Royal Cornwall Hospitals
NHS Trust

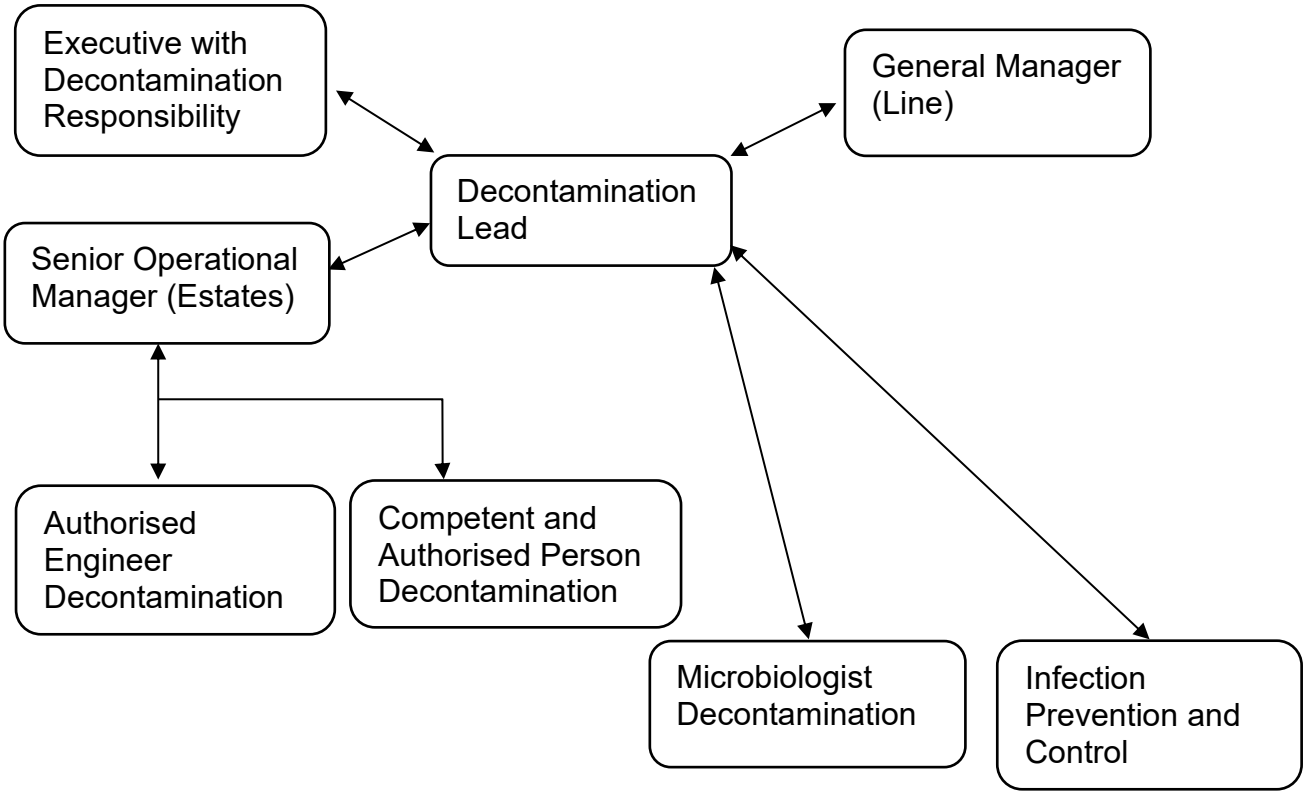
Decontamination Policy

V2.1

September 2025

Summary

Organisational Decontamination Reporting Structure



HTM Decontamination Key Personnel Organogram

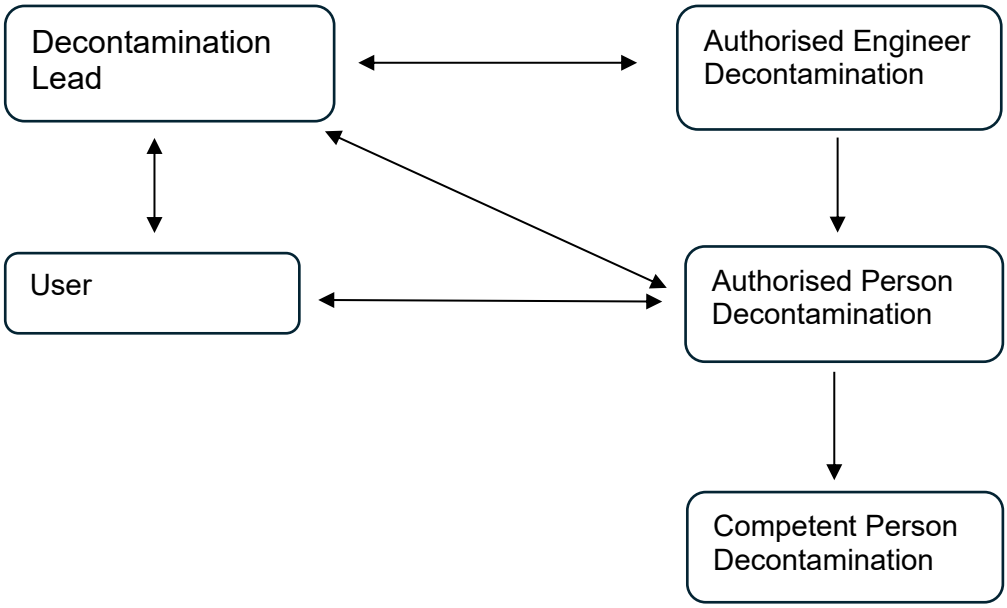


Table of Contents

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. This policy provides an explanation of the process(s) required regarding the decontamination of equipment. To provide safe, clean, disinfected or sterilised equipment to control the spread of micro-organisms.

1.2. Whilst the advice contained in this policy relates particularly to microbiological hazards, equipment may also become contaminated with chemicals which may be corrosive, irritant, toxic, cytotoxic or radioactive. The same requirements of decontamination to provide safe equipment apply in such instances and should be included in safe systems of work.

1.3. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

2.1. To promote the safest possible environment for patients through the identification and application of best practice in the decontamination of re-usable medical devices.

2.2. To provide compliant guidance in line with national guidelines to all staff who undertake the decontamination of medical devices within the RCHT.

2.3. To provide guidance to staff in selecting the most appropriate method of decontamination for medical devices based on the level of risk.

2.4. To promote consistency in decontamination practices across the Trust.

3. Scope

3.1. **The principles of this policy are:**

3.1.1. That the Trust will continually review and develop practices in order to comply with all present and future medical device legislation within resources available.

3.1.2. That the Trust will undertake risk assessments on all processes utilised in the decontamination of medical devices.

3.1.3. That the Trust will undertake Risk Assessments of the environmental conditions in all locations where the decontamination of medical devices is undertaken.

3.1.4. That the outcomes of all Medical Device Decontamination Risk Assessments are presented to the Decontamination Risk Assessment Group.

3.1.5. That every medical device will be adequately cleaned, disinfected or sterilised according to its function so as to protect as far as reasonably practical the health, safety and welfare of its staff, patients and those recipients who are involved in inspection, service, repair or transportation of medical devices or equipment.

3.1.6. That the Trust will ensure adequate provision of disinfectants, cleaning agents and equipment necessary to achieve the required standard of decontamination.

3.1.7. That the Trust will provide appropriate environmental conditions for the decontamination of medical devices.

3.1.8. That regular audits of the processes applied in the decontamination of medical devices will be undertaken with outcomes being reported to Ward / Theatre Managers and Matrons as well as to the Decontamination Risk Assessment Group.

4. Definitions/Glossary

Employees are**:**

- Direct employees of the Trust.
- Employees of other organisations but directly managed by the Trust.

4.1. **Microbial agent**: Any micro-organism, cell culture, or human endoparasite, including any which have been genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health.

4.2. **Decontamination:** The decontamination of re-usable medical devices is the combination of processes, which if not correctly undertaken, individually or collectively, may increase the likelihood of microorganisms being transferred to patients or staff. Decontamination is a process, which removes or destroys contamination and thereby prevents microorganisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response.

The decontamination process is required to make medical devices:

- Safe for staff members to handle.
- Safe for use on the patient.

Three processes of decontamination are commonly used:

4.2.1. **Cleaning**: A process which physically removes contamination but does not necessarily destroy microorganisms. The reduction of microbial contamination is not routinely measured and will depend upon many factors, including the efficiency of the cleaning process and the initial bioburden. Cleaning removes micro-organisms and the organic material on which they thrive.

4.2.2. **Disinfection**: A process used to reduce the number of viable micro-organisms, but may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation.

4.2.3. **Sterilisation**: A process used to render an object free from microorganisms including viruses and bacterial spores. Normal sterilisation methods will not destroy prions.

4.2.4. **Single-use device: (**See Appendix 5, Single Use Medical Device Policy). Any device deemed unsuitable by the manufacturer for re-processing. Such products will be labelled with the words “single use” or other synonymous reference and may have the symbol:

4.2.5. Staff members must not re-use any single use devices. Staff who disregard this information and prepare single use products for further use will transfer legal liability for the safe performance of the product from the manufacturer to themselves, or to the Trust.

5. Ownership and Responsibilities

5.1. The Executive Responsible for Decontamination is the Chief Operating Officer:

Designate a Nominated Decontamination Lead with organisational responsibility for the effective and technically compliant provision of decontamination services (Medical Devices).

5.2. Nominated Decontamination Lead:

- Be organisationally responsible for the effective and technically compliant provision of decontamination services (Medical Devices).
- Be responsible for the implementation of an operational policy for decontamination. He/she should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment. The Decontamination Lead is also responsible for monitoring the implementation of the policy.
- Report on Incidents and on decontamination related issues and risks to the RCHT Infection Prevention and Control (IPAC) Committee and to the Decontamination Risk Assessment Group (DRAG).

5.3. Decontamination Implementation Assistant:

Assist the Decontamination Lead in implementing Trust strategies for safe decontamination of medical devices in accordance with national and local guidelines.

5.4. Decontamination Risk Assessment Group:

- Fulfil the roles and responsibilities detailed in HTM 01-01, HTM 01-04 and HTM 01-06.

- Chaired by the Director of Infection Prevention and Control (DIPC) and will include the following members:
    - Executive Responsible for Decontamination (Director of Operations).
    - Director of Infection Prevention and Control (DIPC) (Chair).
    - Consultant Nurse/Deputy DIPC.
    - Trust Decontamination Lead (Deputy Chair).
    - Infection Prevention and Control Representative.
    - Sterile Services Department Operations Manager.
    - Consultant Medical Microbiologist/Infection Control Doctor.
    - Head of Estates Operations / Deputy Head of Estates Operations.
    - Authorising Engineer (Decontamination).
    - Authorised Person (Decontamination).
    - Endoscopy Department Manager.
    - ENT Outpatient Representative.
    - Heads of Nursing (Anaesthetics, Critical Care, Theatres and Specialist Services) or deputies.
    - Head of Clinical Technology.
    - Mortuary Manager.
    - Senior Facilities Manager (Mini Laundry).
    - The Surgical Instrument Manager – only to attend on specific request.

    In attendance:

    - Health and Safety Advisor / Head of Health and Safety.
    - Representative from the Estates and Facilities Performance and Governance Team.
- Provide trust wide direction and will report directly to the Executive on all matters relating to the decontamination of Medical Devices.
- Identifying and implementing appropriate essential standards and best practice for the decontamination of all re-usable medical devices.
- Identifying through risk assessments current levels of compliance with essential standards and best practice for the decontamination of all re-usable medical devices.

- Producing a schedule for achieving essential standards and a plan for progressing to best practice within a time scale that does not exceed two years from identification of the need.

- Assessing the training needs associated with the introduction of policies, procedures and revised systems of working.

- Ensuring that training needs are met and recorded.

- Ensuring that audits of decontamination activities are undertaken at agreed frequencies.

- Evaluating the effectiveness of decontamination activities.

- Collating evidence relating to decontamination activities.

- Preparation of policies and procedures relating to decontamination.

5.5. **Directors and Managers**

- Must ensure that this policy and its associated procedures are fully adhered to by all staff working within their area of responsibility.

- Ensure that this policy is available to all staff working in their area of responsibility.

- Ensure staff are aware of, and implement, correct practice in the decontamination of re-usable medical devices.

- Ensure that no re-usable medical devices are purchased or trialled unless cleaning / decontamination instructions are available and have been reviewed and approved by the Trust Decontamination Lead.

- Ensure devices designed as ‘Single Use Only’ are never reused.

- Ensure that staff performing decontamination duties receive training appropriate to the equipment and practices within individual departments. This may be received during mandatory/update training for that specific device. Inadequately trained staff may fail to decontaminate instruments or equipment properly, thus putting patients or other staff at risk. They may also risk their own health and safety if they are unaware of safe practice standards. Managers must record all decontamination related training given within the area for which they are responsible. This must include the date that training was given, an acknowledgement by the trainee that the training has been understood, and confirmation by the trainer of the trainee’s competence for each task.

- Ensure that all staff involved in the use, maintenance and decontamination of medical devices are properly supervised and that their performance is monitored in line with the medical devices training matrix.

- Be responsible for identifying and replacing where practicable instruments/equipment that are difficult to clean and/or in poor condition with versions that have been approved by the Trust Decontamination Lead / Decontamination Risk Assessment Group, and which are easier to clean.

- Consider the decontamination process when procuring devices, obtaining specialist advice from the Infection Prevention Control Team and the Decontamination Lead.

- Ensure that appropriate risk assessments are carried out and are recorded in accordance with Trust protocols prior to the decontamination of equipment and the use of chemicals. The outcomes of all risk assessments must be forwarded to the Decontamination Lead who will present these to the Risk Assessment Group.

- Report all incidents involving a decontamination procedure on Datix in accordance with the Trusts policy on incident reporting. It is further required that such incidents are also reported directly to the Decontamination Lead who will in turn report to the Decontamination Risk Assessment Group.

- Ensure all new disinfectants/cleaning products are referred to the Infection Control team, the Health and Safety department and to the Trust Decontamination Lead for consideration. Trials and the use of new cleaning products within the Trust must be approved by the Hospital Cleaning Committee.

5.6. **Employees**

- Co-operate and assist with the implementation of this Policy, and its associated procedures.

- Be responsible for recording details of the decontamination (including cleaning) of medical devices/equipment where this has been undertaken. This must include:

    - Identification of the item of equipment that has been decontaminated.

    - The date of decontamination.

    - The identity of the member of staff who has undertaken the decontamination.

    - Applying the green label, that signifies that the item in question has been cleaned.

- Bring to the notice of management, any problems or failings associated with the decontamination process.

- Undertake appropriate training courses/programmes as required, including induction and mandatory training. Specific training associated with the decontamination process will be facilitated by the Decontamination Lead, the Decontamination Implementation Assistant, and the Medical Physics Department.

- Records of training must be held at Departmental level for audit purposes and on a central register held by Trust Training, Education and Development.

- Make themselves aware of the Decontamination Policy and follow safe systems of work and control methods (including the use of personal protective equipment) provided for their safety and for the safety of others.

- Promptly report all incidents concerning the decontamination process to their Line Manager in accordance with the Trusts Policy and Procedure on reporting incidents.

- Report any adverse ill health effects arising from the decontamination process to both the Health and Safety Department and the Occupational Health department.

- Seek specialist advice, as necessary.

- Never re-use single use devices.

Employees Decontamination Responsibilities

Automated Validated Decontaminated Process

Sterile Services Department, Endoscopy Decontamination, ENT OPD (Nasal Endoscopes) Mini Laundry, Microbiology, Mortuary, Ultrasound, Cardiac, Hydrogen Peroxide Vapour (HPV) decontamination.

- **User**: The User is defined as the person designated by management to be responsible for the management of the process. The User is also responsible for the Operators.

- **Operator**: The Operator is defined as any person with the authority to operate a validated automated process for either or all cleaning/ disinfection/sterilisation. The Operator is responsible for releasing the medical device as safe to use.

Medical Equipment

Wards and Clinics medical equipment e.g. intravenous infusion pumps, drip stands and pulse oximeters, medical gas bottles and stands, walking aids etc.

- **Ward/Department Managers**: Responsible for the management of the cleaning and cleanliness of medical equipment.

- **Nursing/Clinical/Therapy Staff and Support Workers**: Responsible for cleaning the medical equipment after use in line with Trust policy and manufacturer’s instructions.

Medical Equipment Library

Return and issue of medical equipment for use for Wards/Clinics.

- **Department Manager**: Responsible for the management of the cleaning and cleanliness of the medical equipment within the medical equipment library.

- **Medical Equipment Library Assistants**: Responsible for the issuing/delivering of clean medical equipment and the receiving/collection of medical equipment which is clean and correctly labelled in line with Trust policy.

5.7. **Procurement Department:**

- Be responsible for issuing a Pre purchase questionnaire to prospective suppliers/manufacturers of medical equipment and for obtaining a completed Pre-Acquisition Questionnaire (PAQ) form prior to the trail or purchase of medical devices / equipment of a type not previously used within the Trust. Once returned, the completed questionnaire will be sent to Infection Prevention and Control, Health and Safety, Medical Physics, and the Decontamination Lead for approval before trial/purchase.

- Consult with Health and Safety and Infection Prevention and Control before the introduction of new chemicals for use (or trial) within the decontamination process.

- The introduction of new types of medical devices and alternative / new decontamination chemicals will be considered by the Decontamination Risk Assessment Group who will be responsible for approving and for recommending their trial and possible introduction to the Medical Devices Group.

5.8. **Infection Prevention and Control Department:**

- Provide specialist advice for the suitability of equipment prior to purchase and during use. This will include approving the design of equipment e.g., difficult to clean areas, dust traps etc. Such advice must be copied to the Decontamination lead who will submit to the Risk Assessment Group.

- Provide information and advice to enable managers and users to undertake risk assessments on levels of decontamination required.

- Assist in and undertake risk assessments as required by the Decontamination Risk Assessment Group.

- Conduct investigations into areas of special risk advising on safe practice.

- Audit practice and monitor standards in line with current legislation and guidance.

5.9. **Sterile Services Department:**

- Report to the Decontamination Lead who will liaise with Infection Prevention and Control, the Decontamination Risk Assessment Group and to the Executive Responsible for Decontamination as appropriate.

- Provide decontamination services which will comply with current legislation and guidelines.

- Provide specialist advice on decontamination and sterilisation as appropriate.

- Report any significant or major decontamination incidents to the Decontamination Lead, who will liaise with Infection Prevention and Control, Health and Safety, the MHRA and where appropriate to the Executive responsible for Decontamination and to the Decontamination Risk Assessment Group.

- Ensure full compliance with ISO EN 13485 and UK MDR 2002.

- Ensure that the Department is subject to external audit from a registered notified body at intervals determined by ISO EN 13485 in order to maintain accreditation of the Quality system.

- Provide assurance that any Corrective actions deemed necessary through external audit are closed out to the satisfaction of the approved body within agreed timescales.

5.10. **Health and Safety Department:**

- Advise on the suitability (from a Health and Safety perspective) of all policies, procedures, systems of working and use of chemicals associated with the decontamination process.

- Advise (from a Health and Safety perspective) on the environmental suitability of activity areas used or intended to be used for decontamination activities.

- Ensure that Health and Safety risk assessments relating to all activities related to decontamination, including the movement of equipment and devices are undertaken as required and that the results of these are communicated to the appropriate Manager and to the Decontamination Lead who will in turn present to the Decontamination Risk Assessment Group.

6. Standards and Practice

6.1. **Training**

The Trust understands the issues surrounding decontamination including its responsibilities to inform, instruct and train employees in the safe effective decontamination practices including COSHH Requirements including the use and disposal of chemical disinfectants. Managers must ensure that staff are aware of current decontamination methods and in the principles of Infection Prevention and Control, and that they have received approved and documented training in those methods and systems.

Department Managers must record, update, and maintain records of staff training. These must be available for internal or external audit as required.

6.2. Personal Protective Equipment

Appropriate Personal Protective Equipment e.g., gloves, respiratory and eye protection, aprons etc. will be available for use wherever necessary. It is the responsibility of employers to monitor the correct and safe working of the protective measures and to produce procedures that explain what is to be worn, and when. It is the employee's responsibility to follow such procedures.

Classification of Infection Risk Associated with the Decontamination of Medical Devices.

Risk	Application	Recommendation
High	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area.	Sterilisation.
Intermediate	Items in contact with intact skin, mucous membranes, or body fluids, particularly after use on infected patients or prior to use on immuno-compromised patients.	Sterilisation or disinfection required. Cleaning may be acceptable in some agreed situations.
Low	Items in contact with healthy skin or mucous membranes or not in contact with patient.	Cleaning.

Please see Appendix 3 for more guidance on selecting the appropriate level of decontamination for the item to be decontaminated.

6.3. Essential standards in the decontamination of medical devices and equipment

6.3.1. The Decontamination Environment.

All medical devices requiring sterilisation or high-level disinfection are decontaminated in compliant facilities that are designed for the process of decontaminating medical devices through validated processing systems and controlled environmental conditions to ensure that all potential environmental, cross infection, handling, and medical device usage risks are minimised.

6.3.1.1. Low risk items e.g. infusion devices are cleaned in designated areas of wards/clinics etc. in accordance with the processes included within this policy.

6.3.2. **Cleaning**

In order to decontaminate medical devices effectively, irrespective of whether disinfection and/or sterilisation is required, all organic debris (e.g., blood, tissue, and other body fluids) must be removed from the item prior to disinfection and/or sterilisation. Effective cleaning of medical devices prior to disinfection or sterilisation is of the utmost importance in reducing the risk of transmission of infectious agents.

6.3.2.1. Automated washing methods are preferred to manual cleaning, due to the provision of efficient reproducible processes, which can be controlled and validated. All items that are suitable for automated cleaning should be processed within the Sterile Services Department. If in doubt, staff should contact the Decontamination Lead for advice.

6.3.2.2. When manual cleaning is the only option, the guidance outlined in appendix 5 must be followed.

6.3.2.3. Manufacturer's instructions must be followed for all elements of the decontamination process. Where advised in manufacturer's instructions, items must be dismantled before cleaning. This will allow for all areas of the item being cleaned to be accessed during the decontamination process. Manufacturer's instructions should be retained in all areas where medical equipment is cleaned. Staff should contact the Decontamination Lead for advice if manufacturer's instructions are not available of if the instructions are not clear to follow.

6.3.3. **Reassembly**

It is essential that following decontamination equipment/devices that have been disassembled prior to the cleaning process are correctly reassembled according to manufacturer's guidance. Staff must be adequately trained to be able to disassemble and reassemble equipment and check that it is operating normally before re-use.

6.3.4. **Labelling**

Following decontamination, medical devices must be labelled as follows:

6.3.4.1. **Items decontaminated within SSD:**

These must be labelled after sterilisation with a label that is fully compliant with UK MDR 2002. This must bear the word "Sterile," and contain the processing batch number, date of processing and expiry date as well as contact details of the SSD.

6.3.4.2. **Items decontaminated within an Automatic Endoscope Re-Processor (AER):**

- If the endoscopes that have been decontaminated are not identified for immediate patient use, they must be placed in endoscope storage cabinets/endoscope drying cabinet with print outs of the processing cycle attached.

- When transported for patient use, each endoscope must be laid in a tray identified for the purpose and be delivered to the treatment room together with the processing data print out. The tray must be enclosed within a purpose specific cover during transportation.

6.3.4.3. **Equipment cleaned for return to the Medical Equipment Library, or to Medical Physics.**

Such equipment must be labelled with a “Green is Clean label and where appropriate with a certificate of decontamination, (e.g., where an item is to be sent for service / maintenance / repair or disposal). These can be obtained from the Decontamination lead on ext. 5060.

6.3.5. **Transportation**

6.3.5.1. Equipment and other medical devices including instruments must be transported so as to prevent microbial contamination or damage and protect the individual transporting them.

6.3.5.2. Containers used for transportation must be suitable for purpose, rigid, enclosed, and easily decontaminated for re-use. Any inserts for supporting the device must also be easily cleaned.

6.3.5.3. Records of which items of equipment are transported, on what date, by whom, and between which locations must, be made and retained for audit.

6.3.5.4. Containers, trolleys, boxes etc. used for transporting soiled items for decontamination should be labelled with the word **Biohazard**.

6.3.5.5. Containers, trolleys, boxes etc. used for transporting decontaminated items after decontamination should be labelled **Decontaminated Medical Devices**.

6.3.6. **Storage**

6.3.6.1. The environmental conditions of the areas designated for storage and distribution should ensure the integrity of all materials and products i.e. clean, well-ventilated, and secure. The accommodation should afford adequate protection to prevent contamination or deterioration of the product. Stock

rotation should be used for storage i.e. FIFO (First in, First out).

6.3.6.2. Records must be made detailing dates and the identities of items entering and leaving storage areas.

6.3.6.3. Checks of expiry dates of decontaminated items must also be undertaken at regular intervals in order that those items that require to be decontaminated again can be identified, removed from stock, and be sent for subsequent decontamination.

6.3.7. **Compatibility**

6.3.7.1. Personnel responsible for reprocessing reusable medical devices must always follow the manufacturer's instructions. Personnel responsible for managing the decontamination process must:

6.3.7.2. Ensure that the decontamination agents (detergents, water, including ultrasonic activity where utilised) used are compatible with both devices and reprocessing equipment.

6.3.7.3. Consult the medical device and reprocessing equipment manufacturer/supplier before changing any decontamination process and obtain their written approval for the change in decontamination process. Once this is received the request to change must be forwarded to the Decontamination Lead who will present to the Decontamination Risk Assessment Group.

6.3.7.4. Decontaminate reusable medical devices in accordance with the instructions provided by the device manufacturer.

6.3.7.5. Ensure that appropriate decontamination facilities and compatible agents are available before purchasing new devices.

6.3.7.6. Follow the instructions for use supplied by the manufacturer of the decontamination agent.

6.3.7.7. If in doubt, consult the Decontamination Lead.

6.3.8. **Record Keeping**

6.3.8.1. The Consumer Protection Act (1987) (6), and in particular Product Liability has implications for the processing of devices used for patient care. It is essential to maintain adequate records that demonstrate how a particular device was processed. This includes a description of the method/s employed together with details of available trained personnel with copies of training records. The organisation should have the ability to demonstrate how instruments/equipment have been processed through the decontamination cycle.

6.3.8.2. For surgical instruments and endoscopes, records must be maintained and retained, to enable instruments to be traced to individual patients.

6.3.9. **Tracking and Traceability**

6.3.9.1. It is important to be able to trace surgical instruments through the decontamination process to which they have been subjected to ensure that processes have been carried out correctly.

6.3.9.2. In the event of a sterilisation cycle failure products can then be recalled. Records should be maintained for all sets identifying:

- The decontamination method used.
- The name of the person undertaking decontamination.
- Details of the item/set being processed.

6.3.9.3. Records should be kept by the organisation for a minimum of 11 years. A computerised system is used for this purpose within the Sterile Services Department.

6.3.9.4. Systems exist which allow traceability between set and patient. This identifies which set was used for the patient and the decontamination process it has undergone.

6.3.9.5. Such a system is required in the event of a 'look back' exercise.

6.3.9.6. Tracking systems are also available for endoscopes processed through automated endoscope re-processors (AER's).

6.4. Decontamination of Equipment Prior To Service or Repair

Anyone who inspects services repairs or transports medical devices and equipment has a right to expect that they have been appropriately treated so as to remove or minimise the risk of infection or other hazards e.g. chemical or radiation.

Medical devices must be decontaminated through an approved process prior to them being sent for service or repair, and all devices presented for service or repair must be provided with a decontamination certificate according to the Trusts procedure (appendix 2). When completing the Decontamination Certificate staff must confirm that the appropriate process, as detailed in appendix 2 of this document, has been followed.

6.5. Decontamination Related to Equipment on Loan

6.6.1. Loaning of theatre instrument trays for use within RCHT

Instrumentation or equipment may be loaned to the Trust so that a

particular procedure can be performed. The instruments may be loaned both from manufacturers and other hospitals and are returned after use. This practice increases the risks associated with the decontamination and reprocessing of such devices because the organisation may not be familiar with them.

6.6.2. All loan instrumentation loaned from an instrument supplier must be decontaminated by the Trusts accredited Sterile Services Department (SSD) both before and after use in accordance with the manufacturer's instructions.

6.6.3. On the first occasion that instruments are loaned to the Trust from an instrument supplier, the SSD must receive the instrumentation at least 48 hours before planned use in order to establish that the instrumentation is appropriate for processing within the SSD's decontamination facilities, to allow for the instrumentation to be added to the SSD Track and Trace database and to enable staff training to take place. On subsequent occasions that the instrumentation is loaned to the Trust, the instruments must be delivered to the SSD for decontamination at least 24 hours before the scheduled use. On all occasions that re-usable instrumentation is loaned to the Trust, the instruments must be accompanied by a certificate of decontamination from the previous organisation that has used the instrumentation.

6.6.4. Where instrumentation is loaned from another healthcare provider, the instrumentation loaned must be decontaminated by the RCHT SSD unless the healthcare provider has decontaminated the instrumentation in a fully compliant and accredited (EN ISO 13485, with UK MDR 2002) decontamination facility that is registered with the MHRA as being compliant. In such circumstances, the packaging materials must be checked for integrity and steriliser indicators must show that the instrumentation has passed through a satisfactory sterilisation process. Healthcare providers who issue decontaminated and sterile instrumentation to the Trust for patient use must be asked to confirm their status of compliance with UK MDR 2002 and to give their MHRA registration details to the Trust prior to the loan being agreed. In the event that the instrumentation has not been decontaminated by a compliant Decontamination Facility / SSD, the Trust must arrange for the instrumentation to be decontaminated before and after use by the Trusts SSD.

6.6.5. It is illegal to use re-usable instrumentation that have been decontaminated by a Decontamination Facility that is not compliant with EN ISO 13485 and UK MDR 2002, and that is not registered with the MHRA as a compliant decontamination provider.

6.6.6. In addition to a decontamination certificate, loaned instrumentation must be accompanied by relevant reprocessing instructions and a comprehensive list of contents. If these are missing or if you do not have the facilities to follow them (e.g. inappropriate sterilisation time/temperature relationships are quoted) the instruments should not be used.

6.6.7. Adequate time must be allowed to carry out effective decontamination by the Trusts SSD after use prior to the loaned instrumentation being returned to the owner of the instrumentation. This must not compromise the processing schedules for Trust owned instrumentation. The Trust will decontaminate instrumentation after use but will not wrap the instruments in “Tray Wrap Packaging.”

6.6.8. Following post use decontamination, the SSD will issue a decontamination certificate which will accompany the loaned instrumentation to its next destination.

6.6.9. Prior to the use of loan sets, the SSD will ensure that systems are in place to allow loan instrumentation to be tracked through the decontamination processes and subsequently to the patient upon which it is to be used.

6.6.10. **Loaning of RCHT owned trays for use by other healthcare providers.**

Prior to loaning any instruments/trays to any non-Trust hospitals/Health Care Providers, approval must be sought from the Care Group Nurse or Matron.

6.6. **Transfer of Ownership and Disposal of Used Medical Devices**

Prior to the disposal of used medical devices they must be adequately decontaminated, and a decontamination certificate provided.

6.7. **Spillage of Blood and Body Fluids**

6.8.1. The spill should be dealt with as soon as possible.

6.8.2. The removal of blood and body fluid spills in clinical areas is the responsibility of the clinical staff in that department, not the cleaning staff. Outside clinical areas responsibility for cleaning should be identified locally and will depend on the size of the unit/hospital and the personnel available.

6.8.3. Gloves and plastic aprons must be worn as a minimum when dealing with spill of blood or body fluids. If there is any risk of splashing, eye/face protection must be worn.

6.8.4. Where the spillage may contain sharp material, forceps should be used to remove the sharp material, placing it immediately in a sharps bin.

6.8.5. If the spillage is large, soak up the excess fluid using paper towels and carefully place these in a clinical waste bag.

6.8.6. Where there is a large blood spill, a 10,000-ppm chlorine releasing agent must be used as part of the cleaning process.

6.8.7. Clean surface with warm water and detergent using a disposable cloth or mop.

6.8.8. If the spill is on a carpeted area this should be disinfected following cleaning using a steam cleaner or wet extract carpet shampooer.

6.8.9. Curtains or loose fabric covers should be laundered or dry cleaned.

6.8.10. Ensure that the area is well ventilated during the cleaning process.

6.8. **Related Policies and Procedures**

This policy is to be read in conjunction with the following policies:

- Control of Substances Hazardous to Health (COSHH) Policy.
- Cleaning Policy.
- Waste Management Policy.
- Standard Infection Prevention and Control Policy.
- Equality and Diversity Statement.
- Equality Impact Assessment.

7. Dissemination and Implementation

7.1. Ward and Department managers must ensure that staff are aware of this policy and that it is available for staff to access via RCHT intranet document library. The Decontamination Risk Assessment Group will assist in raising awareness of key issues regarding this policy.

7.2. As this policy has already been implemented no implementation plan is required.

7.3. It is the Ward and Department managers responsibility to ensure that all staff are aware of the need and method of decontamination for all items of equipment and have received appropriate training. Training given to individuals should be recorded and reviewed regularly.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Fitness for safe use following decontamination.
Lead	Decontamination Lead.

Information Category	Detail of process and methodology for monitoring compliance
Tool	a) For SSD, EN ISO 13485 b) For flexible Endoscope Decontamination, JAG Audit Tool c) For Medical Equipment decontaminated on wards / clinical areas, Internal audit tool.
Frequency	a) Annually external audit complemented by internal audits as required by EN ISO 13485. b) Annually. c) Monthly random sampling. Trust Decontamination Lead reports outcomes at quarterly Infection Prevention and Control Committee (IPACC) and at the Decontamination Risk Assessment Group.
Reporting arrangements	The completed report is sent to the joint DIPC for presentation to the Infection Prevention and Control Committee (IPAC) with minutes being circulated to the Nurse Executive and to the Chief Operating Officer who is the Executive responsible for decontamination. The Chief Operating Officer has agreed to attend the Decontamination Risk Assessment Group (DRAG) in order to provide a direct link to the Executive for Decontamination Risks, Issues and Strategies. The Decontamination Lead presents the report to the (IPACC) and gives more detail to the DRAG. Both groups are expected to read and interrogate the report to identify deficiencies in the system and act upon them.
Acting on recommendations and Lead(s)	Required responsible persons and actions will be identified and completed in a specified timeframe.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within a specified time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders. Where any changes impact upon the Trust Decontamination Policy, this will be updated by the Decontamination Lead with approval being necessary from the Microbiologist (Decontamination), the DIPC, and the Chief Operating Officer.

9. Updating and Review

9.1. The policy will be updated at least every two years.

9.2. Any suggested changes between policy reviews must be brought initially to the IPAC Committee, these will then be discussed at the DRAG.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment.

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Decontamination Policy V2.1.
This document replaces (exact title of previous version):	Decontamination Policy V2.0.
Date Issued/Approved:	26 August 2025.
Date Valid From:	September 2025.
Date Valid To:	April 2028.
Author/Owner:	Matthew Dyer, Decontamination Lead.
Contact details:	01872 255060.
Brief summary of contents:	This policy outlines the process required regarding decontamination of medical equipment. To provide safe, clean disinfected or sterilised equipment to control the spread of micro-organisms.
Suggested Keywords:	Decontamination.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Operating Officer.
Approval route for consultation and ratification:	Decontamination Risk Assessment Group. Infection Prevention and Control Committee. Director of Infection Prevention and Control.
Manager confirming approval processes:	Louise Dickinson, Director of Infection Prevention and Control.
Name of Governance Lead confirming consultation and ratification:	Joanne Taylor, Deputy Director of Infection Prevention and Control.
Links to key external standards:	None required.
Related Documents:	HTM 01-01, HTM 01-04, HTM 01-06.
Training Need Identified:	No.

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/Infection Prevention and Control

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
14 Jan 2014.	V4.2.	Revision drafted to take account of archiving of HTM's introduction of CFPP's and establishment of Risk Assessment Group.	Mark Lavery, Trust Decontamination Lead.
20 October 2015.	V7 Draft.	Pending Approval.	Mark Lavery, Trust Decontamination Lead.
3 October 2018.	V8.	CFPP's now HTM and added HTM 01-04. Add ultrasound probes to decontamination methods.	Matthew Dyer, Interim Decontamination Lead.
30 November 2020.	V9.0.	Combining RCHT and CFT Decontamination Policies.	Leslie Lawson-Kinross, CFT Medical Devices Lead (Interim), Patient Safety Coordinator - Clinical Effectiveness.
31 March 2021.	V1.0.	Combining RCHT and CFT Decontamination Policies.	Matthew Dyer, Decontamination Lead.
31 December 2024	V2.0.	Uncombine RCHT and CFT Decontamination Policies. Reformatted to current RCHT policy template.	Matthew Dyer, Decontamination Lead. Karen Powell, IPAC Administration Lead.
30 July 2025	V2.1	Appendix 4: Added use of peracetic wipes for commodes and bed pan holders. Change detergent wipes to universal wipes. Visually simplified Decontamination Reporting Structure.	Rashima Hamdan, Senior IPAC Specialist Practitioner. Liam Button, IPAC Lead Practitioner.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy/policy/proposal/service function to be assessed:	Decontamination Policy V2.0.
Department and Service Area:	Infection Prevention and Control.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Matthew Dyer, Decontamination Lead.
Contact details:	01872 255060

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To set the overarching decontamination strategy for RCHT.
2. Policy Objectives	To provide information and guidance to all staff in relation to decontamination.
3. Policy Intended Outcomes	To provide a rationale for all aspects of decontamination activity within RCHT.
4. How will you measure each outcome?	Audit of all areas where decontamination is undertaken. Audit of decontamination related incidents. Audit of training.
5. Who is intended to benefit from the policy?	All patients and staff.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/visitors: No • Local groups/system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Infection Prevention and Control Committee. Decontamination Risk Assessment Group. Louise Dickinson, Director of Infection Prevention and Control. Governance Department.
6c. What was the outcome of the consultation?	Approval.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	

Protected Characteristic	(Yes or No)	Rationale
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Matthew Dyer, Decontamination Lead.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Summary of Methods for Decontamination of Equipment or Environment

Introduction

The Trust has a responsibility to ensure that patients and employees are not put at risk by handling or using items of equipment that may be contaminated. This responsibility extends to all staff handling equipment, engineering staff, Medical Physics staff, Manufacturers and contractors' employees and others who perform maintenance, inspection, or repair.

Due to the design and use of equipment purchased throughout the Trust being so diverse the aim of these guidelines is to give the user general principles and recommendations for the cleaning and decontamination of equipment.

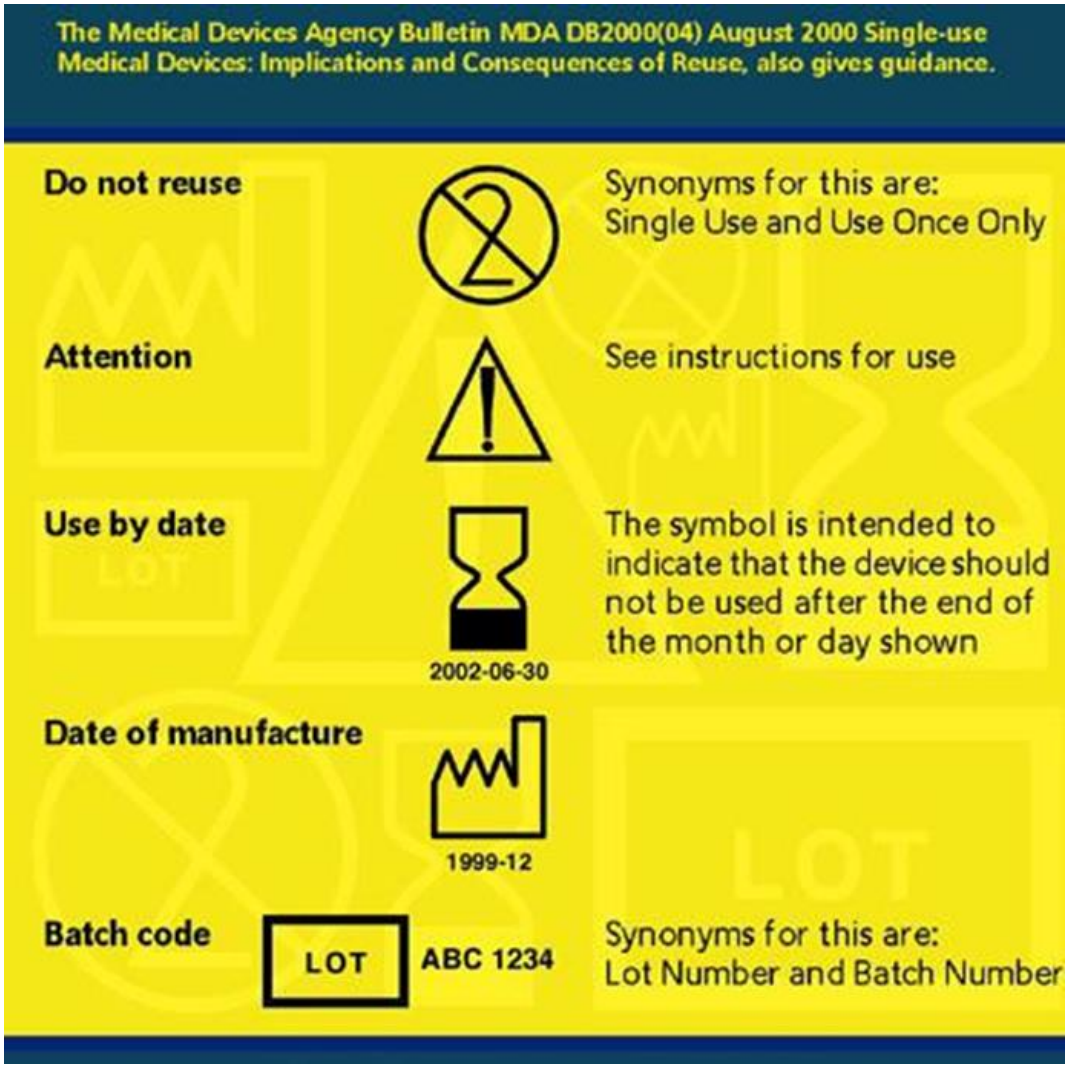
Prior to purchasing or using any item of equipment it is the responsibility of the user to ensure that the equipment can/has been decontaminated adequately.

Definitions

Definition	Description
Cleaning	The physical removal of micro-organisms and the organic material on which they thrive.
Disinfection	The removal or killing of potential pathogenic micro-organisms but not usually spores.
Equipment	Any item of equipment that has direct contact with the patient, be it diagnostic, therapeutic, or for direct care of the patient (e.g., bedpan bases, beds, commode, mattresses).
Sterilisation	The complete removal or destruction of all forms of microbial life including spores. (Sterility assurance level (SAL) of 10^{-6} or 1:1 000 000).
Single use only	Should be used once and discarded.
Single patient use	Should be used for single patient use only. NB. Ensure manufacturer's recommendations on frequency, methods and number of uses are adhered to.

Symbols used on Medical Packaging

Outlined below are some commonly used symbols on medical devices. Any staff handling medical devices should be aware of these symbols.



The most appropriate method of decontamination

The aim of this section is to inform the user of the most appropriate method of decontamination to be used for equipment. The Sterile Services Department (SSD) should always be use for the decontamination of equipment if appropriate. All equipment designed for patient use should be decontaminated before and after use.

Any item of equipment that has direct contact with the patient, be it diagnostic, therapeutic, or for direct care of the patient (e.g., bedpan bases, beds, commode, mattresses) must be decontaminated following use.

All equipment should be stored in a clean, dry designated area. Where practical, equipment should not be stored on floor. Storage racking should be used where appropriate.

The choice of decontamination method may be related to the infection risk associated with the intended use of the equipment. Other factors that must be considered include:

1. The nature of the contamination.
2. The time required for processing.
3. The heat, pressure, moisture, and chemical tolerance of the object.
4. The availability of the processing equipment.
5. The quality and risks associated with the decontamination method.
6. The manufacturer's guidance.

Cleaning, disinfection, and sterilisation are all processes which remove or destroy micro-organisms. The method of decontamination will depend on the infection risk associated with the equipment/medical device. These risks can be classified as high, intermediate, low, and minimal (Ayliff et al 2000).

Cleaning

Cleaning with detergent and water will remove most micro-organisms from a surface. A further reduction in numbers occurs as the surface dries. Thorough cleaning and drying will be adequate treatment for most surfaces and furniture in the hospital environment. Cleaning of equipment before disinfection or sterilisation is essential.

Disinfection

Disinfection using either heat or chemicals will destroy non-sporing bacteria and most viruses, reducing them to a safe level. Disinfection is required for items in contact with intact skin or mucous membranes e.g., respiratory and non-intentionally invasive equipment or items not associated with a patient with particularly transmissible/virulent infections. Chemicals disinfection should only be used if heat treatment is impractical or undesirable, e.g., for skin, flexible endoscopes, etc.

Sterilisation

Sterilisation means the complete destruction or removal of all micro-organisms, including bacterial spores. Items involved with a break in the skin or mucous membranes should be sterilised, e.g., surgical instruments, wound care products, and products intended for parenteral use or for instillation into body cavities.

Autoclaving with steam above atmospheric pressure (121ºC - 134ºC), is an acceptable method for hospital use, however the use of sterilisers within the Trust is restricted. All items requiring steam sterilisation must be sent to the SSD at RCH. Chemicals with sporicidal activity (e.g., glutaraldehyde, peracetic acid etc.) may sterilise but are less reliable, requiring lengthy exposure times (those specified by the supplier of the chemicals must be applied), rinsing to remove toxic residues, and should be avoided if possible. Control of substances hazardous to health (COSHH) regulations must be followed when using any toxic or irritant substance.

Risk Assessments

Due to the design and use of equipment purchased being diverse it is essential that risk assessments are undertaken prior to use to include the following:

- How is the item of equipment decontaminated?
- Is the item intended for reuse? i.e., establish that it is not described as single use.
- For what purpose is the device used? i.e., is it invasive? Is it used in contact with skin, body fluids or potentially infectious materials?
- How do manufacturers recommend it is cleaned, disinfected, and sterilised?
- Can it be disassembled to facilitate cleaning?
- Is decontamination required at the point of use?
- Will it withstand an automated process?
- How soon will it be needed?
- Can it be wrapped to protect it from recontamination?
- How many times can it be reprocessed?
- Does processing constitute a hazard to patients and/or staff? If so, is COSHH hazard data and monitoring equipment available?
- Can it withstand cleaning with detergent and water?
- Can it withstand the high temperatures used for disinfection and sterilisation?
- Can it withstand disinfectants e.g., chlorine releasing agents?
- If the manufacturers guidelines recommend the use of chemical disinfectants the following needs to be considered:
    - Is the disinfectant recommended by infection control?
    - Does the use and storage comply with COSHH?
    - Will the product adequately decontaminate equipment?
    - How cost effective is the disinfectant?
    - Can it be adequately and safely stored?
    - What is the availability of the disinfectant and is there an alternative?

Choice and Use of Disinfectant

Factors which affect the disinfectant activity:

1. The concentration of disinfectant – ensure that the dilution follows the manufacturer's instructions and is appropriate to the task.

2. The number and type of microbial contamination – the greater the number of microbes present the more difficult the surface to disinfect. Choosing the right disinfectant to kill the microbe, some microbes being more resistant than others.

3. The cleanliness of the surface – the presence of organic matter e.g., pus blood.

Heat

Autoclave if materials are not likely to be damaged by high temperatures, otherwise washer disinfectors or low- temperatures steam.

Chemical disinfection Index

a) Chlorine-releasing agents.

b) alcohol (use either 60-70% ethyl of isopropyl alcohol).

c) Gigasept PA and other solutions agreed by the ICT.

Appendix 4. A – Z Guide of Methods of Decontamination for Equipment

Item	Method of Decontamination	Frequency
Alcohol hand rub holders – end of bed.	Universal wipe, dry thoroughly.	Daily and on discharge/ transfer.
Airways.	Single Use.	Single Use.
Anaesthetic equipment.	Disposable or return to SSD.	
Arm rests.	Wash with warm water and detergent, detergent/ universal wipe, dry thoroughly*.	After each patient.
Audiometer headphone.	Universal wipe, dry thoroughly.	After each patient.
Bath.	Wash with warm water and detergent, rinse thoroughly.	After each patient.
Baby changing mat.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each patient.
Bed frames.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Daily and on discharge/ transfer.
Bed, under bed.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Weekly and on discharge/transfer.
Bed cradles.	Wash with warm water and detergent or universal wipe, dry thoroughly*.	Daily and on discharge/ transfer.
Bed pan holder.	Wipe with Peracetic Wipes (Red Clinell) and allow to dry or Wash with solution of combined detergent and Sodium hypochlorite (1000ppm).	After each patient.
Bedpan holder (diarrhea).	Wipe with Peracetic Wipes (Red Clinell) and allow to dry or Wash with solution of combined detergent and Sodium hypochlorite (1000ppm).	After each patient.
Bed pan.	Disposable, macerate.	

Item	Method of Decontamination	Frequency
Bowls (patient wash bowls).	Single use disposable.	Single use.
Brushes, hair	Single Patient Use.	Single Use.
Brushes, nail	Single Patient Use.	Single Use.
Brushes, surgical nail.	Single Use.	Single Use.
Breast pumps.	Single Patient Use. Accessories washed with warm water and detergent, rinsed thoroughly and disinfected in dishwasher or steam steriliser. Pump wiped with Universal wipe.	After every use.
Clip boards, note holders at end of bed.	Universal wipe, dry thoroughly.	Daily and on discharge/ transfer.
Cloths (for cleaning).	Disposable: Yellow – Kitchen. Red – Bathroom and Toilets. Blue Ward and General Areas. Green – Isolation rooms and Theatre.	Single Use for each bed space or side room.
Commodes.	Wipe with Peracetic Wipes (Red Clinell) and allow to Dry. Wash with solution of combined detergent and Sodium hypochlorite (1000ppm).	After each use. Daily.
Cots and Incubators.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Discharge/transfer and prior to admission.
Crockery and cutlery.	Dishwasher (cycle should heat disinfect, ≥ 80^0C for 1 minute).	After use.
Drip stands.	Universal wipe.	Daily.
Drugs trolley.	Universal wipe.	Weekly.

Item	Method of Decontamination	Frequency
Duvets.	Wash with warm water and detergent or Universal wipe e, dry thoroughly.	After each patient.
Earpieces (Auroscope).	Preferably disposable. If reusable: immerse and clean in warm water and detergent and wash thoroughly. Rinse and dry thoroughly.	Single Use.
Ear Syringe Machine (Propulse).	Flush system with fresh tap water. Drain water from system and flush with Sodium hypochlorite solution (10,000ppm). Dry reservoir tank with paper towel. Clean tips with warm water and detergent or Universal wipe – ensure all debris removed. Rinse under running water and immerse in Sodium hypochlorite solution (10,000ppm) for 10 minutes.	Before each use. After each use.
ECG and Cardiac machines.	Monitor: Damp dust with Universal wipe. Leads: Universal wipe. Electrodes: Disposable.	Daily. Daily and after each patient. Single Patient Use.
Electric razor.	Single Patient Use (patient's own razor).	Single Patient Use.
Endoscope (flexible).	Follow instructions in Endoscopy policy.	After each use.
Endoscope (rigid).	Return to SSD.	After each use.
Examination couch.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each patient.
Examination couch frame.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Daily.

Item	Method of Decontamination	Frequency
Enteral tube feeding syringes.	Single Use.	Single Use.
Eye protection (goggles, visors).	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	As required.
Floor cleaning equipment: Mop heads. Bucket.	 Disposable or launder (cycle should heat disinfect, ≥ 65^0C for 10 minutes or ≥ 71^0C for 3 minutes). Wash with warm water and detergent, rinse and dry thoroughly.	 Daily and after use in isolation room and cohort bay. Daily and after use in isolation room and cohort bay.
Hoist (frame).	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Daily.
Hoist sling.	Single Patient Use launder if visibly soiled.	Single Patient Use.
Laryngoscope. Reusable handles.	Disposable blades/handles. Wash with warm water and detergent or Universal wipe, dry thoroughly. In cases of heavy soil send to SSD.	Single Use. After each use.
Mattress.	Wash with warm water and detergent or Universal wipe, dry thoroughly.	Weekly and on discharge/transfer.
Mattress (alternating/ specialist).	Wash with warm water and detergent or Universal wipe, dry thoroughly.	Weekly and on discharge/transfer.
Medicine pots, spoons.	Single Use.	Single Use.
Nebulizer equipment Acorns.	Disposable Detergent and water.	Single Use. After each nebulised dose.
Oxygen masks/nasal cannula.	Disposable.	Single Patient Use.

Item	Method of Decontamination	Frequency
Pillow.	Wash with warm water and detergent or Universal wipe, dry thoroughly.	Weekly and on discharge/transfer.
Raised Toilet Seat.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each patient.
Resuscitation equipment		
Airways.	Disposable.	Single Use.
Self-inflating bag, e.g. Ambu-bag.	Disposable or use with disposable filter (change after each use).	Single Use.
Suction tubing and liner.	Disposable.	Single Use.
Swivel connector.	Disposable.	Single Use.
Sharps Trays.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each use.
Sigmoid scopes.	Disposable. Protect insufflator bulb with a filter.	Single Use.
Spacer (for teaching patients inhalation technique).	Wash with warm water and detergent, rinse, and air dry.	After each use.
Specula (vaginal).	Preferably disposable. Reusable: return to SSD. Wipe gel from speculum immediately after use.	Single Use. After each use.
Stethoscope.	Universal wipe.	Before and after each use.
Sphygmomanometer.	Universal wipe, dry thoroughly.	Daily.
Disposable cuff.	Disposable.	Single Patient Use.
Vinyl cuff.	Universal wipe, dry thoroughly.	After each patient.
Sputum pots.	Disposable.	

Item	Method of Decontamination	Frequency
Syringe drivers.	Switch off and disconnect from electricity supply. Universal wipe, dry thoroughly.	After each patient or weekly.
Suction apparatus	Use rigid container with a disposable liner.	
Rigid outer container.	Universal wipe, dry thoroughly.	Weekly and on discharge/transfer.
Tubing.	Disposable.	Single Patient Use.
Catheters/Yankaeur.	Disposable.	After every use.
Filters.	Disposable.	Change every 3 month in high use area and every 12 months in low use areas.
Telephone.	Universal wipe, dry thoroughly.	Daily.
Thermometers		
Tempadot.	Disposable, dry thoroughly.	Single Use.
Electronic.	Use with single-use cover/sheath.	Single Use.
Tympanic		
Display window.	Universal wipe.	Daily.
Probe covers.	Disposable.	Single Use.
Probe tip and mount.	Universal wipe, dry thoroughly.	Daily.
Tourniquets		
Fabric tourniquets.	Avoid use.	Single Patient Use.
Rubber tourniquets.	Universal wipe, dry thoroughly.	After each use.
Disposable tourniquets.	Recommended in trauma and isolation rooms.	Single Use.

Item	Method of Decontamination	Frequency
Toys		
Made from non-absorbent materials.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Weekly and when soiled.
Made from absorbent materials.	Avoid for communal use.	
Trolleys		
Dressing trolley.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each use.
Transfer trolley.	Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each use.
Linen trolley.	Empty and wash with warm water and detergent or Universal wipe, dry thoroughly*.	Daily.
Ultrasound scanner/probe		
Devices used in non-invasive procedures on intact skin.	Manufacturer approved wipes.	After each use.
Devices used in semi-critical procedures (semi-invasive and non-invasive). Probes used for TOE/TV/TR ultrasound/venepuncture/cannulation/wound assessments.	Automated high-level disinfection.	After each use.
Critical use transducers.	Return to SSD for sterilisation.	After each use.
Urinary Drainage Systems		

Item	Method of Decontamination	Frequency
Catheters (indwelling) and drainage bag. Overnight drainage bags. Stand/hanger. Urine jugs (plastic) Urine jugs (pulp).	Disposable. Disposable. Disposable. Disposable.	Single Use. Single Use. Single Use. Single Use.
Vase (flower).	Wash with warm water and detergent in a designated sink, dry thoroughly. Do not use patient or clinical sinks.	After discarding flowers or weekly, whichever is sooner.
Volumetric Infusion Pump.	Switch off and disconnect from electricity supply. Universal wipe e, dry thoroughly.	After each patient or weekly.
Vomit bowls.	Disposable.	Single Use.
Weighing scales. Contact points.	Wash with warm water and detergent or Universal wipe, dry thoroughly*. Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Weekly or when visibly soiled. After each use.
Wheelchair, Contact points.	Wash with warm water and detergent or Universal wipe, dry thoroughly*. Wash with warm water and detergent or Universal wipe, dry thoroughly*.	Weekly. After each use.
X-Ray machine.	Wash with warm water and detergent or Universal wipe, dry thoroughly.	Daily or when visibly soiled.
X-Ray wedges.	Inspect integrity of cover. Wash with warm water and detergent or Universal wipe, dry thoroughly*.	After each use.

* Wash with warm water and neutral detergent or Universal wipe and dry with paper towel. If contaminated with body fluid, first wash with warm water and neutral detergent or wipe with Universal wipe and then disinfect with chlorine releasing agent 1000ppm (10,000 for blood spills).

Further cleaning guidance from the Association of Healthcare Cleaning Professionals, NHS National Patient Safety Agency, The revised healthcare cleaning manual.

https://www.ahcp.co.uk/wp-content/uploads/NRLS-0949-Healthcare-clea-ng-manual-2009-06-v1.pdf

Appendix 5. Procedure for Manual Cleaning

Decontamination by Manual Cleaning

Manual cleaning would normally be undertaken either by employing immersion or non-immersion techniques depending on the construction of the device and according to the manufacturer guidelines.

Immersion method – Procedure for Manual Cleaning

To minimise the risk to personnel undertaking manual cleaning, splashing and the creation of aerosols must be avoided at all times.

a) Fill the clean sink (not hand wash basin) with water and detergent (detergent dilution and water temperature should be in accordance with manufacturer's instructions and/or local documented policy/procedures).

b) Wearing protective clothing, dismantle or open the instrument/equipment to be cleaned and fully immerse in the solution in order to displace trapped air and to ensure penetration of the lumen if hollow instruments/equipment are being cleaned. Consideration should be given to the use of a protein-enzyme dissolving solution when cleaning medical devices with lumens or complex parts.

c) Brush, wipe, agitate, irrigate, jet wash or hand spray the item to dislodge and remove all visible soil, taking care to ensure the item remains under the surface of the water at all times to prevent the creation of aerosols.

d) Remove the item from the sink and drain any excess detergent prior to rinsing the item thoroughly with clean water or water jet gun under the surface of the water.

e) Remove and drain the item before drying using the preferred method.

f) Complete any necessary documentation to record the item being processed and the method and solutions employed.

If either the cleaning solution or the rinse water becomes obviously soiled or contaminated, it should be changed and the process repeated.

NB: Cleaning materials should be safely disposed of in accordance with local policy in the appropriate waste containers following use.

Jet guns should only be connected to the cold-water supply.

Non-Immersion Hand Washing Methods

Are appropriate for certain equipment where items will become compromised by soaking in aqueous solutions, e.g., electrical and electronic equipment. These items should be cleaned in accordance with manufacturer's instructions.

Factors Affecting Manual Cleaning

Due to the lack of acknowledged methods of control available to the user to test the efficacy of manual cleaning processes, the user should be aware of the factors which may affect the efficiency of this method of cleaning. These include:

a) Staff training and competence.

b) Water temperature (it is important to be aware that protein coagulates at 35ºC and must not be used for initial immersion of devices prior to cleaning).

c) Detergent concentration.

d) Nature and method of soil removal.

e) Accessibility of fluid to the item.

Appendix 6. Decontamination of Equipment Prior to Service or Repair

The Trust has a legal requirement under The Health and Safety at Work etc. Act 1974, The Management of Health and Safety at Work Regulations 1992, COSHH Regulations 2002, and the Health Act 2006 to ensure that people, (staff, patients, visitors, contractors) are not exposed to unnecessary risks through contaminated items.

All decontamination procedures must be undertaken by suitably qualified, trained and supervised staff, using suitable methods of decontamination.

Anyone who inspects, services, repairs or transports medical, dental or laboratory equipment either on hospital premises or elsewhere has a right to expect that the medical devices have been appropriately treated so as to remove or minimise the risk of infection or other hazards, e.g., chemical, radioactive.

Medical devices and equipment which may be contaminated with body fluids, chemicals, radioactive toxic or other harmful substances, intended for inspection, service, repair or off-site transportation, must be provided with a declaration of contamination status.

Consideration must be made for manufacturer's instructions which require the avoidance of submersion of the device in chemical substances should the integrity of the instrument be damaged, e.g., endoscopes. By continuing with the normal reprocessing procedure further harm and higher cost for repair would entail.

In situations where decontamination of the item is not possible the details of type of contamination must be clearly stated on the decontamination certificate.

If the item is the subject of complaint or investigation, decontamination may alter or influence the investigation; therefore, the advice of the investigating body must be sought prior to decontamination.

If items are for repair off site:

1. Prior warning must be given to the intended recipient.

2. The condition (decontamination status), of the item must be clearly labelled so that it can be determined prior to opening of the inner packaging. This may be achieved by enclosing the documentation in an envelope marked 'Examine enclosed documents before unpacking.'

3. The packaging should be sufficiently robust to withstand transportation in order to prevent spillage or leakage of the contents.

Items that are visibly contaminated must not be presented or sent for inspection, service or repair. All outward signs of contamination must be removed. Equipment presented with visible signs of contamination will NOT be accepted for repair.

Condemned equipment must be decontaminated wherever practicable before following the Trust's condemning procedure. In certain cases, it may be necessary to dispose of equipment which cannot be decontaminated. In such cases the equipment should be condemned, and the most appropriate method of disposal should be used. Refer to the waste disposal policy or seek the advice of the waste control officer.

It is the responsibility of the user department to ensure compliance with this policy and its procedures.

Appendix 7. Single-use Medical Device Policy

1. Introduction

Single use refers to the medical device that is intended for use on an individual patient during a single procedure and then discarded. Single use devices are not intended to be reprocessed and used on another patient. If a device is reprocessed and it is not fit for its intended purpose, both the re-processor and the professional user may be committing an offence.

The reuse of ‘single-use’ devices has legal implications. It is the policy of the Royal Cornwall Hospitals NHS Trust that medical devices designated for a single episode of use are not to be reused under any circumstances. Anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.

2. Indications against Re-use

Devices designated for ‘single use’ must not be reused under any circumstances.

Key points are:

i. The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

ii. The reuse of single-use devices has legal implications:

- Anyone who reprocesses or reuses devices intended by the manufacturer for use on a single occasion bears full responsibility for its safety and effectiveness.

- Anyone who reprocesses a single-use device and passes it to a separate legal entity, (for example the independent healthcare sector), has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device. (MHRA DB2006 (04)).

3. Technical Implications

The most important factor open to influence is instrument decontamination.

A single-use device may be manufactured in such a way that decontamination may damage or alter the device to such an extent that further use is unsafe. The following problems have been identified:

- Inadequate cleaning and sterilisation.
- Material alteration.
- Mechanical failure.
- Potential for cross-infection.
- Reactions to endotoxins.

- Chemical residues from washer/disinfection processes.
- Physical damage to sterilisers and other equipment.

If a device is reprocessed and it is not fit for its intended purpose, both the re-processor and the professional user may be **committing an offence** under one or more of the following acts:

- Health and Safety at Work Act 1974.
- Consumer Protection Act Part 1.
- General Product Safety Regulations 1994.
- Medical Devices Regulations 1994.

4. Action by healthcare professionals

- Look for the DO NOT REUSE symbol on device packaging.
- After use dispose of device safely as per clinical waste policy Symbol Used on medical devices and their packaging for single use:

Single-Use:	Use by Date:
	

The ‘use by’ symbol is intended to indicate that the device should not be used after the end of the month or day shown.

5. Single Patient Use Medical Devices

Some devices are designated for Single Patient Use. This will be clearly stated on the packaging. These devices include such items as nebulisers, disposable pulse oximeter probes, and certain specified intermittent catheters.

Always follow the manufacturer’s instructions regarding cleaning and disinfection between uses on a named patient only. Never reprocess and use on another patient.

References/ Bibliography

Medicines and Healthcare products Regulatory Agency (2006) Single-use Medical Devices: Implications and Consequences of Reuse DB2006 (04). London: Medicines and Healthcare products Regulatory Agency.

British Standards Institution (1997) Graphical symbols for use in the labelling of medical devices BS EN 980:1997. London: British Standards Institution.

Medicines and Healthcare products Regulatory Agency (2006) Managing Medical Devices DB2006(05). London: Medicines and Healthcare products Regulatory Agency.

Appendix 8. Policy for the Decontamination of Flexible Endoscopes

1. Introduction

This policy covers the basic principles for cleaning and disinfection of endoscopic equipment, which includes:

- Flexible gastrointestinal endoscopes.
- Bronchoscopes.
- Cystoscopes.
- Ureteroscopes.
- EUS Scopes.
- Choledochocoscopes.
- Nasal Endoscopes.

The decontamination procedures must comply with the guidelines produced by the British Society for Gastroenterology (BSG) Endoscopy Committee and the British Thoracic Society. There are currently no published guidelines specific to endoscopes used in the ENT environment. However, the Trust is establishing a central decontamination process for all flexible endoscopes.

Any patient undergoing endoscopy may be infected with potentially transmissible infections such as HIV, hepatitis B, hepatitis C, Salmonella or mycobacteria. The purpose of cleaning and disinfection therefore is to prevent the exposure of all individuals to potential pathogens.

Current methods of endoscope disinfection are unable to destroy the infecting agent in CJD/vCJD and therefore therapeutic endoscopy should be avoided wherever possible in patients with known/ suspected or at risk of transmissible spongiform encephalopathy (e.g., CJD, vCJD or UK Plasma recipients). If therapeutic endoscopy is essential, the Infection Prevention and Control Team and Endoscopy Matron must be contacted.

2. Policy Scope

This policy applies to all members of staff, including locum/agency staff, involved in the cleaning and decontamination process of endoscopic equipment. Everyone who uses or handles any type of endoscope must be familiar with the procedures referred to in this policy, which therefore includes all satellite areas where endoscopes are used. The policy also includes guidance and recommendations on the safe and controlled storage of all flexible endoscopes, using cabinets specifically designed for this purpose. The policy describes all of the processes for the correct cleaning and decontamination of endoscopes including traceability procedures policy, which therefore includes all satellite areas where endoscopes are used (West Cornwall Hospital). The policy also includes guidance and

recommendations on the safe and controlled storage of all flexible endoscopes, using cabinets specifically designed for this purpose. The policy describes all of the processes for the correct cleaning and decontamination of endoscopes including traceability procedures.

3. Aim of Policy

The aim of the policy is to ensure that the cleaning and decontamination of all endoscopes follows recognised guidelines, and that the Trust is compliant with current national standards. This policy is also to ensure that there is complete traceability for the use, maintenance and cleaning processes of endoscopes. All of the processes included in this policy are there to protect the patient from potential harm that may be caused if the equipment used has not been decontaminated to the highest possible standards.

4. Duties

Sterile Services Department also manages the Endoscopy Decontamination at both Royal Cornwall Hospital and West Cornwall Hospital. It is the user who has the ultimate responsibility for certifying that the Automated Endoscope Re-processor (AER) is fit for use (see HTM 01-06). The Trust's Estates Department is responsible for ensuring that all endoscopes and AER's are correctly maintained, either in-house or by a contractor, and appropriate maintenance records are kept. The Sterile Services Manager / Sterile Services Operational Manager must also ensure that the weekly testing of the final rinse water is undertaken.

The Decontamination Lead must approve / reject the results and circulate these to all end users, Head of Estates and IPC. All users of endoscopes are responsible for examining the scopes for any damage prior to use on a patient.

5. Definitions

- EWD: (Endoscope Washer Disinfector) capable of disinfection and rinsing to a reproducible standard and where the performance can be validated and verified.

- Manual Cleaning: The physical removal of infectious agents (but not necessarily their destruction) and the organic material which can shield them from disinfectants, e.g., a neutral detergent or enzymatic cleaner in warm water.

- Disinfection: The process of reduction in viable infectious agents to a safe level, e.g., by using chlorine dioxide (Tristel®) or Peracetic Acid (Gigasept®).

- Decontamination: The process of cleaning combined with disinfection or sterilisation that makes medical devices safe for reuse.

- EDC: (Endoscope Drying Cabinet) A cabinet, which is specially designed to store/dry endoscopes in a clean and dry environment, using HEPA (High Efficiency Particulate Air) filtration.

6. Best Practice

The Royal Cornwall Hospitals Trust is committed to achieving Best Practice in Endoscope Decontamination and as such will adopt the principles described below. Any failure to achieve the standards described below will be identified through audit and will be subject to Risk Assessment and a corrective action plan.

The following is a summary of the report of a working party of the BSG Endoscopy Committee (June 2020).

Summary of Report

1) Decontamination of endoscopes should be undertaken by staff trained and educated in the procedures within dedicated and well-designed rooms. There should be one way flow of endoscopes between dirty returns and clean dispatch areas to prevent cross contamination. Best practice is that there should be physical separation of dirty and clean procedures and areas, each with its own detailed procedures. The washroom area, if separated dirty and clean rooms are used, should have a negative pressure in comparison to the clean side. See Health Technical Memorandum (HTM) 01-06 part B. If a single room procedure is used, the room must be well designed to ensure a good and safe flow is well managed. Units should be moving away from single room facilities and all new designs should have split rooms with clearly segregated clean and dirty areas.

2) Staff training should be implemented using a competency framework and should be documented and revalidated annually. Training should include an awareness of the channel configuration of all endoscopes, manual cleaning procedures and of the endoscope washer disinfectors (EWD) and available irrigation adaptors, and any post cleaning processes (e.g., controlled environment storage cabinets [CESCs]) or portable storage systems, such as vacuum packing, that may be in use. See HTM 01-06 part D. These systems must be checked on a regular basis and validated by the manufacturer.

3) Traditionally, it has been recommended that before the start of each list, each endoscope to be used should undergo a full reprocessing cycle unless last used and decontaminated within the preceding 3 hours. Where appropriate quality assurance data are available, the use of CESCs or portable storage systems may obviate the need for repeat endoscope reprocessing at the start of each list.

4) Thorough manual cleaning with a CE mar ked detergent that is compatible with the disinfectant, including the brushing and flushing of all accessible endoscope channels, must be undertaken before automated endoscope disinfection within an EWD. This routine must be undertaken during lists, between patients and after each patient examination.

5) Units should no longer be using aldehyde and alcohol-based disinfectants because of their fixative properties, which in theory could anchor prion and other proteins within endoscope channels. Units should employ single use disinfectants within purpose designed washer disinfectors.

6) All detergents and disinfectants must be compatible with the EWD and endoscope and used at the correct temperatures and concentrations in accordance with the detergent and disinfectant manufacturers' instructions. Machine testing should include the efficacy and reproducibility of the detergent and disinfectant dosing system, in accordance with the EWD manufacturer's instructions.

7) It is important to ensure that both the endoscope and EWD manufacturers have type tested the chosen detergents and disinfectants that are compatible for use with their products.

8) It is essential that all reprocessing stages are included and documented after every use of the endoscope, and that none is omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even those that were not used during the preceding patient procedure.

9) EWDs should be used to wash and disinfect all endoscopes following manual cleaning. Manual disinfection alone is unacceptable. Some endoscopes may need to be sterilised depending upon their intended use, with a sterilisation process that is compatible with the endoscope. Users must ensure that the correct adaptors are available for all endoscopes to ensure irrigation of all channels. See HTM 01-06 part E.

10) Filtered air should be used as part of the drying process for each endoscope at the end of each EWD cycle. CESCs are recommended to store cleaned endoscopes. These are designed to deliver high efficiency particulate filtered air (HEPA) to the internal channels at the appropriate temperature and flow rate. Due to its fixative properties, the use of alcohol to assist in drying endoscopes is no longer recommended.

11) Water used in an EWD should be free from particulate and chemical contamination and microorganisms. This can be achieved either by using water purification systems, which can be a combination of high-level filtration and additional disinfection methods (e.g., ultraviolet light), or by using a reverse osmosis plant. In line water softeners may be needed if the local supply delivers hard water. The final rinse water should be sampled from the EWD and tested weekly for its microbiological quality in accordance with International Organization for Standardization ISO 15883 4:2018 or HTM 01-06 part E. Trending of results is advised to identify any potential problems.

12) Hospitals undertaking endoscopy outside normal working hours will need to ensure that any remote facility is able to accept endoscopes for reprocessing on weekend days and public holidays. All endoscopes should be reprocessed as soon as possible following use, but routinely within 3 hours. Endoscope drying and storage facilities need to be present both in the endoscopy unit and in the remote facility. Any processed endoscope that remains outside such storage facilities or are unwrapped will need to be used within three hours of reprocessing, which must include (i) the transportation time between reprocessing or leaving storage at the remote site and the return to storage at the endoscopy unit PLUS (ii) the time between storage and use in the next patient in the unit itself. An electronic tracking and traceability system is mandatory for units relying on a remote decontamination facility.

13) A record should be kept of the serial number of each endoscope used on each patient. This log should include any loan endoscopes. This is important for any future contact tracing when possible endoscopic transmission of disease is being investigated. Details of each decontamination step, including the operator performing the bedside clean, leak test and manual, clean, the EWD and the cycle, details, including cycle, number, used in decontaminating that endoscope should also be kept. This log should also include loan endoscopes.

14) The agent of variant Creutzfeldt Jakob disease (vCJD) is believed to be resistant to all forms of conventional sterilisation. The risk of transmission of this agent is extremely low provided that scrupulous attention to detail is routinely employed in the decontamination process after every patient. In particular, all accessible endoscope channels should be brushed through with a single use purpose made device or brush tipped wire assembly that has an appropriate length and diameter for each channel.

15) Any endoscopic procedure that breaches gut mucosa and is followed by the withdrawal of an unsheathed accessory through the working channel of an endoscope is deemed “invasive.” Procedures that cause tissue vaporisation (e.g., diathermy) are also deemed “invasive.” If an invasive procedure is undertaken in i) a patient with definite or probable vCJD, ii) a patient in whom a diagnosis of vCJD is being considered or iii) a patient at increased risk of vCJD (in whom infection should be presumed) through receipt of labile blood products, such as red cells from a donor who later developed vCJD, it will necessitate the subsequent quarantining of the endoscope used.

16) The performance of an “invasive” procedure (defined in it 15 above) in a patient at risk of vCJD due to receipt of pooled plasma concentrates is no longer deemed to confer a high risk of endoscope contamination. A single quality assured decontamination cycle according to these guidelines is considered sufficient, but the endoscope should be decontaminated separately from other equipment within an EWD and with a single use disinfectant. There is no longer a requirement to quarantine the endoscope provided that routine traceability data can demonstrate thorough reprocessing.

17) Single use accessories should always be used. The choice of single use biopsy forceps, guidewires and cytology brushes helps to minimise any possible risk of transmitting prion disease. Reusable accessories should be used only in situations where no single use equivalent accessory exists, and they should be heat tolerant for sterilisation in the Sterile Services Department. Procedures should include a system for tracking use in each patient in these circumstances.

18) Rubber biopsy port caps must be discarded after all procedures involving the passage of biopsy forceps, guidewires and/or other accessories through the endoscope. Other detachable valves (primarily air/water and suction valves/pistons) should be manually cleaned according to the manufacturers’ instructions, then decontaminated with their corresponding endoscopes in an EWD, keeping the valves and endoscopes together as a traceable unique set. There is an increasing move towards using single use endoscope valves to enable full traceability and to prevent cross infection caused by inadequate processing.

19) Due to the increase in demand for endoscopy, many units have had to expand in limited space, with the result that decontamination facilities have been moved to a location away from the endoscopy unit. Used endoscopes and their internal channels must be kept moist during transfer to decontamination facilities, and it is best practice that endoscopes are placed in an EWD within 3 hours of patient use. In addition, there must be electronic tracking of endoscopes between units and remote facilities.

20) By contrast, the channels of reprocessed endoscopes should ideally be dried prior to use in the next patient.

21) Control systems, like appropriate monitors, environmental testing, low level extraction and routine health screening, should be undertaken to minimise risks to staff. Occupational health records should be retained for 30 years.

22) All staff involved in endoscopy and in endoscope decontamination should wear appropriate personal protective equipment (PPE) in line with local policy.

23) Out of hours endoscopy should not be performed unless there is an individual available who has been assessed as competent in pre cleaning and manual cleaning processes. If the decontamination facility is remote from the endoscopy unit, it is best practice to be able to accept endoscopes for reprocessing every day of the week. A detailed risk procedure must be in place for this process.

24) Endoscopes used invasively for example for Natural Orifice Transluminal Endoscopic Surgery (NOTES), and choledochoscopes should be manually cleaned, processed through an EWD and finally sterilised using a validated, compatible sterilisation process. High level disinfection is not sufficient. Reusable sheathed accessories passed up the bile duct may also require sterilisation.

Exclusions

Flexible endoscopes that enter normally sterile body cavities are regarded as “critical devices” and these flexible endoscopes must be decontaminated by manual cleaning, automated washing, and disinfection, followed by sterilisation using a process that is compatible with the endoscope. Examples of such endoscopes that may require sterilisation include choledochoscopes, those used for NOTES (natural orifice translumenal endoscopic surgery) cystoscopes, utereteroscopes and nephroscopes This guidance is not intended for critical or high-risk devices, although the procedures for cleaning and disinfection prior to sterilisation do apply.

Appendix 9. Decontamination Instruction Sheet

Instructions for Decontamination

Location:
Type of Equipment:
Serial Number:
Model:
Manufacturer:
Cleaning:
Disinfection:
Sterilisation:
Additional Comments:
Signature of Infection Prevention and Control:
Completed by Print Name: Designation: Signature: