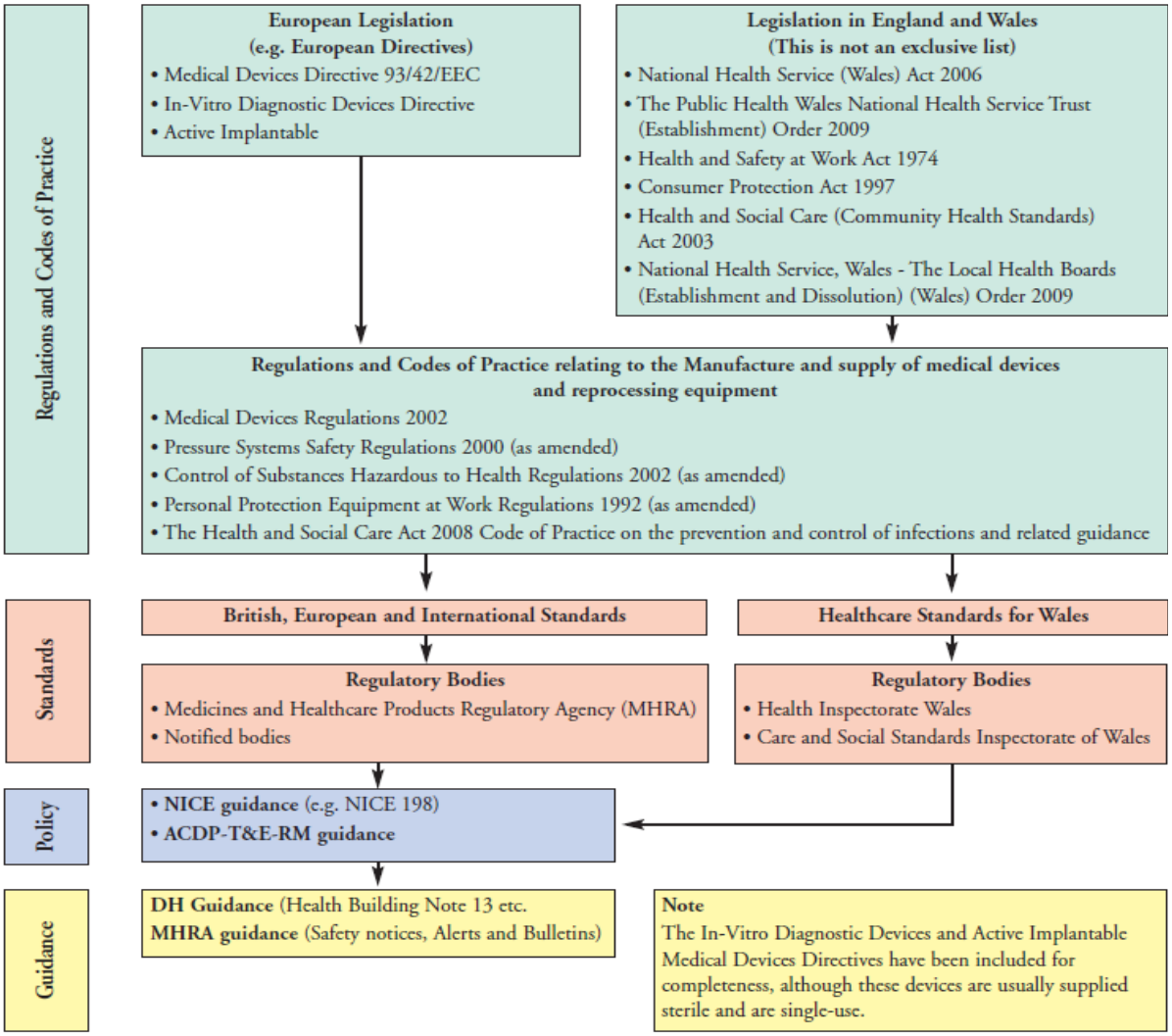


Figure 3. Original Figure from WHTM 01-01Decontamination of Medical Devices within Acute Services. Part A: Management and Environment.

In Wales there is national decontamination management structure:

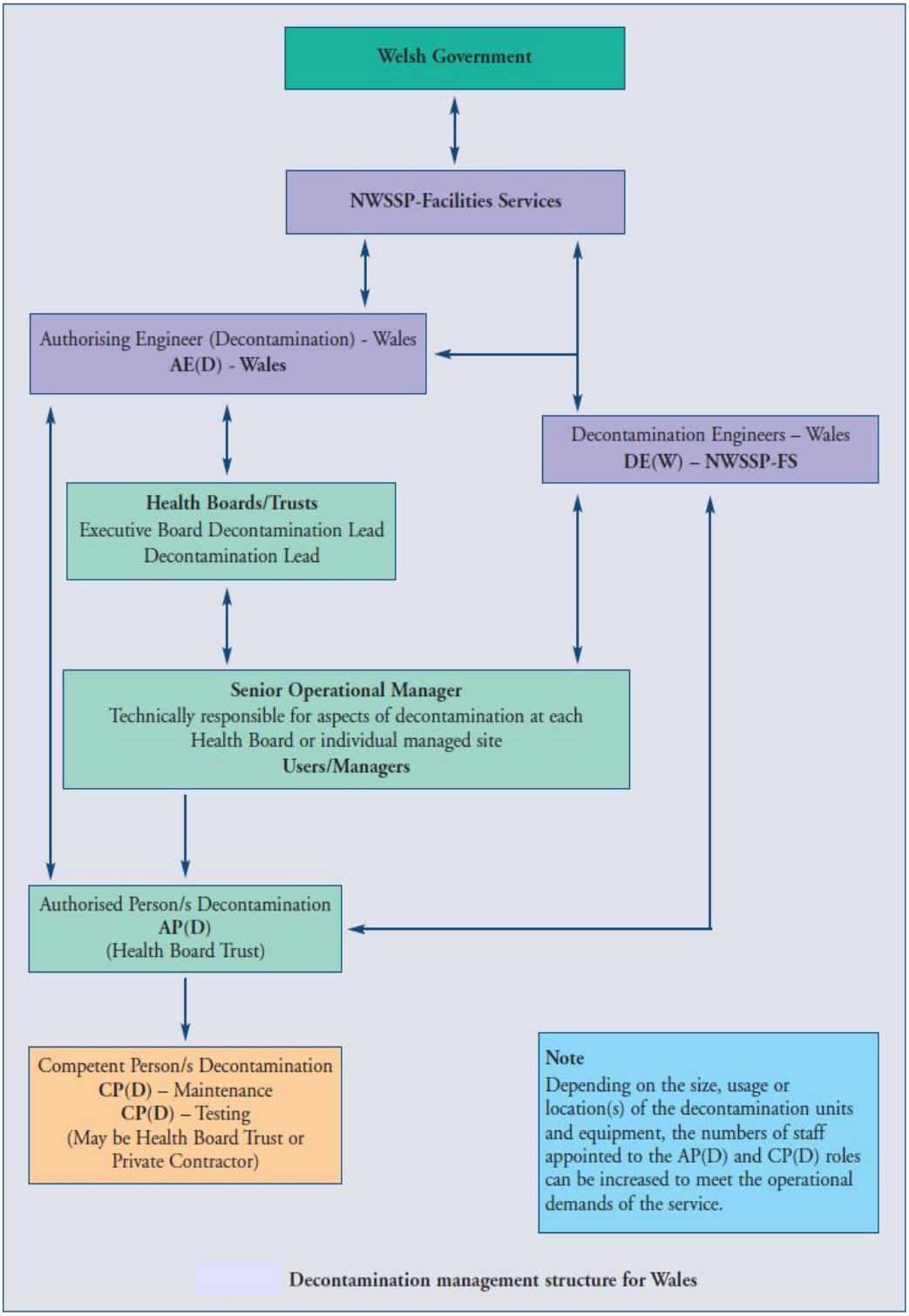
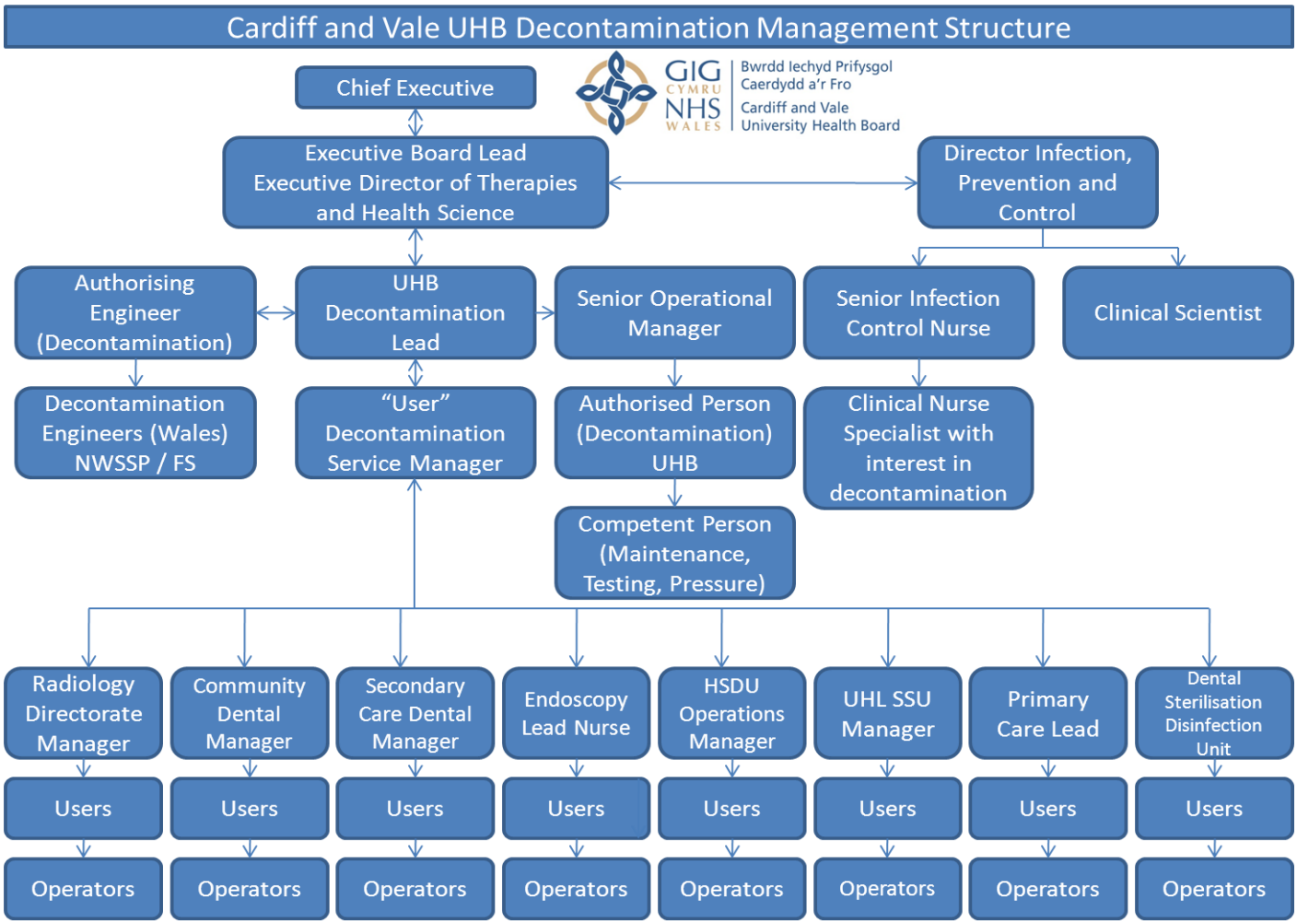


Figure 4. Original Figure from WHTM 01-01Decontamination of Medical Devices within Acute Services. Part A: Management and environment.

At Cardiff and Vale UHB the Executive Board Lead for Decontamination with responsibility for achieving acceptable standards of decontamination which meet statutory regulatory directives is the Executive Director of Therapies and Health Science. The Executive Director of Therapies and Health Science has in turn delegated responsibility to the Assistant Director of Therapies and Health Science as Decontamination Lead for the UHB.

Figure 5: Organogram for the management of decontamination at Cardiff and Vale UHB.



WHTM 01-01 and WHTM 01-05 establishes a number of functional requirements necessary to ensure appropriate standards are met within the UHB. All individuals must be appropriately qualified, knowledgeable and experienced to demonstrate competence to undertake formal roles as established in WHTM 01-01 (Part A) and WHTM 01-05 (Section C, Chapter 9)

Table 2: Nominated individuals as set out in WHTM 01-01 and WHTM 01-05: Decontamination of medical devices within acute services. Part B: Common Elements.

WHTM 01-01 and WHTM 01-05 Role	General areas of responsibility	UHB Designated Individual
Executive Board Lead	Has ultimate management responsibility for decontamination in the UHB	Executive Director of Therapies and Health Science
Decontamination Lead	Organisationally responsible for the effective and technically compliant provision of decontamination services.	Assistant Director of Therapies and Health Science
Senior Operational Manager	UHB role responsible technically, professionally and managerially for the engineering aspects of decontamination	Director of Capital, Estates & Facilities
User	Responsible for the management of the decontamination processes and operators, management of surgical instrument decontamination and to ensure decontamination equipment is fit for use	Service Manager Decontamination
Authorising Engineer (Decontamination) (AE(D))	Provide independent and impartial advice on all aspects of decontamination	Senior Decontamination Engineer, NHS Wales Shared Services Partnership - Facilities Services
Authorised Person (Decontamination) AP(D)	UHB estates management role responsible for the practical implementation and operation of safety policy and procedures relating to the engineering aspects of decontamination equipment	Assistant Mechanical Project Engineer
Competent Person (Decontamination) CP(D)	Responsible for validation, testing and maintenance of decontamination equipment	Assistant Mechanical Project Engineer
Competent Person (Pressure Systems) CP (PS)	Engineer responsible for drawing up a written scheme of examination for the system.	Assistant Mechanical Project Engineer
Decontamination Engineers (Wales) NWSSP- FS	Support and undertake the testing programme of decontamination equipment on behalf of Welsh Government	Decontamination Engineers, NHS Wales Shared Services Partnership - Facilities Services
Lead for Infection Prevention and Control	Responsible for advising the 'User' on all infection control aspects	Director of Infection, Prevention and Control
Microbiologist (Decontamination)	Responsible for advising the 'User' on microbiological aspects of decontaminating medical devices	Director of Infection, Prevention & Control

Operators	Responsible for operating decontamination equipment. These tasks must be defined in job descriptions and records of regular training and competence assessment must be available.	Multiple operators in all clinical services which utilise reusable medical devices.

7. DECONTAMINATION TRAINING AND COMPETENCE

Decontamination is a science in its own right. Staff undertaking decontamination must be competent and properly trained to ensure consistent, predictable and high quality decontamination outcomes in all clinical areas in the UHB. 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 on-going staff training. Personal protective equipment must be worn to undertake decontamination practices where indicated by risk assessment.

The User who is responsible for the day-to-day management of decontamination processes (including equipment) has responsibility for ensuring that the equipment is operated safely and efficiently. Where necessary the User should seek professional advice from an Authorising Engineer (Decontamination) (AE(D)) and the decontamination engineers at NWSSP-FS on all aspects of the decontamination process, including procurement, maintenance and testing, and ensure that maintenance and testing is carried out by a suitably qualified Competent Person (Decontamination) (CP(D)) with the assistance from a Microbiologist (Decontamination) where microbiological testing is required.

8. SURGICAL INSTRUMENT MANAGEMENT INCLUDING ENDOSCOPES

Management of surgical instruments in WHTM 01-01 (Parts A to E) relates to those used in acute care. In this context, management of surgical instruments should make sure that all infection risks associated with surgical and interventional radiological procedures are removed where practically possible.

It is important to understand that utilising existing processes it takes a minimum time of between 8 to 10 hours to produce a sterile surgical instrument set within the UHB's sterile services facilities including the Hospital Sterilisation and Disinfection Unit (HSDU) and Dental Sterilisation and Disinfection Unit (DSDU). Whilst every effort is made to affect a return of the set(s) as soon as safely possible, timing cannot be altered to accommodate demand. Therefore stocks of critical medical equipment should be sufficient to accommodate the necessary cycle time for safe and effective decontamination so that patient or operator safety is never compromised. The same requirement applies to endoscopes acknowledging that the decontamination cycle time can be considerably shorter using an Automated Endoscope Reprocessor (AER) or sometimes called an Endoscope Washer Disinfector (EWD).

8.1 Keeping instruments moist between use and reprocessing

Advisory Committee on Dangerous Pathogens (ACDP) 2015 guidance 'Minimise transmission risk of CJD and vCJD in healthcare settings' states that allowing surgical instruments to dry for more than fifteen minutes before reprocessing greatly increases the amount of residual protein contamination. ACDP guidance also indicates that the level of residual protein on surgical instruments should not exceed 5 µg after sterilisation. Therefore instruments should be transported to the nearest MDD accredited Sterile Service Department (see section 15) immediately after the close of the procedure, for cleaning and reprocessing, or as soon as practically possible. This time must not exceed 3 hours.

Prions which are the causal agent in Transmissable Spongiform Encephalopathies (TSEs) (see section 9) are hydrophobic proteins. The attachment of hydrophobic proteins to surfaces becomes less reversible if they are allowed to dry fully onto a surface. Keeping the environment around soiled instruments at or near saturation humidities (moist) prevents full attachment of hydrophobic proteins such that they are more efficiently removed by cleaning.

A number of means are available to generate moist conditions, including the use of enclosed containers/bagged trays used with single-use moist pads, gels, foams, water sprays or other methods as determined locally with the User and AE(D). However, whatever method is used, care should be taken to ensure that all parts or surfaces of the surgical instruments are constantly exposed to the moist environment. The preferred methodology should be documented by the Clinical Service in local standard operating procedures which will be authorised by the User. These processes must form part of staff training programmes and competence assessments. The transport of surgical instruments for decontamination will also form part of the UHB's routine decontamination audit cycle.

8.2 Tracking and Traceability

It is important to be able to track surgical instruments through the decontamination process to which they have been subjected to ensure that processes have been carried out correctly. In the event of a sterilisation cycle failure products can then be recalled. This duty extends to the life cycle usage of all 'critical' reusable medical devices used in high risk procedures (figure 2, table 1) no matter whether they are owned, loaned or ex demo purchased products.

Tracking and traceability records are kept by the UHB for a minimum of 15 years. A computerised system is used for this purpose within the HSDU and DSDU at the University Hospital of Wales (UHW) and Sterile Service Unit (SSU) at University Hospital Llandough (UHL). The same system allows full traceability to each patient.

Any related information, which may include the number of times 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 and enables corrective action to be taken when necessary. These records must link directly to patients where they were used.

Records are 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 being processed;

d. which patients have been treated with the tray;

e. the equipment cycle details.

Single instruments (screws, plates, implantable items etc.) used in patient procedures and included in sterile packs individual or part of an instrument set, any such items must be fully traceable. Sets of instruments are issued with a barcode label which are scanned into the patients electronic theatre record.

Where this system is not available the removable bar code sticker must be inserted in the patients operating notes and, if possible, into the theatre register. This identifies which set was used for the patient and the decontamination process it has undergone.

Tracking systems are used for endoscopes processed through AERs where the same principles of tracking and traceability apply.

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.

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 instrument marking technologies should be considered. Advice on suitable technologies must be sought from the User.

Accurate identification of instruments is essential for the correct reunification of instruments with their sets following repair or replacement.

For those instruments, including delicate components such as electronic devices or imaging related markers, the use of single instrument identification should be used. When marking is combined with properly managed decontamination procedures the individual instrument may be correctly identified as requiring a non-standard approach to washing, disinfection or sterilisation.

Accurate instrument identification and tracking and traceability also retains the integrity of the instruments warranty and for instruments which are limited in terms of the number of use cycles, authorised by the manufacturer under CE marking.

When single-use surgical instruments are used, they must be separated from reusable surgical instruments and disposed of at the end of the procedure. It is

important that the single-use instruments are not allowed to enter reusable instrument sets.

8.5 Handling of Surgical Instruments on loan from other Organisations

In the event of use of loaned surgical instruments e.g. trial instruments provided by suppliers, these devices will require thorough and appropriate decontamination processes prior to use. They will then be subject to the same rigorous decontamination systems as the equipment owned by the UHB in line with manufacturer's reprocessing instructions. They all also subject to all 'tracking and traceability' requirements (section 8.2). Advice form the User should be sought before accepting any loan equipment to ensure that the UHB has appropriate decontamination processes available to deal with the equipment**.**

8.6 Single Use / Single Patient Use Device

The expression single use on the packaging of medical devices means that the manufacturer:

- Intends the device to be used once and then discarded.
- Considered the device in not suitable for use on more than one occasion.
- Has evidence to confirm that reuse would be unsafe

The above symbol is used on medical device packaging indicating **'DO NOT RE-USE'** and may replace any wording.

8.7 Storage of sterile goods

All sterile goods must be stored in clean dry conditions with environmental control systems in place to monitor temperature and humidity. The shelving or storage units should be easy to clean and this should be done on a regular basis to prevent the build-up of dust. The door to the storage room should be kept closed. Items in torn or damaged packaging will not be sterile; this equipment must therefore not be used and either returned to the relevant unit for reprocessing if non-disposable or discarded in the case of single use items.

Packs of reusable instruments that are processed through a MDD with a sterilisation date of more than one year should be returned for reprocessing. Packs of reusable instruments that are processed in local decontamination facilities in accordance with WHTM 01-05 should be stored as detailed in Section B, Chapter 2. Storage of

Sterile instruments must be subject to regular surveillance audits to ensure all sterile items are 'in date'.

8.8 Theatre and clinical instruments used within the acute setting.

All re-useable instruments must be decontaminated and inspected to ensure that they are "fit for purpose" prior to packing and sterilising. Any faulty instruments found must be sent for repair or replaced. If sent for repair, a concession of quarantine of the set must be agreed and sanctioned with the relevant theatre clinical leader.

Wet packs - if there are signs of dampness on the outer wrap or moisture on the equipment after removal from packaging, the instrument trays must be returned for reprocessing.

Sterile instruments which are dropped during surgery should be managed in accordance with the 'Dropped Instrument Algorithm' Appendix 2.

8.9 Endoscopes

All endoscopes with lumens must be reprocessed using validated automated processes authorised by the User and AE(D). See Appendix 5 for endoscope decontamination pathway. Reprocessed endoscopes must be inspected to ensure that they are clean and safe for re-use. Endoscopes will remain safe to use for 3 hours after reprocessing unless stored in a validated drying cabinet or a dedicated cassette. The quality and continued fitness-for-purpose of all endoscopes should be periodically reviewed in accordance with manufacturer's instructions. All endoscopes must be on an approved maintenance contract.

Endoscopes must be stored securely in dedicated, validated drying cabinets which have been approved for use by the User and AE(D). Safe storage time will be determined by the User and AE(D) and confirmed through the validation process. This will allow maximum safe storage time for endoscopes after decontamination. It will also prevent unauthorised access and permit easy identification of endoscopes from tracking and traceability purposes.

The Decontamination Group will co-ordinate local risk assessments of endoscopes in collaboration with the UHB's Medical Equipment Group. These risk assessments are mandated by WHTM 01-06 Decontamination of flexible endoscopes. Part A: Policy and management. This will standardise equipment where practicable and drive forward consistent quality improvements.

8.10 Endoscope transport and storage

The British Society of Gastroenterology (BSG) Standards contained in its 'Guidance on Decontamination of Equipment for Gastrointestinal Endoscopy' indicates that endoscopes must never be kept outside storage facility / cabinets that have been approved by the User for more than 3 hours without being reprocessed. This is to include:

- transportation time between reprocessing or leaving storage at the remote site

- return to storage at the endoscopy unit;
- the time between storage and next patient use in the unit itself.

Vacuum packing systems can be used to stabilise endoscopes for greater than 3 hours if decontamination cycle times exceed the 3 hour rule. In these circumstances advice must be sought from the User.

All endoscope storage cabinets including drying cabinets must be approved by the User for use at any Cardiff and Vale UHB facility. Capital equipment items will also require sign off by the Medical Equipment Lead for the UHB as part of the procurement process.

8.11 Laryngoscopes

If single use laryngoscope handles are not available, reusable laryngoscope handles must be decontaminated appropriately between each patient use, in accordance with the manufacturer's instructions. The laryngoscope handles where possible must be returned to sterile services for reprocessing.

Some Video laryngoscopes are temperature sensitive and must be reprocessed through an AER or sterilised using low temperature sterilisation (ethylene oxide / hydrogen peroxide).

9. MANAGMENT OF INSTRUMENTS POTENTIALLY CONTAMINATED WITH TRANSMISSABLE SPONGIFORM ENCEPHALOPATY (TSE) PROTEINS.

Transmissible Spongiform Encephalopathies (TSEs) (otherwise known as prion diseases) are rare, fatal degenerative diseases affecting the central nervous system (CNS). TSE conditions include Creutzfeldt–Jakob disease, new variant Creutzfeldt–Jakob Disease (nvCJD, a human disorder related to Bovine Spongiform Encephalopathy), Gerstmann–Sträussler–Scheinker syndrome, Fatal Familial Insomnia, Kuru, and Variably Protease-Sensitive Prionopathy.

TSEs are caused by unconventional infectious agents currently thought to be infectious proteins (apparently without nucleic acid) known as prions. Prions do not share the normal properties of viruses or bacteria. Consequently TSEs are resistant to many conventional decontamination processes. They are not significantly affected by disinfectants such as formalin and ethylene oxide, and infectivity persists after standard autoclaving (for example, 134°C for three minutes). They are also extremely resistant to high doses of ionising and ultraviolet irradiation, and some residual activity has been shown to survive for long periods in the environment. Research shows that the use of Hydrogen Peroxide sterilisation can improve prior de-activation, and should be considered wherever possible for high risk sets. This should be discussed with the User and AE(D).

The Advisory Committee on Dangerous Pathogens (ACDP) in its guidance 'Minimise transmission risk of CJD and vCJD in healthcare settings' has categorised surgical procedures on patients known, or suspected, to have CJD into high, medium and low risk, depending on the type of tissue involved. Therefore instruments in contact

with high-risk tissues must not move from one instrument set to another NICE guidance has categorised the central nervous system and posterior eye (retina and optic nerve) high-risk tissues.

For surgical instruments that come into contact with high risk tissues:

- The User will ensure that processes are in place to ensure supplementary instruments remain with the set to which they have been introduced.
- Rigid rather than flexible neuroendoscopes must be used wherever possible.
- All accessories used through neuroendoscopes must be single-use.
- The National Institute for Health and Care Excellence Interventional Procedure Guidance 196 recommends a separate, segregated pool of reusable instruments and neuro-endoscopes for patients born before, and after 1st January 1997 who are due to undergo high-risk procedures. However the agreed procedure followed at Cardiff and Vale Health Board has been determined by risk assessment and has been accredited by the notified body acting on behalf of the MHRA which is the designating and competent authority in the UK.
- All neuro-surgery instruments are segregated within the disinfection area, are processed on a designated washer disinfector cycle and wrapped in a designated wrap to identify the set as high risk. All paediatric instruments for the All Wales Childrens Hospital, are processed on a designated load, and are identified with a designated wrap indicating Children's Hospital for Wales.

Single-use instruments should only be used if they are of equivalent quality to reusable instruments to mitigate surgical, clinical quality risks. Expert decontamination advice must be sought by Neurosurgery services when procuring surgical equipment. The User, AE(D) and the UHB's Medical Equipment Group should be consulted prior to purchase of new neurosurgical equipment. This will allow proportionate and balanced decision to be made weighing up clinical and infection risks. This decision must be documented as a formal risk assessment. This risk assessment must be signed by the Clinical Board Director for Specialist Services, the User, AE(D) and Microbiologist (Decontamination).

10. RETURNING EQUIPMENT SAFELY FOR REPROCESSING

It is essential that reusable medical devices sent to the UHB's sterile service units are returned in a safe manner which will not unduly expose members of staff in these units to an "infection" risk / "sharps" injury. Medical devices should be rigorously cleaned with no visual contamination present on the medical device prior to transport. Sharps should be appropriately sheathed or covered to reduce the risk of injury.

Breaches of this duty of care will be dealt with under the UHB's 'Disciplinary Policy'.

11. INCIDENT REPORTING

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 e-Datix system (or paper reports where e-Datix is unavailable) within the UHB by the relevant operators. 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).

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 to sterilisers include:

a. poisoning by sterilant;

b. any illness caused by a pathogen.

Depending on the severity of the in impact of the decontamination incident it may be reported to Welsh Government as a Serious Incident. Where incidents involve a defect in decontamination equipment these should additionally be reported to the MHRA through their online 'Yellow Card' reporting system and tabled for discussion at the UHB's Medical Equipment Group. The Clinical Engineering Department at UHW can be contacted for advice.

The User should be made aware of all adverse incidents involving decontamination so that necessary advice can be provided on necessary remedial or corrective actions. Where necessary the User will consult the AE(D) for advice. All incidents involving decontamination should also be discussed at the UHB’s Decontamination Group.

Operators and others concerned with the operation of items of decontamination equipment should know what action to take in the event of an incident or failure. This should be included in local decontamination training programmes. Serious defects or incidents which must be reported include:

a. failure to properly decontaminate a product;

b. danger to personnel;

or

c. damage to the product.

If a serious defect occurs, the item of decontamination equipment should be immediately withdrawn from service and should not be used until all necessary repairs have been made and a repeat validation has been carried out. If the defect involves a pressure vessel, an inspection by the CP(PS) is required.

Certain types of defect should be reported to NWSSP-FS. Reportable defects are those where some central action might be helpful in bringing about necessary improvements in the standards of safety, design, construction, performance reliability or economics. Examples of reportable defects include:

a. accidents involving sterilisers;

b. failures of the integrity of the pressure vessel – that is, failures of door mechanisms, explosions and bursting or cracking of parts of the chamber, door, jacket or structural members;

c. incipient or potential defects likely to lead to such failures;

d. failures of basic safety devices connected with the closing or opening of the door and pressurisation of the chamber;

e. failures of electrical safety;

f. any constructional features which do not conform to safety codes or with accepted good practice, or are hazardous in some way;

g. any unusual circumstances which may jeopardise safety or proper functioning (for example, if safety devices or the automatic process controls can be defeated under certain conditions);

h. inability of a properly maintained and operated machine to meet its specified performance standards;

i. unreliability, persistent malfunction, frequent failures of particular components or any other feature which generates excessive or abnormally expensive maintenance or operational requirements, having regard to the intensity of use and operating conditions;

j. electromagnetic interference to or from other equipment, and particularly to computer control systems.

All adverse incidents involving transportable (bench-top) sterilisers should be reported to the MHRA utilising their on-line 'Yellow Card' system. The reporting procedure is set out in its medical device bulletin DB2011(01) – Reporting adverse incidents and disseminating medical device alerts.

Adverse incidents involving permanently installed sterilisers should be reported to the AP(D), MHRA and NWSSP-FS. The reporting procedure is set out in the Welsh Government MDA/2004/054 (Wales) - Reporting defects and failures relating to non-medical equipment, engineering plant, installed services, buildings and building fabrics. The User should display a notice on, or near, each item of decontamination equipment setting out the appropriate reporting procedure.

12. DECONTAMINATION PERMIT TO WORK SYSTEM

The permit to work form (Appendix 3) is designed for use with decontamination equipment which is used to:

1. decontaminate reusable medical devices and good;

2. produce sterile products;

or

3. make safe infected items.

A permit to work must be completed every time decontamination equipment is taken out of service for routine testing, repair and maintenance by the CP(D).

The CP(D) will sign the permit to allow the equipment back into routine use. The User must also sign the permit. After repairs following a breakdown and after quarterly testing, both, AP(D) and the User should sign the permit to allow the equipment back into use. The DE(W) from NWSSP-FS 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 authorized 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.

In addition, when particular departmental specific requirements dictate (such as when testing involves using biological indicators), other personnel should sign the permit. This could include the Microbiologist (Decontamination) or the Quality Control Pharmacist or Laboratory Quality Manager or Safety Officer to comply with departmental quality management systems.

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

13. DECONTAMINATION OF EQUIPMENT PRIOR TO SERVICE OR REPAIR

Anyone who inspects, services, repairs or transports medical, dental or laboratory equipment, either on hospital premises or elsewhere, has a right to expect that medical devices and other equipment have been appropriately decontaminated; appropriate documentation must be provided to indicate the decontamination status of the item (Dept. Health MHRA DB20039(05) June 2003). Cardiff and Vale UHB has a duty of care to those individuals to provide a complete and accurate declaration of contamination status form (Appendix 4)

If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, suppliers etc. may refuse to handle such items until they have been decontaminated and a declaration provided. These standards are also applicable to outsourced maintenance / repair services and evidence of compliance should be established as part of any service tender process.

In particular situations, for example when in the condition of an item which is the subject of complaint or investigation may be altered or influenced by a decontamination process, the investigator may wish the item not to be decontaminated. In such situations, the advice of the investigating body should be sought and, if the item is to be dispatched from the hospital premises:

- prior warning should be given to the intended recipient.
- the condition of the item should be clearly labelled so that it can be determined prior to opening of the inner packaging.
- the packaging should be sufficiently robust to withstand transport.
- the packaging should ensure that the content of the inner pack cannot contaminate the outer one.
- Items subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand. Any loaned items being returned to a manufacturer or supplier should also be decontaminated. Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the manufacturer for investigation. In this situation, contact the manufacturer to find out the most appropriate method of decontamination.
- Once decontamination has been completed, the items should be labelled accordingly and a declaration of contamination status form completed (or sent electronically) (Appendix 4).

Decontamination of Medical Devices to be returned to the Equipment Loan Service at UHW and UHL should be discussed with the UHB's Clinical Engineering Department.

14. DISPOSAL OF DECONTAMINATION WASTE

Waste Management for the Health Board is the responsibility of the Operational Services. All decontaminated waste should be disposed of in accordance with the Cardiff and Vale UHB's 'Waste Management Policy'.

15. STERILE SERVICES

All reusable medical devices used in acute settings will be reprocessed in a Medical Device Directive (MDD) accredited facility. MDD accredited sterile services for the Health Board are provided by:

- Hospital Sterilisation and Disinfection Unit (HSDU) - UHW
- Sterile Services Unit (SSU) - Llandough Hospital
- Dental Sterilisation and Disinfection Unit (DSDU), University Dental Hospital, UDH, UHW campus

The UHB's HSDU and DSDU provides a decontamination and sterilisation service to all Operating Theatres, Wards and Departments at UHW and UDH. The Units' Quality Management System complies with BS EN ISO 9001:2008, BS EN ISO13485:2013 and the Medical Device Directive 93/42/EEC, the Medical Devices Regulations S1618 and the subsequent amendments of 2007/47/EC.

16. LOCAL REPROCESSING

The standards for decontamination are the same regardless of the locality the health care setting where of the decontamination equipment is used (e.g. primary care Dentistry, Podiatry, Ophthamology, Artificial Limb and Appliance Service (ALAS), Joint Equipment Stores (JES), Diabetic Retinopathy Screening Service for Wales (DRSSW) etc.). Local reprocessing will only be performed in exceptional circumstances in community settings where it is not reasonably practicable to send 'critical' medical devices (figure 2) used for high risk interventions (table 1) to an MDD accredited facility. This decision must be supported by a comprehensive and robust documented risk assessment signed by the relevant Clinical Board Director (PCIC or Dental), Director of Infection Prevention and Control, the Decontamination Lead and User. If the decision is made to continue with local reprocessing then it MUST conform to all applicable standards and guidance, maintained with periodic auditing of processes and facilities to assure on-going compliance. The UHB's decontamination group will provide oversight to these audits.

17. ENVIRONMENTAL STANDARDS FOR DECONTAMINATION FACILITIES.

All UHB facilities in which medical devices are to be reprocessed should have appropriately segregated processes. The environmental conditions should be controlled to prevent contamination (this includes both microbial and particulate contamination). "Environmental conditions" not only refers to the cleanliness of

surfaces, fittings and equipment, but also to ventilation and air quality in respect of filtration, airflow patterns and relative air pressures.)

Health Building Note 13 provides comprehensive guidance to allow the UHB to make informed decisions about how to meet these standards (with support from NWSSP-FS). This guidance must be referenced when refurbishing existing decontamination facilities or designing new builds.

Water quality is critical to effective decontamination in automated repossessing machines and must adhere to standards established in WHTM 01-06 Part B 'Design and installation'. Guidance must be sort from the User, the IP&C team and AE(D) when installing water systems or assessing water quality. Assurance will be sought by the Water Safety Group on compliance to available water quality standards. Regular checks of water quality must be undertaken to check that the periodic final rinse-water tests comply with standards contained in WHTM 01-06 "Decontamination of flexible endoscopes. Part D: Testing methods" Particular attention must be given to ensure that Total Viable Count (TVC) for Colony Forming Units (CFU) are within limits described in WHTM 01-06 Part D.

18. HYDROGEN PEROXIDE VAPOUR (HPV) DECONTAMINATION

The UHB has a number of 'Dry Mist Hydrogen Peroxide Area Decontamination' machines at UHW and UHL. Hydrogen Peroxide Vapour (HPV) is a vapour form of hydrogen peroxide (H2O2) with applications as a low-temperature antimicrobial vapour used to decontaminate enclosed and sealed clinical areas where it decontaminates exposed room / equipment / fixture / fittings surfaces. It can also be used to decontaminate suitable medical equipment in dedicated enclosed and sealable rooms.

HPV is effective against a wide range of microorganisms including bacteria, viruses and fungi. It is particularly useful in reducing incidence of common HCAIs such as Norovirus, Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Enterococci (VRE), Clostridium difficile (C. diff), Acinetobacter baumanii, Pseudomonas aeruginosa and antibiotic-resistant Klebsiella pneumoniae. The HPV machines are easily transportable, therefore in the event of outbreaks on other sites other than UHW and UHL they can easily be brought into use. The efficacy of HPV has been repeatedly demonstrated against bacterial endospores, which are the most resistant organisms commonly found on environmental surfaces.

HPV decontamination can be arranged through the Operational Services department. Advice should be sought from the UHB's IP&C team to ensure the efficacy and appropriateness of the use of HPV. The UHB's Clinical Engineering Department should be consulted if medical devices are to be decontaminated using HPV to ensure that the device is suitable for HPV decontamination. This will ensure that decontamination is in line with manufacturer's guidance and that the device will not be adversely affected by the process.

19. TROPHON DECONTAMINATION SYSTEM FOR ULTRASOUND TRANSDUCERS (PROBES)

The Trophon decontamination system also uses hydrogen peroxide to decontaminate intracavity probes (ultrasound transducers). Trophon units have been strategically located in high risk clinical areas where the use of this system is both economically viable and it's cycle time optimises clinic capacity. In areas where Trophon systems are not available the Tristel Trio wipe system must be used to decontaminate ultrasound probes in keeping with UHB procedures and following local Standard Operating Procedures.

20. V-PRO LOW TEMPERATURE STERILISATION SYSTEM

The V-Pro system is available to decontaminate heat and moisture sensitive medical devices. The V-Pro uses hydrogen peroxide vapour and can be utilised to decontaminate single or dual channel flexible endoscopes. It is also used for specialist decontamination of complex medical equipment e.g. the Urology Surgical Robot. The User will be able to provide advice on the best technology available in the UHB to decontaminate medical devices.

21. ETHYLENE OXIDE DECONTAMINATION

The use of Ethylene Oxide (EtO) on UHB premises is prohibited on UHB premises as it is a recognised explosive hazard. Any medical equipment which cannot be sterilised using technologies available in the UHB (V-Pro or other HPV systems) must be sent off site to accredited EtO Decontamination. The User will provide advice on the suitability of EtO decontamination and UHB approved off site providers,

22. CHEMICAL DISINFECTION

Only disinfectants approved by the Infection Prevention and Control Department can be used in the UHB. No other disinfectant should be used.

It is essential that only personnel with the appropriate training handle disinfectants. Suitable protective clothing must be worn including impervious gloves, plastic aprons and goggles or face shields if splashing is likely.

Disinfectants must be used at the correct concentration recommended in this procedure. Using disinfectants at concentrations lower than those stated will reduce their effectiveness. Use at higher concentrations is wasteful, may leave residues, exposes the user to greater risk of sensitisation, in some circumstances reduces effectiveness and could be damaging to equipment.

22.1 Hypochlorites and Dichloroisocyanurate

e.g. Haz-Tab®, Actichlor®, Presept®, Milton®

These have a wide range of activity against bacteria, fungi and viruses, including bacterial spores. These are the disinfectants of choice for use against viruses and environmental decontamination where blood is involved.

They are however readily inactivated by organic matter, lose their activity on storage, are corrosive to metals and should be used on clean surfaces. They are supplied as liquids, tablets or powder for use on blood spillages. It is important that the correct concentrations in parts per million (ppm) are used for specific situations (see Table 3).

Table 3. In-use concentrations.

USE	AVAILABLE CHLORINE	
	%	PPM
BLOOD SPILLAGE	1.0	10 000
ENVIRONMENTAL DECONTAMINATION	0.1	1 000
INFANT AND OTHER FEEDING UTENSILS	0.0125	125

Care must be taken when making up the solutions or when diluting them because of their corrosive nature.

Table 4: In - use concentrations of hypochlorite solutions

STOCK SOLUTION (PPM)	USE	REQUIRED DILUTION OF STOCK
10 000	BLOOD SPILLAGE	UNDILUTED
	ENVIRONMENTAL DECONTAMINATION	1 IN 10
	INFANT AND OTHER FEEDING UTENSILS	1 IN 80
100 000	BLOOD SPILLAGE	1 IN 10
	ENVIRONMENTAL DECONTAMINATION	1 IN 100
	INFANT AND OTHER FEEDING UTENSILS	1 IN 800

Hypochlorite solutions are usually supplied as either a 100 000 ppm (i.e. 10%) stock solution or 10 000 ppm (1%) (Milton®), the required dilutions for use therefore depend on the initial concentration of hypochlorite and its intended use (see Table 4)

Sodium dichloroisocyanurates (NaDCC) are supplied in tablet form (e.g. Haz- Tab®, Actichlor®) and are made up by dissolving a given number of tablets in a measured amount of water. The size of the tablets and the number needed to provide the working dilutions of the disinfectant varies depending on the manufacturer. It is therefore essential that these products are made up as directed by the manufacturer.

22.2 Alcohols

e.g. Ethanol and Isopropanol

These have good bactericidal activity but are not sporocidal; activity against Mycobacterium tuberculosis is limited, fungicidal activity is good and they are active against most viruses. They have rapid action but do not penetrate well into organic matter and should only be used on physically clean surfaces.

The usual concentrations used are 70% for ethanol and 60 - 70% for isopropanol.

It is essential that alcohols are not used at higher concentrations than those given above nor should they be diluted.

22.4 Quaternary ammonium compounds (QACs)

e.g. Dettol®

This group of disinfectants have a poor range of microbial activity and are not recommended for hospital use.

23. CLEANING EQUIPMENT AND MATERIALS

23.1 Dry cleaning

In patient treatment areas and food preparation and service areas, use either a vacuum cleaner or dust-attracting mop. The bag of the vacuum cleaner should be checked before use and discarded when half full. Vacuum cleaner filters should be checked on a monthly basis.

Dust attracting mops if used for an excessive period will fail to retain dust. The head, whether disposable or non-disposable, should be changed in accordance with the manufacturer's instructions. The reusable type of head should be processed centrally following instructions given by the manufacturer.

23.2 Wet cleaning

Sluice rooms, toilets and other moist areas require wet cleaning at least once a day. Detergent in water is usually adequate (without the need for a disinfectant) and should be prepared fresh for each task.

Cleaning solutions should be changed frequently and removed from patient treatment areas and discarded as soon as cleaning is finished. A wheeled stand with two colour-coded buckets should be used, to allow discard water to be separate from the clean solutions when mops are being used. Where the microfibre system is in use the pads are colour coded.

After use mop heads should be centrally processed in a washing machine and then dried thoroughly and stored dry. After use buckets should be rinsed and stored inverted to assist drying. All equipment should be inspected at regular intervals and replaced or repaired as necessary. The solution storage tanks of scrubbing

machines should be drained completely at the end of the working day and allowed to dry thoroughly.

23.3 Materials

Disposable cloths should be used for the cleaning of surfaces or alternatively detergent impregnated single use wipes. A colour coded system for cloths to indicate which areas they can be used in should be in place. The Infection Prevention and Control Committee should approve all cleaning materials and cleaning agents.

24. DECONTAMINATION OF THE ENVIRONMENT

A clean and physically dry environment reduces infection risks and is more aesthetically pleasing to patients, visitors and staff. A wet and dirty environment will encourage microbial growth and the spread of potential pathogens.

Cleaning equipment and used cleaning solutions are a potential source of microorganisms in large numbers and should be removed from patient and food preparation areas immediately after cleaning is completed.

Thorough cleaning alone is usually sufficient to reduce the risk of infection. Disinfectants are not normally required and should only be used where indicated (e.g. terminal cleaning and disinfection of a room previously occupied by a patient with known infection).

25. DISINFECTION AND CLEANING OF LABORATORY MEDICINE (PATHOLOGY) BLOOD SAMPLE / BODY FLUID SAMPLE SPILLAGES

25.1 Types of spillage

If the spillage is contained within a specimen bag, then a senior member of staff of the relevant laboratory should be informed so that the specimen can be dealt with as appropriate.

If a spillage occurs from the specimen bag but is contained within a transport box then this should be taken to the laboratory concerned, and a senior member of staff informed.

If a spillage occurs which results in the contamination of the floor or walls then the first action to be taken is to prevent the spread of the fluid and to make the area as safe as possible to the general public and other members of staff. The incident should then be reported to the appropriate line manager.

25.2 Containment of spillage

The containment of the spillage is best achieved using either a chlorine releasing granular disinfectant, if available, or absorbent paper hand towels.

A sufficient amount of either must be used to absorb the spillage and to stop spread.

If possible a member of staff should then guard the area until such time as the person designated to disinfect and clean the area arrives.

N.B. Disinfectant granules (chlorine releasing) must not be used in the containment of urine spillage. Paper towels should be used for this purpose.

25.3 Equipment required

The person designated to clean the area should be equipped with: -

- disposable gloves
- plastic aprons
- clinical waste bags (orange)
- disinfectant granules, sodium dichloroisocyanurate (NaDCC, e.g. Actichlor® disinfectant granules in 500 g packs), or a chlorine based disinfectant solution (1%, 10 000 ppm, e.g. sodium hypochlorite)
- detergent and cleaning equipment to clean the area after disinfection

25.4 Treatment of spillage

- Where the area is treated with disinfectant granules these should be left for the period of time recommended by the manufacturer.
- Wearing disposable gloves the granules should then be cleared using a dustpan and brush and placed into a clinical waste bag.
- If the spillage involves contaminated sharps (e.g. broken glass) the "sharps/granules" should be disposed of into a "sharps bin" using the dustpan and brush without directly handling the sharp object(s).
- Gloves should then be removed and disposed of as clinical waste and a clean pair put on.
- If there is any evidence of fluid still being present then the area of contamination should be retreated.
- After the granules have been removed the site should be cleaned with detergent and water and allowed to dry.
- All gloves and aprons should be disposed of into a clinical waste bag, which should be securely tied and sent for incineration.

25.4.1 In the event of paper towels being used (e.g. for the containment of urine spills) to contain the spillage then:-

- The area should be flooded with a 1% sodium hypochlorite solution (10 000 ppm).

- The area should then be left for a period of 20 minutes.
- The paper towels should then be removed and placed into a clinical waste bag while wearing a pair of disposable gloves and the area retreated with fresh disinfectant.
- The area should be cleaned with a detergent and water solution and allowed to dry.
- All gloves and aprons should be placed into a clinical waste bag, which should then be securely tied, labelled and sent for incineration.

If possible a warning sign should be placed at the point of spillage during this period.

If there is any doubt as to what action should be taken with any given spillage then contact the Infection Prevention & Control Department.

26. RESPONSIBILITIES

The UHB's Quality Safety and Experience (QSE) Committee is responsible for the approval of the Decontamination Procedure.

Clinical Boards and individual Directorates will be responsible for the implementation of the procedural document in clinical areas.

Distribution of the procedural document will be through the UHB's intranet site.

27. AUDIT

MDD accredited facilities are subject to audits by external agencies (notified bodies) in line with a detailed audit plan and will also be subject to interim unannounced audits.

MDD accredited facilities and local decontamination facilities will be required to have comprehensive Standard Operating Procedures (SOPs) covering each stage of the reusable medical equipment decontamination cycle and should be available for local self-audit to ensure standards are continuously maintained. Adhoc audits of compliance with the IP&C SOPs will also be carried out by the Infection Prevention and Control Department, as part of their procedure audit programme. These audits must adhere to the standards established by "Local Self-Assessment Audit for Assessing Implementation of WHTM 01-05: 'Decontamination in Primary Care Dental Practices' and related Infection Prevention and Control issues."

28. DISTRIBUTION

The document will be published on the UHB Intranet site.

29. REFERENCES

The following national standards and guidance has been used to support this policy:

1. MHRA DB2006(05) Managing Medical Devices Managing Medical Devices: Guidance for healthcare and social services organisations . Medicines and Healthcare Product Regulatory Agency (April 2015).

2. WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part A: Management and Environment

3. WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part B: Common Elements

4. WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part C: Steam Sterilisation and Steam for Sterilisation

5. WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part D: Washer Disinfectors

6. WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part E: Alternatives to Steam for the Sterilisation of Reusable Medical Devices

7. WHTM 01-05 Decontamination in Primary Care Dental Practices and Community Dental Services

8. WHTM 01-06 Parts A-D Decontamination of Flexible Endoscopes

9. Local Self-Assessment Audit for Assessing Implementation of WHTM 01-05: 'Decontamination in Primary Care Dental Practices' and related Infection Prevention and Control issues. Department of Health (2011)

10. The National Institute for Health and Care Excellence (NICE) interventional procedure guidance 196: Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures (2006)

11. Minimise transmission risk of CJD and vCJD in healthcare settings, Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Risk Management Subgroup Department of Health, (October 2015)

12 British Society of Gastroenterology (BSG) Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy: The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee (2015 Edition)

13. Health Building Note (HBN) 13: Sterile Services Department, NHS Estates, Department of Health (2004).

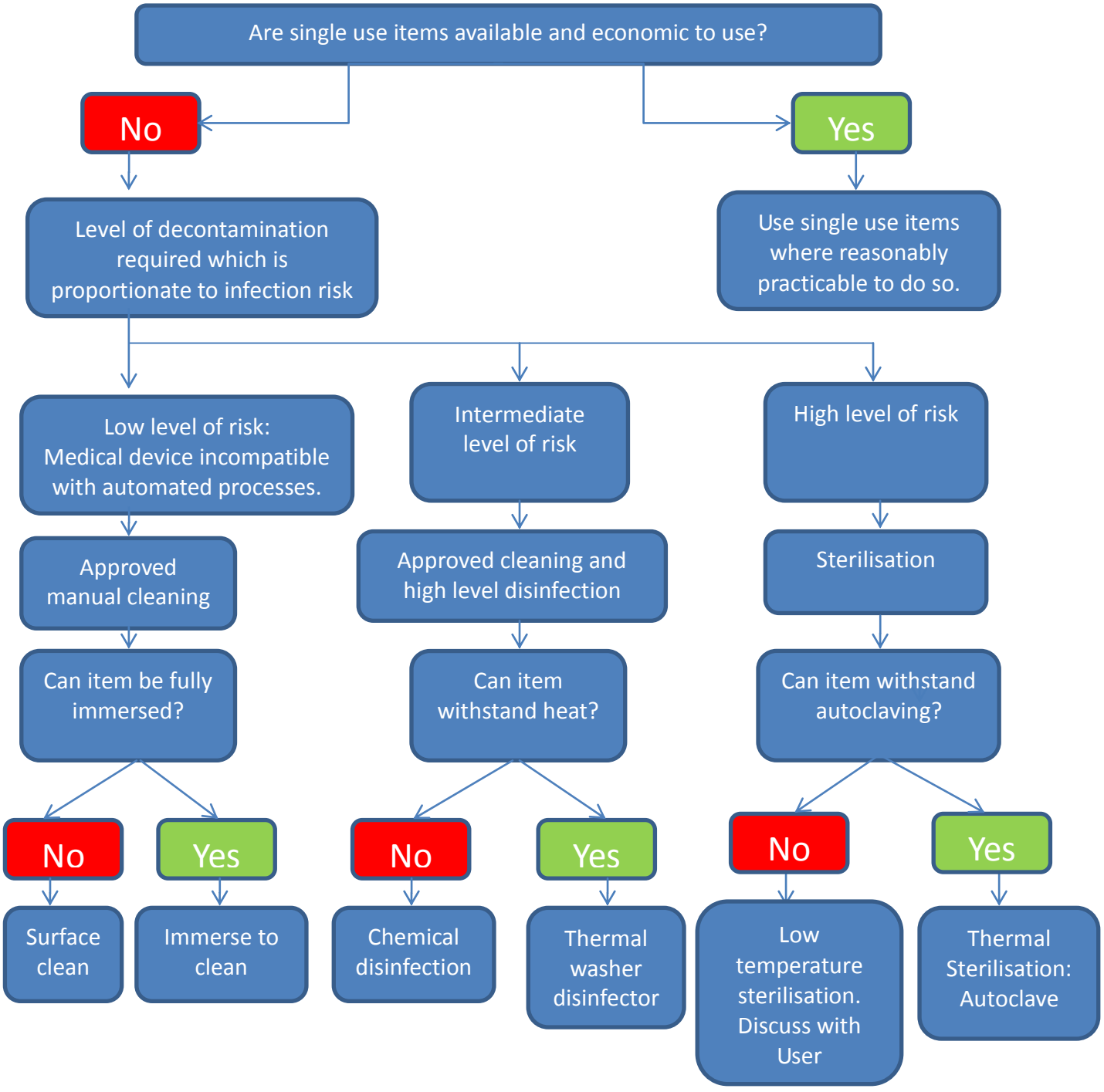
14. Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC.

15. Medical Devices Regulations 2002 (as amended)

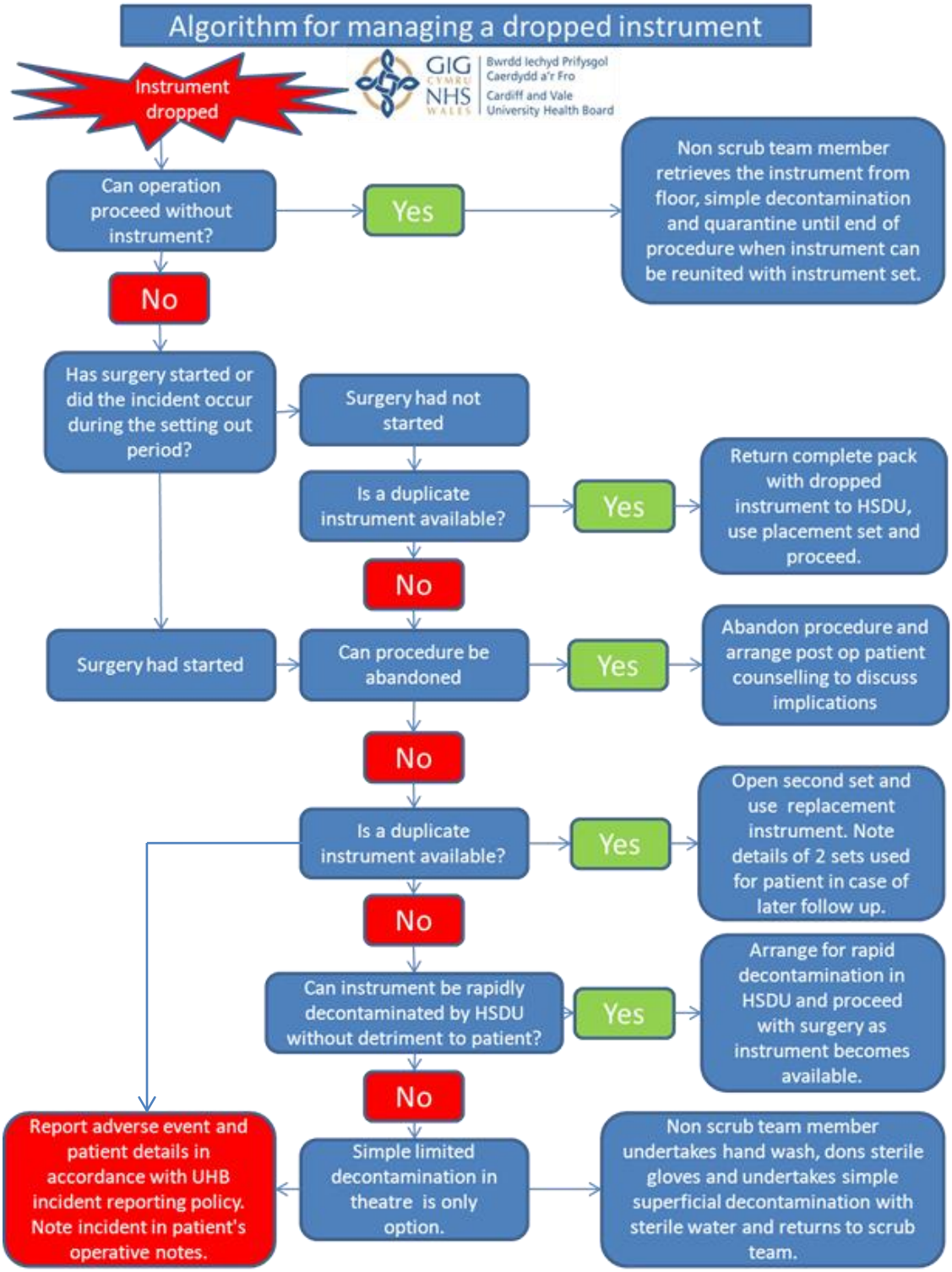
Appendix 1.

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

Algorithm for choosing appropriate decontamination processes.



Appendix 2. Algorithm for managing a dropped instrument.



Appendix 3. Permit to work system.

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

This permit only relates to the hazards caused by the possible microbiological or chemical contamination of the decontamination equipment. The decontamination equipment is not guaranteed safe against any other source of risk. Information regarding point of isolation and method statements can be obtained separately from the AP(D)

Location/Department of Decontamination Equipment: _____

Manufacturer:_____	Asset No:_____
Serial No:_____	Model No:_____
Permit Issued by the Sterile Service Operations Manager Name:_____	Signature:_____
Re-issued Permit: Yes/No	Relates to previously issued permit No___
Date of issue:_____	Time of issue:_____
Date Permit expires: _____	Time:_____

User Acknowledgment

I confirm that the decontamination equipment has been decontaminated and cleaned as required to render it safe for maintenance and repair*

It is not possible to guarantee that the decontamination equipment is free of contamination. Guidance on safe working practices is attached*

**Delete as applicable*

User Details (To be completed by Authorised User/Department Manager/Person in Charge)

Name:_____ Signature _____

Date:_____ Time:_____

Receipt

I accept responsibility for carrying out work on the above decontamination equipment.*
I have received the guidance on safe working practices.* **Delete as applicable*

CP(D)Name: _____ Signature: _____

Date: _____ Time: _____

Details of work carried out
Tick as applicable:

Warranty	
Contracted Service/Test	
Repair	
Other	
Quarterly Maintenance/Test	
Bi-annual Maintenance/Test	
Annual Maintenance/Test	
Advisory	

Explanation of work carried out:

_____

Hand Back

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

CP(D) Name: _____ Signature: _____

Date: _____ Time: _____

Cancellation

The permit is now cancelled.
The above equipment is safe and fit for use.

Name: _____ Signature: _____

Date: _____ Time: _____

I accept the above equipment back into service as fit for use.

Name: _____ Signature: _____

Date: _____ Time: _____

Appendix 4. Declaration of decontamination status

NHS WALES GIG CYMRU

No: 18608

INSPECTION, SERVICE, REPAIR OR TRANSPORT OF MEDICAL AND LABORATORY ITEMS/EQUIPMENT

CLEARANCE CERTIFICATE HS/CC/95

This item/equipment will NOT be accepted unless the following information is completed in full

1 TO _____ FROM _____

_____ _____

_____ _____

_____ _____ TEL _____

2 Description of item/equipment _____

Bar code/serial no. _____ Order/Requisition No: _____

Please answer all questions by circling YES or NO and give further details in the space provided.

3. Has this item/equipment been exposed internally or externally to hazardous materials as indicated below?

		Provide further details here
YES/NO	Blood, tissue, body fluids, respired gases, pathological samples, etc.	
YES/NO	Chemicals or substances hazardous to health.	
YES/NO	Other hazards/biohazards.	

4. Has the item/equipment been suitably decontaminated? *If YES, indicate method and materials*

YES/NO	External	
YES/NO	Internal	

5. Has the item/equipment been suitably prepared to ensure safe handling/transportation?

YES/NO	

6. Has the item/equipment been involved in a reportable incident or occurrence (see notes)?

YES/NO	

7. Authorised signature _____ Name (print) _____

Designation _____ Date _____ Tel. No: _____

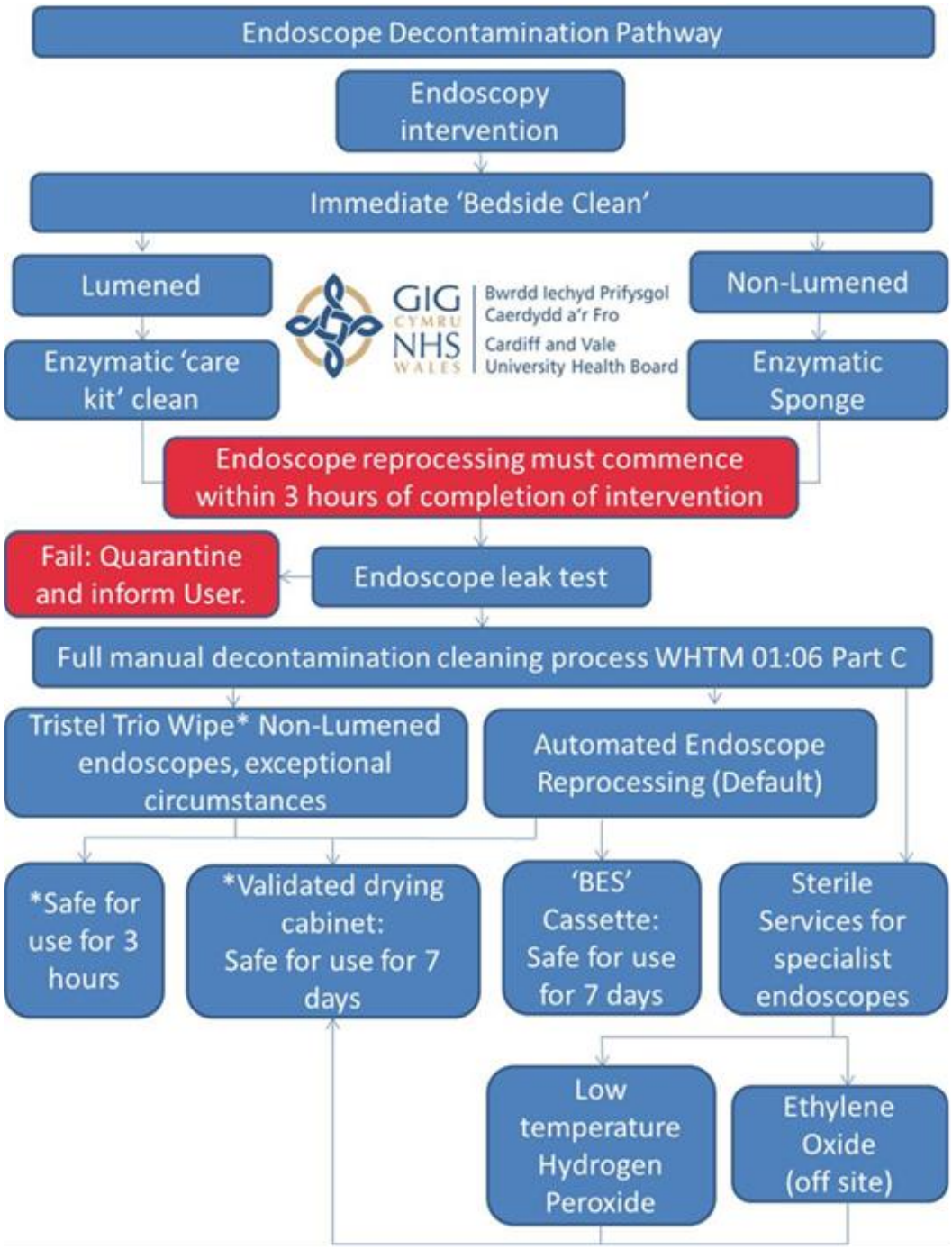
ADDITIONAL INFORMATION OR FAULT REPORT

8. Please give as much detail as possible _____

_____

_____

Appendix 5: Endoscope Decontamination Pathway



Appendix 6: Periodic Final Rinse Water Test Standards.

Water test (click on link)	Satisfactory results	Frequency
Total organic carbon	Less than 1 mg/L	Yearly or as agreed by the AE(D) and/or microbiologist. See WHTM 01-06 Part B paragraph 2.40
Appearance	Clear, bright and colourless	Yearly
pH	5.5 to 8.0	Yearly
Endotoxins See WHTM 01-06 Part B paragraph 2.36	Less than 30 Eu/ml	Yearly or as requested by the Infection Prevention team or AE(D) if a problem exists or at the installation of a new AER.
Electrical conductivity	Less than 40 µS/cm at 25°C for Ro water quality.	Weekly
Electrical conductivity	Less than 300 µS/cm at 25°C for mains water quality.	Weekly
Hardness Ro water standards	Less than 50 mg/L $CaCO_3$	Weekly (if appropriate)
Hardness See Table 3 in WHTM 01-06 Part B Mains water standard	Less than 200 mg/L $CaCO_3$	Weekly (if appropriate) Where hardness levels are approaching the recommended limits, visual inspection of AER and endoscopes should be carried out to ensure there are no deposits on the surfaces.
Total viable count	Less than 10 cfu/100 mL acceptable	Weekly See Appendix 7.
Environmental mycobacteria	Non-isolated in 200 mL sample	Quarterly This test will need to be monitored and trended by the user with a formal risk procedure in place for continued machine use.

Original Figure from WHTM 01-06 "Decontamination of flexible endoscopes. Part D: Testing methods"

Appendix 7: AER Rinse Water Total Viable Count Results Guide

Aerobic colony count (cfu) in 100mL	Interpretation	Action and advice	Colour grade
<1 cfu	Satisfactory	Use as normal	Green
1 – 9 cfu on a regular basis	Acceptable – indicates that bacterial numbers are under a reasonable level of control	Use as normal	Green
10 – 100 cfu	Risk Assess Gram Stain and oxidase test results needed. Send for ID if single organism growth. ZN stain GPB. Confirm ID of any Oxidase positive Gram negative organisms. Copy of results to ICD/IP&C team	**Take the AER out of service pending risk assessment and investigations** **(It must be remembered that by default the machine will have been operating potentially for a further 5 days since the positive sample was taken):** 1 Carry out formal risk assessment, based upon clinical needs on whether to continue decontaminating GI 'scopes, (take advice in light of organism ID re decontamination of bronchoscopes/cystoscopes and ERCPs). To assist organisations making the risk assessment, it is recommended that quantified test results are supplied from the accredited laboratory. 2 Run additional self disinfection cycle on the AER, or super-chlorination, undertake remedial work on the water distribution system to investigate the problem – e.g. check the purification/filtration system and any internal components on the AER. Instigate a re-test of the rinse water. 3 A corrupted water sample may only be applicable to single bay of AER. 4 Seek advice re continued use of the AER from ICD/IP&C team and AE(D) or AP(D).	Orange
>100cfu	Risk Assess As above and send organisms for identification as required	**AER should be taken out of service until water quality has improved/ issue resolved.** 1 Investigations should be undertaken as above, along with the AER. 2 It is a requirement of BS EN ISO 15883/4 that microbial contaminants of water used for final rinse applications should be maintained consistently below 10 cfu/100 ml sampled when tests carried out in accordance with the EN ISO 15883 standard. Additionally, samples should be free of *Legionella*, *Pseudomonas aeruginosa* and Environmental mycobacteria. 3 **Seek advice regarding continued use of the AER from ICD/IP&C team and AE(D) or AP(D).** **Multi-disciplinary teams should work together to identify the source of contamination within the final rinse supply.**	Red

Original Figure from WHTM 01-06 "Decontamination of flexible endoscopes. Part D: Testing methods".