GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW 28-TP01 **Version Number:** 1 **Date of Next review:** April 2022

Decontamination Procedure

Introduction and Aim

This document supports the Public Health Wales Decontamination Policy by describing actions undertaken by Public Health Wales staff, and those contracted to deliver services on the organisation's behalf, with regard to implementation of current Decontamination guidance and standards.
The aim is to ensure consistent application of best practice and adherence to recommended guidance.

Linked Policies, Procedures and Written Control Documents

Decontamination Policy http://howis.wales.nhs.uk/sitesplus/888/page/54697

Infection Prevention and Control Policyhttp://howis.wales.nhs.uk/sitesplus/888/page/54697

Medical Devices and Equipment management policy

National Infection Prevention and Control Manual
http://www.nipcm.hps.scot.nhs.uk/

Health and Care Standard 2.4.
(http://www.wales.nhs.uk/sitesplus/documents/1064/24729_Health%20Standards%20Framework_2015_E1.pdf

Decontamination of Medical Devices: A development plan for healthcare organisations 2016 http://www.wales.nhs.uk/sitesplus/888/news/39931

Scope

This Procedure is applicable to all staff who are responsible for and/ or involved with any elements of the decontamination process for reusable medical devices. It is also applicable to staff who are involved with decontamination of healthcare equipment prior to inspection, service, maintenance or repair.

Equality and Health	An Equality and Health Impact Assessment has been

Impact Assessment	undertaken.
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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 Corporate Governance Team.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	
V1				This Decontamination Procedure document has been developed in order to comply with the Public Health Wales requirements to create two distinct Policy and Procedure documents.

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1.Introduction

Decontamination is a term used to describe a combination of processes to clean, disinfect and /or sterilise healthcare equipment. Inadequately decontaminated healthcare equipment can be a source of transmission for microorganisms and may subsequently cause Healthcare associated infections (HCAIs). Public Health Wales is committed to eradication of preventable HCAI's. In order for the organisation to ensure the consistent undertaking of correct decontamination procedures for specific healthcare equipment Public Health Wales provides specific guidance and resources for staff such as the Decontamination Policy, this Procedure document and access to the online National Infection Prevention and Control Manual (http://howis.wales.nhs.uk/sitesplus/888/page/54697)

Effective decontamination processes for medical devices and care equipment ensures such items do not pose an infection risk for service users and /or healthcare staff. Failure to recognise the requirements of adequate decontamination increases the risks of infection that can cause significant morbidity and mortality. Public Health Wales needs to consider not only the quality and safety of equipment used but also its decontamination.

It is essential that medical devices and care equipment are managed safely to ensure they are used within manufacturer guidance, cannot harbour organisms and can be effectively decontaminated.

- Single use devices must not be reprocessed or re-used under any circumstances.

- Effective decontamination processes ensure the safety of patients, Public Health Wales staff, outside contractors who are employed to use, maintain and repair medical equipment and service users where applicable.

2. Roles and responsibilities

2.1 Chief Executive

The Chief Executive has a strategic responsibility to ensure the Decontamination policy is adhered to while the operational authority for decontamination of equipment lies with the individual user and clinical /departmental managers.

2.2 Public Health Wales

Public Health Wales has a responsibility to ensure

- Facilities and equipment used by the organisation for decontamination must comply with relevant Welsh Health Technical Memoranda (WHTM http://www.nwssp.wales.nhs.uk/welsh-health-technical-memoranda-whtms-) and Health Building Notes (HBN http://www.nwssp.wales.nhs.uk/welsh-health-building-notes-whbns-) requirements for good practice as well as Medicines and Healthcare products Regulatory Agency (MHRA) directives (https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety)

- Medical devices must be managed in accordance with Health and Safety policy (http://nww2.nphs.wales.nhs.uk:8080/PHWPoliciesDocs.nsf/5633c1d141208e8880256f2a004937d1/971668bcf8f59b17802582be0051cd49/$FILE/PHW10%20Health%20and%20Safety%20Policy%20v3.pdf.)

- Failure to comply with legislative requirements leaves a healthcare provider liable to prosecution. The trust could be the subject of litigation if it could not prove that there were management systems in place.

- Compliance is measured using observations and environmental audits the results of which will be monitored by the Infection Prevention and Control Group.

2.3 Manager's Responsibilities

Managers have responsibility to ensure that:

This and all other related policies, including online access to the National Infection Prevention and Control Manual http://www.wales.nhs.uk/sitesplus/888/page/95007

- Is available to all staff.

- Staff receive the appropriate training in Decontamination, this should include; how to decontaminate equipment, managing single-use devices appropriately, adherence to manufacturer's guidance and waste management policy;

- Staff are trained to recognise the symbol for single use and other packaging marks and record expiry dates on all products prior to use, where applicable;

- Single use devices are used in accordance with the Medicines and Healthcare Products Regulatory Agency (MHRA) guidance (https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety and are chosen, according to risk, over reusable devices;

- Staff adhere to the manufacturer's guidance and waste management policy for disposal of such devices;

- There is an incident reporting system available for staff to use if a medical device fails or is used inappropriately; and

- The medical devices register is reviewed regularly to accurately reflect all equipment currently in use and the method of decontamination.

- Adequate storage space is available so that Medical devices are stored safely to prevent damage and securely and in accordance with manufacturer guidance re temperature/humidity/packaging etc.??

2.4 Staff

Staff have an individual responsibility to:

- To attend appropriate training on Infection Prevention and Control to include decontamination;

- Utilise available resources, both written and online for information on issues relating to decontamination;

- To recognise the symbol for single use and other packaging marks and record expiry dates on all products prior to use where applicable;

- Single use devices are used in accordance with MHRA guidance and are chosen, according to risk, over reusable devices;

- Adhere to the manufacturer's guidance and waste management policy for disposal of such devices;

- Report any incidents in a timely manner via the incident reporting system if a medical device fails or is used inappropriately; and

- The medical devices register is reviewed regularly to accurately reflect all equipment currently in use and the method of decontamination.

- To manage medical devices in a manner that prevents damage and adheres with manufacture instructions for storage and disposal.

- Must not modify devices.

2.5 Infection Prevention and Control Nurse

The Infection Prevention and Control nurse has the responsibility to:

- Ensure all policy and procedure documents are reviewed and updated promptly to reflect current evidence;

- Provide infection prevention and control training and information to staff, to include information about decontamination processes as part of the mandatory training requirement;

- Work with Shared Services to participate in decontamination audits of facilities in Health Board premises and provide feedback;

- Engage in pre-procurement scrutiny of any medical devices purchased, to ensure effective decontamination can be performed with NHS Trust agreed products and within appropriate facilities

- Escalate any identified risks with regard to inadequate decontamination to the Infection Prevention and Control Group initially and subsequently to the Quality, Safety and Improvement Committee.

3. Definitions

Decontamination is the combination of processes, including cleaning, disinfection and /or sterilization, used to render a re-useable item safe for further use. The decontamination process is intended to:

- Make the item safe for staff to handle without presenting an infection hazard;
- Make the item safe for use on a patient, (after any additional processing) including, when relevant, ensuring freedom from contamination that could lead to incorrect diagnosis.

The levels of decontamination are:

- **Cleaning**: the process that physically removes soiling including large numbers of micro-organisms and the organic material on which they thrive.
- **Disinfection**: the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.
- **Sterilisation**: the process used to render an object free from viable micro-organisms including viruses and bacterial spores. (BS EN 556-1:2001).

4. Best practice

The essential requirements for good decontamination practice are:

- Management controls are in place and effected;
- Medical devices are used appropriately i.e.
    - Fit for purpose;
    - In accordance with manufacturers' instructions;
    - Properly maintained, monitored and validated;
    - Used by staff who are fully trained and competent;
    - Conforming to standards and requirements;
    - Track and trace systems link device usage to individual patients;
    - Robust records are maintained throughout the process;

- Appropriate facilities are provided; and single use instruments are not decontaminated for subsequent use.

Public Health Wales must ensure that systems and processes are in place for the regular maintenance and service of reusable devices. In addition there must be safe systems established for those individuals who inspect, service or repair medical or laboratory equipment on either healthcare premises or elsewhere. This will ensure that the items have been properly decontaminated to remove or minimise the risk of infection.

Care equipment can become contaminated with blood, other body fluids, secretions and excretions and transfer infectious agents during the delivery of care.

Care equipment is classified as either:

- Single-use: used once then discarded. The packaging carries this symbol;

- Single patient use: for use only on the same patient;
- Reusable invasive equipment: used once then decontaminated via centralised decontamination service e.g. surgical equipment; endoscopes
- Reusable non-invasive equipment (often referred to as communal equipment): reused on more than one patient following decontamination between each use e.g. AAA ultrasound probe, commode.

Single used devices must not be reprocessed or re-used under any circumstances.

4.1 Risk Assessment:

The decontamination methods must be chosen according to the risk associated with the use of a particular piece of equipment and according to the risk that inadequate decontamination poses to patients and staff.

4.2 Classification of infection risk associated with the decontamination of medical devices:

Risk	Application of Item	Recommendation
High	In close contact with a break in the skin or mucous membrane. Introduced into sterile body areas	Sterilization
Intermediate	In contact with mucous membranes Contaminated with particularly virulent or readily transmissible organisms Prior to use on immunocompromised patients	Sterilization or disinfection required Cleaning may be acceptable in some evidence based situations.
Low	In contact with healthy skin Not in contact with a patient	Cleaning

5. Purchasing Medical Devices:

Medical device refers to an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

i. Diagnosis, prevention, monitoring, treatment or alleviation of disease
ii. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
iii. Investigation, replacement physiological process, or
iv. Control of conception.

All medical devices used must be CE marked. The manufacturer must provide decontamination instructions and user information for all CE marked products. If the manufacturer is not fulfilling their obligations then the MHRA should be notified. The Infection Prevention and Control Nurse must be consulted prior to the purchase of reusable medical devices. This is to determine whether there are suitable facilities for both decontamination and maintenance of the device and that the decontamination instructions are in accordance with products recommended.

When considering the purchase of devices the following issues must be taken into account:

- Whether a single-use or a reusable product is more appropriate for the circumstances?
- How easy it is to clean e.g. does the device need dismantling before cleaning?
- Has the organisation the capability to decontaminate devices with electrical components, as described by the manufacturer?
- Is the in-use life of the device specified by the manufacturer?
- Can the method of cleaning specified by the manufacturer be achieved?
- What cleaning agents are recommended and does this comply with local infection control policies, COSHH and health and safety requirements?
- If steam sterilisation is recommended is it compatible with European sterilisation temperatures, (134°C for a minimum of three minutes)?
- If the product is heat or pressure sensitive what alternative mean of decontamination are recommended and can they be achieved?

6. Decontamination Methods:

Compatibility with the chosen method will be determined from information supplied by the equipment manufacturer. The choice of decontamination method will depend on the nature of the contamination and exposure of the device as well as the heat, pressure, moisture and chemical tolerance of the object.

i) Cleaning:

Cleaning must be undertaken manually or mechanically, (e.g. as part of the function of a washer-disinfector or ultrasonic machine). A neutral detergent solution or detergent impregnated disposable wipe is usually sufficient to effectively clean a low risk medical device. An enzymatic detergent may be required prior to high level disinfection and /or sterilisation to increase the removal of proteins

and organic matter before reprocessing. Staff working in decontamination units must be trained in accordance with the Microbiology Advisory Committee (MAC) manual. Cleaning, which is an essential pre-requisite of any decontamination process prior to disinfection or sterilisation, (as identified by the decontamination cycle- Appendix 1) is imperative.

All medical devices/ care equipment must as a minimum, be cleaned immediately after use on a patient/ service user. Manufacturer guidance must be adhered to, to ensure that the properties of the device are not altered by incorrect reprocessing or decontamination.

Manufacturers' guidance must be adhered to for use and decontamination of all care equipment.

Decontamination of reusable non-invasive care equipment must be undertaken:

- Between each use
- After blood or body fluid or other visible contamination
- At regular predefined intervals as part of an equipment cleaning protocol
- Before disinfection; and
- Before inspection, servicing or repair.

Key actions for cleaning (Refer to http://www.nipcm.hps.scot.nhs.uk/media/1409/nipcm-appendix7-20180712.pdf):

- Appropriate Personal Protective Equipment (PPE) must be supplied and worn before any decontamination process as documented in the MAC manual, (2010).

- The process must involve vigorous rubbing of all surfaces of the item before rinsing the item in clean water, (to remove detergent, microbes and organic matter).

- Thorough drying of equipment is essential before storage or use on the next patient.

- Consider covering the equipment to prevent collection of dust and potential contamination.

- The correct dilution of cleaning agent must be used in accordance with manufacturer guidance.

- The exact cleaning procedure will vary according to the physical nature of the medical device or surface being cleaned.
- All reusable non-invasive equipment must be rinsed and dried following decontamination.

Cleaning protocols should include responsibility for; frequency of; and method (including appropriate cleaning solutions/disinfectants) of equipment decontamination. Staff should be instructed on how to handle disinfectants/ antiseptics carefully and advised what protective clothing is required. Any PPE required will be supplied by the employer. Reference should always be made to the COSHH risk assessment for each product. Disinfectants should never be mixed with other products and always be used in the correct dilution: higher or lower concentrations are wasteful and potentially harmful.

Certain disinfectants will bear expiry dates and they must not be used after that date. Where chemicals need to be diluted or mixed, always use freshly prepared solutions that are dated and labelled accordingly with strength and do not store longer than advised, (usually 24 hours but refer to manufacturer guidance).

ii) Disinfection:

Disinfection should only be used where sterilisation is not required and where cleaning with detergent and hot water is inadequate. Manual disinfection using approved disinfectants is adequate for low risk items but moist heat with mechanical cleaning is the preferred disinfection technique using a washer-disinfector for medium-high risk items. Specific information for specialised purposes e.g. laboratory, endoscopy, are not included as local protocols and procedures apply.

iii) Automated washer-disinfectors:

There are currently no automated washer-disinfectors within Public Health Wales but staff employed in partner organisations should be aware of local protocols and comply with legislation and national initiatives. The partner Trusts must comply with HTM guidelines.

Washer-disinfectors must be serviced regularly and be operated and comply with HTM 01-(01) guidelines (http://www.nwssp.wales.nhs.uk/sitesplus/documents/1178/Welsh%20Health%20Tech%20Memo%2001-01%20Decontamination%20%28002%29FINAL%20FINAL.pdf)

As Bowel Screening is the only programme within Public Health Wales that commissions colonoscopy services from Health Boards, there must be an audit programme in place to ensure compliance with centres undertaking this procedure.

iv) Chemical Disinfection:

Chemical disinfectants for medical and patient care equipment should be avoided unless there is an identified need, e.g. equipment is contaminated with blood or some other body fluids.

The Infection Prevention and Control Nurse should be consulted for approval of any new disinfectants purchased.

v) Sterilisation:

Sterilisation is the complete removal or destruction of all viable microorganisms including viruses and bacterial spores.

6.1.2 Storage of Sterile Products and Decontaminated Medical Devices:

- The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stock.
- Shelving should be easily cleaned and allow the free movement of air around the stored product.
- Products must be stored above floor level away from direct sunlight and water in a secure, dry and cool environment.

Before being used the sterile product should be checked to ensure that;

- The packaging is intact and the product is still within the expiry date.
- The sterilisation indicator confirms the pack has been subjected to an appropriate sterilisation process.

6.1.3 Decontamination of equipment prior to inspection, service or repair:

Equipment may be inspected serviced or repaired both on site and elsewhere, by both staff and contractors. Staff must not be placed at risk by being exposed to contaminated items (Refer to http://www.nipcm.hps.scot.nhs.uk/media/1412/nipcm-appendix9-20180712.pdf)

All equipment must be appropriately decontaminated before inspection, service or repair and a certificate of decontamination completed.

7. Monitoring and auditing

Clinical areas within Public Health Wales will participate in auditing, utilising the Infection Prevention Society Quality Improvement Tools. Results to be reported to the Infection Control group and validation of audits will be performed by the Infection Prevention and Control Nurse.

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Appendix 1: Decontamination process

The processes involved in decontamination are described using the model developed by NHS Estates, of the "life-cycle" of re-usable surgical instruments (see Figure 1.1).

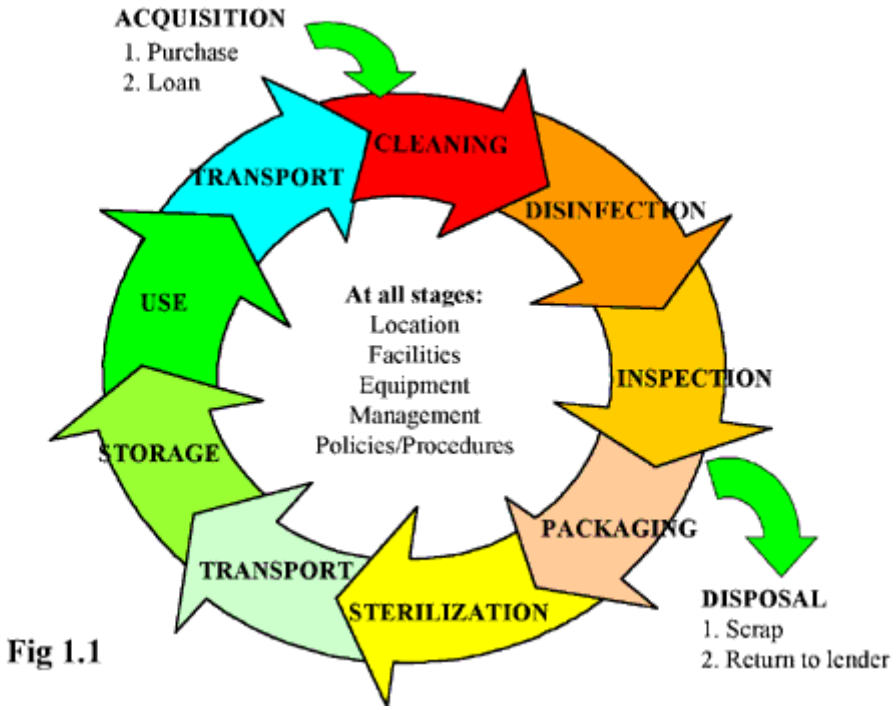

Fig 1.1

To undertake decontamination effectively requires all the processes illustrated in the life cycle to be implemented correctly, with appropriate controls and monitoring in place. The speed at which medical devices pass through the cycle can impact on the efficacy of decontamination. A key factor influencing this is the size of the stock of devices requiring processing. Achieving minimum standards at each stage of the life cycle depends on location; facilities available; equipment used; how the process is managed, and the policies and procedures employed. The basic requirements for good decontamination practice are summarised in Table 1.

Table 1 **Basic requirements for good decontamination practice**

• An effective management control system is in place covering all aspects of the decontamination cycle;
 	
• Appropriate facilities are provided;
 	
• Appropriate equipment is utilised which is:
  ○ Fit for purpose;
  ○ Properly maintained and calibrated;
  ○ Properly monitored and validated.
 	
• Staff are properly trained and supervised;
 	
• Single use medical devices, are not reused;
 	
• Records of decontamination are kept.