

# Decontamination Policy

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## **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 The purpose of this policy is:

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

2.1.2 To provide compliant guidance to all staff who undertake the decontamination of medical devices within the RCHT.

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

2.1.4 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 sterilized 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 Divisional Nurses as well as to the Decontamination Risk Assessment Group.

## 4. Definitions / Glossary

4.1 Definitions used within the Policy are:

- 4.1.1. **Employees** are:
- Direct employees of the Trust.
  - Employees of other organisations but directly managed by the Trust.
- 4.1.2 **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.
- 4.1.3 **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:

- **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.
- **Disinfection** - A process used to reduce the number of viable microorganisms but which 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 sterilization.
- **Sterilization** - A process used to render an object free from microorganisms including viruses and bacterial spores. Normal sterilisation methods will not destroy prions.

- 4.1.4 **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 ☺. 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. Roles and Responsibilities

#### 5.1.1. The Executive Responsible for Decontamination is the Chief Operating Officer who will:

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

#### 5.1.2 Nominated Decontamination Lead will:

- b) Be organisationally responsible for the effective and technically compliant provision of decontamination services (Medical Devices).
- c) 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.
- d) Report on Incidents and on Decontamination related issues and risks to the Hospital Infection Control Committee (HICC), The Medical

Equipment Group and to the Decontamination Risk Assessment group (DRAG).

**5.1.3 Decontamination Implementation Assistant will:**

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

**5.1.4 Risk Assessment Group will:**

Fulfil the roles and responsibilities detailed in CFPP0101 and CFPP0106. Be chaired by the DIPC, and will include the following members:

1. The Executive Responsible for Decontamination
2. DIPC (or designated appointee);
3. Consultant Medical Microbiologist
4. The Decontamination Lead
5. Sterile Services Operations Lead
6. Surgical Instrument Co-ordinator
7. Senior Nurse Representation
8. Authorised Engineer (Decontamination) when available.
9. Estates Manager.
10. Local AP Decontamination
11. Others as co-opted at the discretion of the DIPC.

The Decontamination Risk Assessment Group will provide trust wide direction and will report directly to the Executive on all matters relating to the decontamination of Medical Devices.

The Decontamination Risk Assessment Group will be responsible for:

- 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 timescale 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.

**5.1.5 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 have been reviewed and approved by the Trust Decontamination Lead.

Ensure devices designed as 'Single Use Only' ② 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 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.**

#### **5.1.6 Employees will:**

- 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 & Safety Department and the Occupational Health department.
- Seek specialist advice as necessary.
- Never re-use single use devices.

#### **5.1.7 Purchasing Department will:**

- Be responsible for issuing a Pre purchase questionnaire to prospective suppliers/manufacturers of medical equipment and for obtaining a completed Pre Purchase Questionnaire (PPQ) form prior to the trial 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.

#### **5.1.8 Infection Control Department will:**

- 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.

#### **5.1.9 Sterile Services Department will:**

- 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 9001. ISO EN 13485 and Medical Devices Directive 93/42.EEC.
- Ensure that the Department is subject to external audit from a registered notified body at intervals determined by ISO EN 13495 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 notified body within agreed timescales.

#### 5.1.10 Health and Safety Manager will:

- Advice 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. 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.

### 6.1 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.

## 7. 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 1 FOR MORE GUIDANCE ON SELECTING THE APPROPRIATE LEVEL OF DECONTAMINATION FOR THE ITEM TO BE DECONTAMINATED**

## 8. Essential standards in the decontamination of medical devices and equipment

### 8.1 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.
- 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.

### 8.2 Cleaning

- a) 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.

- b) 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.
- c) When manual cleaning is the only option the guidance outlined in appendix 1 must be followed.
- d) 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 or if the instructions are not clear to follow.

### **8.3. 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.

### **8.4 Labelling**

Following decontamination, medical devices must be labelled as follows:

#### Items decontaminated within SSD .

These must be labelled after sterilisation with a label that is fully compliant with MDD93/42/EEC. 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.

#### Items decontaminated within an Automatic Endoscope Washer (AED).

If the endoscopes that have been decontaminated are not identified for immediate patient use, they must be placed in storage cabinets 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.

#### 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 2816.

## 8.5 Transportation

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

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.

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

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

Containers, trolleys, boxes etc. used for transporting decontaminated items after decontamination should be labelled DECONTAMINATED MEDICAL DEVICES.

## 8.6 Storage

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).

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

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.

## 8.7 Compatibility

Personnel responsible for reprocessing reusable medical devices must always follow the manufacturer’s instructions:

Personnel responsible for managing the decontamination process must:

- a) Ensure that the decontamination agents (detergents, water, including ultrasonic activity where utilised) used are compatible with both devices and reprocessing equipment.
- b) 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 Risk Assessment Group.
- c) Decontaminate reusable medical devices in accordance with the instructions provided by the device manufacturer.

- d) Ensure that appropriate decontamination facilities and compatible agents are available before purchasing new devices.
- e) Follow the instructions for use supplied by the manufacturer of the decontamination agent.
- f) If in doubt, consult the Decontamination Lead.

### **8.8. Record Keeping**

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.

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

### **8.9. Tracking and Traceability**

- a) 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.
- b) 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.
- c) 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.
- d) 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.
- e) Such a system is required in the event of a 'look back' exercise.
- f) Tracking systems are also available for endoscopes processed through automated endoscope washers (AEW's).

## 9. Decontamination of Equipment Prior To Service or Repair

- a) 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.
- b) 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.

## 10. Decontamination Related To Equipment on Loan

### Loaning of theatre instrument trays for use within RCHT

- a) 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.
- b) 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.
- c) 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
- d) 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 (to EN ISO 13485, with MDD93/42/EEC decontamination facility that is registered with the MHRA as being compliant. In such circumstances, the packaging materials must be checked for integrity and sterilizer indicators must show that the instrumentation has passed through a satisfactory sterilization 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 MDD 93/42.EEC 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

- e) 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 MDD93/42/EEC, and that is not registered with the MHRA as a compliant decontamination provider.
- f) 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.
- g) 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".
- h) Following post use Decontamination, the SSD will issue a decontamination certificate which will accompany the loaned instrumentation to its next destination.
- i) 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.

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 Divisional Nurse or Matron, Theatres & Anaesthetics Division, RCHT.

## **11. 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.



## 12. Spillage of Blood & Body Fluids

- a) The spill should be dealt with as soon as possible.
- b) 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.
- c) 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.
- d) Where the spillage may contain sharp material, forceps should be used to remove the sharp material, placing it immediately in a sharps bin.
- e) If the spillage is large, soak up the excess fluid using paper towels and carefully place these in a clinical waste bag.
- f) Where there is a large blood spill, a 10,000 ppm chlorine releasing agent must be used as part of the cleaning process.
- g) Clean surface with warm water and detergent using a disposable cloth or mop.
- h) If the spill is on a carpeted area this should be disinfected following cleaning using a steam cleaner or wet extract carpet shampooer.
- i) Curtains or loose fabric covers should be laundered or dry cleaned.

## 13. Related Policies and Procedures

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

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

## 14. Monitoring Compliance and Effectiveness

Element to be monitored	Fitness for safe use following decontamination
Lead	Decontamination Lead
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	<p>a) Twice annually external audit complemented by internal audits as required by ISO9001.</p> <p>b) Annually</p> <p>c) Monthly random sampling</p> <p>Trust Decontamination Lead reports outcomes at quarterly Hospital Infection Control Committee (HICC) the bi-monthly cleaning committee and at the De-contamination Risk Assessment Group.</p>
Reporting arrangements	<p>The completed report is sent to the joint DIPC for presentation to the Hospital Infection Control Committee (HICC) with minutes being circulated to the Nurse Executive and to the Chief Operating Officer who is the Executive responsible for Decontamination.</p> <p>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</p> <p>The Decontamination lead presents the report to the HICC 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.</p>
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	<p>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.</p> <p>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.</p>

## 15. Updating and Review

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

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

## **16. Equality and Diversity**

16.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

16.2 "Royal Cornwall Hospitals NHS Trust is committed to a Policy of Equal Opportunities in employment. The aim of this policy is to ensure that no job applicant or employee receives less favourable treatment because of their race, colour, nationality, ethnic or national origin, or on the grounds of their age, gender, gender reassignment, marital status, domestic circumstances, disability, HIV status, sexual orientation, religion, belief, political affiliation or trade union membership, social or employment status or is disadvantaged by conditions or requirements which are not justified by the job to be done. This policy concerns all aspects of employment for existing staff and potential employees".

## **17. Equality Impact Assessment**

17.1 All public bodies have a statutory obligation to undertake Equality Impact Assessments on all policy documents. This must be undertaken by the author using the agreed Equality Impact Assessment Template. The completed assessment is to be added to the end of the policy document as an appendix prior to it being ratified.

17.2 The Initial Equality Impact Assessment Screening Form is at Appendix 10

# Appendix 1. 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.

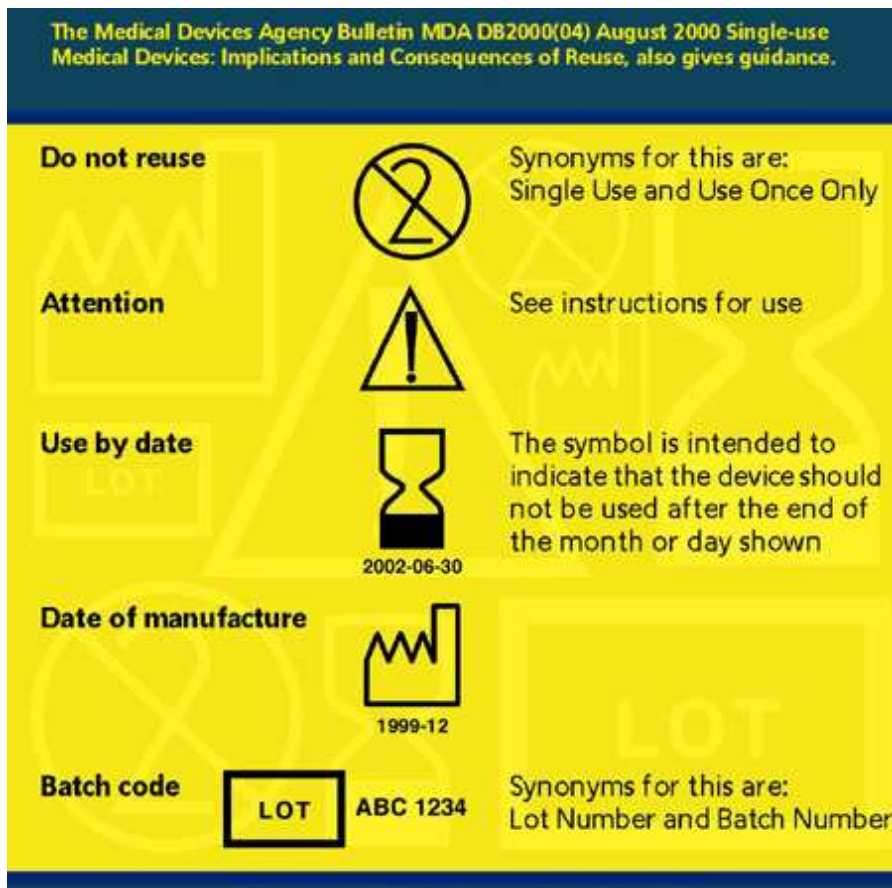
Prior to purchasing or using any item of equipment it is the responsibility of the user to ensure that the equipment can/has been decontaminated adequately.

## DEFINITIONS

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.
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 used 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 sterilization is essential.

### Disinfection

Disinfection using either heat or chemicals will destroy non-spore-forming 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. Chemical 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 (121°C - 134°C), 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 sterilize 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 the item of equipment is 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 sterilized?
- 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?





## Appendix 2. A – Z Guide of Methods of Decontamination for Equipment

Item	Method of Decontamination	Frequency
Alcohol hand rub holders – end of bed	Detergent 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 & detergent or Detergent wipe, dry thoroughly*	After each patient
Audiometer headphone	Detergent wipe, dry thoroughly	After each patient
Bath	Wash with warm water & detergent, rinse thoroughly	After each patient
Baby changing mat	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each patient
Bed frames	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Daily and on discharge/transfer
Bed, under bed	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Weekly and on discharge/transfer
Bed cradles	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Daily and on discharge/transfer
Bed pan holder	Wash with warm water & detergent or Detergent wipe, dry thoroughly.	After each patient
Bed pan holder (diarrhoea)	Wash with solution of combined detergent & Sodium hypochlorite (1000ppm)	After each patient
Bed pan	Disposable, macerate	
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 & detergent, rinsed thoroughly and disinfected in dishwasher or steam sterilizer. Pump wiped with Detergent wipe.	After every use

<b>Item</b>	<b>Method of Decontamination</b>	<b>Frequency</b>
Clip boards, note holders at end of bed	Detergent wipe, dry thoroughly.	Daily and on discharge/transfer
Cloths (for cleaning)	Disposable: Yellow – Kitchen; Red – Bathroom & Toilets; Blue – Ward & General Areas; Green – Isolation rooms & Theatre	Single Use for each bed space or side room
Commodes	Wash with warm water & detergent or Detergent wipe, dry thoroughly*  Wash with solution of combined detergent & Sodium hypochlorite (1000ppm)	After each use  Daily
Cots and Incubators	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Discharge/transfer & prior to admission
Crockery & cutlery	Dishwasher (cycle should heat disinfect, $\geq 80^{\circ}\text{C}$ for 1 minute)	After use
Drip stands	Detergent wipe	Daily
Drugs trolley	Detergent wipe	Weekly
Duvets	Wash with warm water & detergent or Detergent wipe, dry thoroughly	After each patient
Ear pieces (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 Detergent 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

Item	Method of Decontamination	Frequency
ECG & Cardiac machines		
Monitor	Damp dust with Detergent wipe	Daily
Leads	Detergent wipe	Daily and after each patient
Electrodes	Disposable	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 CSU	After each use
Examination couch	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each patient
Examination couch frame	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Daily
Enteral tube feeding syringes	Single Use	Single Use
Eye protection (goggles, visors)	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	As required
Floor cleaning equipment		
Mop heads	Disposable or launder (cycle should heat disinfect, $\geq 65^{\circ}\text{C}$ for 10 minutes or $\geq 71^{\circ}\text{C}$ for 3 minutes)	Daily and after use in isolation room and cohort bay.
Bucket	Wash with warm water & detergent, rinse and dry thoroughly.	Daily and after use in isolation room and cohort bay
Hoist (frame)	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Daily
Hoist sling	Single Patient Use launder if visibly soiled	Single Patient Use

Item	Method of Decontamination	Frequency
Laryngoscope	Disposable blades	Single Use
Reusable blades	return to CSD	After each use
Reusable handles	Wash with warm water & detergent or Detergent wipe, dry thoroughly. In cases of heavy soil send to SSD	After each use
Mattress	Wash with warm water & detergent or Detergent wipe, dry thoroughly	Weekly and on discharge/transfer
Mattress (alternating/specialised)	Wash with warm water & detergent or Detergent wipe, dry thoroughly	Weekly and on discharge/transfer
Medicine pots, spoons	Single Use	Single Use
Nebulizer equipment Acorns	Disposable Detergent and water	Single Patient Use After each nebulised dose.
Oxygen masks/ nasal cannulae	Disposable	Single Patient Use
Pillow	Wash with warm water & detergent or Detergent wipe, dry thoroughly.	Weekly and on discharge/transfer
Raised Toilet Seat	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each patient
<b>Resuscitation equipment</b>		
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 & liner	Disposable	Single Use
Swivel connector	Disposable	Single Use
Sharps Trays	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each use

Item	Method of Decontamination	Frequency
Sigmoid scopes	Disposable. Protect insufflator bulb with a filter	Single Use
Spacer (for teaching patients inhalation technique)	Wash with warm water & detergent, rinse and air dry	After each use
Specula (vaginal)	Preferably disposable  Reusable: return to CSD. Wipe gel from speculum immediately after use	Single Use  After each use
Stethoscope	Detergent wipe	Before & after each use
Sphygmomanometer	Detergent wipe, dry thoroughly	Daily
Disposable cuff	Disposable	Single Patient Use After each patient
Vinyl cuff	Detergent wipe, dry thoroughly	
Sputum pots	Disposable	
Syringe drivers	Switch off and disconnect from electricity supply. Detergent wipe, dry thoroughly	After each patient or weekly
<b>Suction apparatus</b>	Use rigid container with a disposable liner	
Rigid outer container	Detergent wipe, dry thoroughly	Weekly and on discharge/transfer
Tubing	Disposable	Single Patient Use  After every use
Catheters/Yankaeur	Disposable	
Filters	Disposable	Change every 3 month in high use area and every 12 months in low use areas
Telephone	Detergent wipe, dry thoroughly	Daily
<b>Thermometers</b>		
Tempadot	Disposable, dry thoroughly	Single Use
Electronic	Use with single-use cover/sheath	Single Use
<b>Tympanic</b>		
Display window	Detergent wipe	Daily
Probe covers	Disposable	Single Use
Probe tip & mount	Detergent wipe, dry thoroughly	Daily

Item	Method of Decontamination	Frequency
<b>Tourniquets</b>		
Fabric tourniquets	Avoid use	Single Patient Use
Rubber tourniquets	Detergent wipe, dry thoroughly	After each use
Disposable tourniquets	Recommended in trauma and isolation rooms	Single Use
<b>Toys</b>		
Made from non-absorbent materials	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Weekly & when visible soiled.
Made from absorbent materials	Avoid for communal use	
<b>Trolleys</b>		
Dressing trolley	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each use
Transfer trolley	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each use
Linen trolley	Empty and wash with warm water & detergent or Detergent wipe, dry thoroughly*	Daily
<b>Ultrasound scanner;</b>	Dependent on type of procedure; Non-invasive: Detergent wipe, dry thoroughly	After each use
Probe	Invasive: Disinfectant cleaning	After each use
<b>Urinary Drainage Systems</b>		
Catheters (indwelling) and drainage bag	Disposable	Single Use
Overnight drainage bags	Disposable	Single Use
Stand/hanger	Disposable	Single Use
Urine jugs (plastic)	Return to SSD	After each patient
Urine jugs (pulp)	Disposable	Single Use

<b>Item</b>	<b>Method of Decontamination</b>	<b>Frequency</b>
Vase (flower)	Wash with warm water & 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 Detergent wipe, dry thoroughly	After each patient or weekly
Vomit bowls	Disposable	Single Use
Weighing scales	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Weekly or when visibly soiled.
Contact points	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each use
Wheelchair,	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	Weekly
contact points	Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each use
X-Ray machine	Wash with warm water & detergent or Detergent wipe, dry thoroughly	Daily or when visibly soiled.
X-Ray wedges	Inspect integrity of cover. Wash with warm water & detergent or Detergent wipe, dry thoroughly*	After each use

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

## **Appendix 3. 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 35°C 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 4. 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 5. 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 sterilization
- Material alteration
- Mechanical failure
- Potential for cross-infection
- Reactions to endotoxins

- Chemical residues from washer/disinfection processes
- Physical damage to sterilizers 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

### 3. Action by healthcare professionals

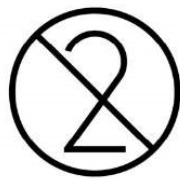
Look for the DO NOT REUSE symbol on device packaging

- 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 6. 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
- Nasal Endoscope

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

It is the responsibility of the Endoscopy Department Manager / Senior Nurse if outside the Endoscopy Department, to ensure that this policy is followed. It is the user who has the ultimate responsibility for certifying that the Automated Endoscope Re-processor (AER) is fit for use (see CFPP 01-064). 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 Endoscopy Department Manager / Nurse in Charge 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
- ESC: (Endoscope Storage Cabinet) A cabinet, which is specially designed to store 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 2014)

### Summary of Report

1. Decontamination of endoscopes should be undertaken by trained staff in dedicated rooms. There should be one-way flow of endoscopes between dirty and clean areas, to prevent cross contamination. Best practice is that there should be physical separation of staff in dirty and clean areas including staff.
2. Staff training programmes should be implemented and documented. 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.
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 is available, the use of drying/storage cabinets may obviate the need for repeat endoscope reprocessing at the start of each list.
4. Thorough manual cleaning with a compatible medical grade (CE marked) low foaming detergent, including the brushing and flushing of all accessible endoscope channels, must be undertaken before automated endoscope disinfection within an endoscope washer disinfectant (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 protein within endoscope channels. Units should employ either single use disinfectants or purpose-designed washer disinfectors that generate single use biocides.
6. All disinfectants should be used at the correct temperature and concentration in accordance with the manufacturers' instructions. Some manufacturers recommend the use of test kits or strips for reusable disinfectants in order to ensure the optimal activity of their product. Machine testing should include the accuracy and reproducibility of the dosing system.
7. It is important to ensure that the endoscope manufacturer has approved the chosen disinfectant as being compatible for use in decontaminating their product, and that the disinfectant is also compatible with the EWD in which it is being used.

8. It is essential that all reprocessing stages are included after every use of the endoscope, and that none are omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even if the channels were not used during the preceding patient procedure.
9. It is essential that the “pre-clean” procedure takes place immediately after removal of the endoscopes from the patient. The manufacturer’s instructions should be followed.
10. Endoscope washer disinfectors (EWD ) should be used for all endoscope decontamination following manual cleaning. Manual disinfection is unacceptable. Users must ensure that the correct adaptors are available for all endoscopes to ensure irrigation of all channels.
11. Filtered air should be used as part of the drying process at the end of the working day prior to endoscope storage. An alternative is to dry and store endoscopes in cabinets that are designed to deliver high efficiency particulate filtered air to the internal channels at the appropriate temperature and flow rate. Because of its fixative properties the use of alcohol is no longer recommended.
12. Water used in an EWD should be free of particulate contamination and of micro-organisms. This can be achieved either by using bacteria-retaining filters or by other methods, for example reverse osmosis. 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 the current relevant EN Standard, Health Technical Memorandum (HTM) or Choice Framework for local Policies and Procedures (CFPP 01-06).
13. A record should be kept of the serial number of each endoscope used for 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 the EWD and cycle parameters used in decontaminating that endoscope should also be kept.
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 a patient with definite or possible vCJD (or in a patient at increased risk 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 14 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 others 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 in preference to reusable accessories. The choice of single use biopsy forceps, guide wires and cytology brushes helps to minimise any possible risk of transmitting prion disease. Reusable accessories should only be used in situations where no single use equivalent accessory exists, and procedures should be available for tracking each patient use in these circumstances.
18. Rubber biopsy port caps must be discarded after all procedures involving the passage of biopsy forceps, guide wires and/or other accessories through the endoscope. Other detachable valves (primarily air/water and suction valves/pistons) should be manually cleaned according to manufacturers’ instructions, then decontaminated with their corresponding endoscopes in an EWD , keeping the valves and endoscopes together as a traceable unique set.
19. Due to the increase in demand for endoscopy, and the implementation of national quality standards for patient privacy and dignity, 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 transfers to remote decontamination facilities and until reprocessing. In addition there must be electronic tracking of endoscopes between units and remote facilities. By contrast the channels of reprocessed endoscopes must be kept dry until the time of next patient use.
20. Health surveillance for staff exposed to disinfectants should be considered, in consultation with occupational health departments. Occupational health records should be retained for 40 years.
21. Those involved in endoscopic practice should be immunised in accordance with local occupational health and infection control policies. All staff should wear single use gloves that are changed after each procedure. Staff involved in endoscope decontamination should also wear appropriate protective clothing.
22. Out of hours endoscopy should not be done unless there is an endoscopy assistant available who has been trained in decontamination practice. If the decontamination facility is remote from the endoscopy unit it must be able to accept endoscopes for reprocessing every day of the week.
23. Endoscopes used for Natural Orifice Transluminal Endoscopic Surgery (NOTES) and choledochoscopes should undergo some form of sterilization process. High level disinfection is not sufficient. Reusable sheathed accessories passed up the bile duct also require special attention (See Section 8).

24. Most of these recommendations are based on advice from expert opinion, which includes advice from the Medicine and Healthcare Products Regulatory Agency (MHRA) and from other Working Parties. Some of the recommendations are derived from microbiological studies. Controlled trials in the field of endoscope decontamination are lacking because of a reluctance to expose “placebo control” patients to an infection risk.
25. A summary guideline on avoiding pitfalls in endoscope decontamination practice has recently been updated by the MHRA

### **Summary of Recommendations**

1. Decontamination of endoscopes should be undertaken at the end of each endoscopy list and between patients by trained staff in dedicated rooms. These staff should understand the varied design of endoscopes and the need to ensure the cleaning of auxiliary channels such as water, exposed elevator wire and balloon inflation channels in endoscopic ultrasound probes.
2. There should be physical separation between dirty and clean areas, with one-way flow of endoscopes, to prevent cross contamination. Best practice is that there should be separation of staff in dirty and clean areas.
3. During lists and between patients a process of thorough manual cleaning with a low foaming neutral medical grade detergent which is compatible with the endoscope is an essential step before endoscope disinfection.
4. All accessible channels of endoscopes should be exposed to this detergent, which should be brushed through using single use purpose built cleaning devices. These should have an appropriate length and diameter for each endoscope channel.
5. The use of automated endoscope washer disinfectors is mandatory; manual disinfection is unacceptable. If the washing cycle is interrupted it will need to be repeated.
6. An effective disinfectant which is compatible with the endoscope and endoscope washer disinfectant should be used in decontamination.
7. Units should no longer be using aldehyde-based disinfectants due to their fixative properties and potential for triggering occupational-related disease.
8. A record should be kept of the model and serial number of each endoscope used (including loan endoscopes) and each reusable accessory used for each patient. This is important for any future contact tracing when possible endoscopic disease transmission is being investigated.
9. It is essential that all reprocessing stages are included after every use of the endoscope, and that none are omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even if the channels were not used during the preceding patient procedure.

10. Endoscopy should be avoided whenever possible in patients with suspected or confirmed vCJD. Where this is considered essential it will be necessary either to discard the endoscope or reprocess it and store for exclusive re-use in the same patient.
11. Quarantining of endoscopes becomes necessary following the performance of invasive endoscopic procedures (including unsheathed biopsy) in patients with or at high risk of vCJD. Endoscopes should be decontaminated singly with single-use disinfectant, but can return to use following endoscopy in the most prevalent at-risk group (plasma product recipients).
12. Endoscopes decontaminated in accordance with these guidelines can return to use following all forms of endoscopy in the most prevalent at-risk group (plasma product recipients).
13. "Single Use" accessories must be used in preference to reusable accessories where a single use alternative is available. This applies to endoscopic biopsy forceps, guidewires, therapeutic accessories and devices for manual cleaning. In circumstances where only a reusable accessory is available, a version that can be autoclaved is preferred. Reusable accessories must be subject to tracking, both for patient use and for decontamination purposes.
14. Rubber biopsy port caps should be discarded after any endoscopic procedures that involve passage of biopsy forceps or other accessories through the valves. Air-water and suction valves, and other detachable accessories, should be cleaned manually, then decontaminated with their corresponding endoscope, keeping all components together as a unique set.
15. Health surveillance of staff should include a pre-employment enquiry regarding asthma, skin and mucosal sensitivity problems. Lung function may need to be documented by means of spirometry, especially if there is a history of pre-existing respiratory symptoms or known asthma. Occupational health departments should conduct a COSHH risk assessment and draw up local staff surveillance policies which may include annual health questionnaires and spirometry.
16. All health care workers involved in endoscopic practice should have been immunised in accordance with local occupational health policy.
17. Staff carrying out endoscope decontamination should wear gowns and single use gloves which should be changed between each endoscope decontamination session. Eye and face protection is essential. Staff should cover wounds and abrasions.
18. Safe working practices in the decontamination area of each unit should be written down and understood by all staff.
19. When transporting endoscopes to and from areas outside the endoscopy unit, they must be transferred in a covered rigid receptacle. For dirty endoscopes the receptacle should be appropriately labelled as a potential medical hazard.

20. If an emergency endoscopic procedure is performed out of hours, an assistant with specialist knowledge of endoscopes and their decontamination must be available.
21. Bacteria-free water should be used in the rinse cycle of automated endoscope reprocessors. It is recommended that the final rinse water from each reprocessor should be confirmed as free of micro-organisms on a weekly basis.
22. Each endoscopy unit must have a policy for dealing with disinfectant spillage. This policy should be agreed with local health and safety advisors and should be prominently displayed within the unit. All staff must be trained in its implementation and be aware of potential chemical and biological hazards.
23. Every unit must have a protocol for dealing with body fluid spillage. The written policy should be agreed with the local infection control team.
24. Disinfectants used in automated endoscope reprocessors must be used at the correct temperature according to the manufacturer's instructions.
25. It is recommended that endoscopes are stored in drying or active storage chambers. Where these are used the early morning decontamination cycle may be waived provided that endoscopes have undergone a full reprocessing cycle within the interval for which the cabinet manufacturer can document absence of microbial re-contamination. In some cases this may be for as long as one month.
26. All detachable components should have been removed at the manual cleaning stage and should not be replaced until the endoscope is next used.
27. Given the "standard precautions" for endoscope decontamination there is little logic to placing "high risk" patients at the end of procedure lists. Nonetheless local infection control policies may dictate that patients with known *Clostridium difficile* – associated diarrhoea, methicillin-resistant *Staphylococcus aureus* or other resistant organisms should be examined after other patients and before the final theatre cleaning is carried out.

## Appendix 7. Decontamination Instruction Sheet

Location:
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Type of Equipment:
Serial Number:
Model:
Manufacturer:

### Instructions for Decontamination

Cleaning:
Disinfection:
Sterilisation:

Additional Comments
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Completed by:	Print Name	Designation	Signature
.....	.....	.....	.....

<i>Signature of Infection Control</i>
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## Appendix 8. References and Acknowledgements

European Standard EN 980. Graphical Symbols for Medical Devices

European Standard EN 554 Sterilisation of Medical Devices – Validation and routine control of sterilisation by moist heat

European Standard EN 46002 Quality systems – Medical Devices – Particular requirements for the application of EN 29002

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The Stationery Office, London

Great Britain (1999) The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1999 The Stationery Office, London

Health Act 2006. Code of Practice for the prevention and Control of Health Care Associated Infections. General Health Protection, Department of Health.

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Medical Devices Agency (1996) Decontamination of Endoscopes. MDA DB 9607  
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Medical Devices Agency (2000) Guidance on the Purchase, Operation and Maintenance of Vacuum Benchtop Steam Sterilisers. MDA DB 2000 (05) Medical Devices Agency, London

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Choice Framework for Local Policies and Procedures (CFPP) 0101-Management and Decontamination of Surgical Instruments used in Acute Care (Dep't of Health).

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NHS Executive (1999) Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the Risk of Transmission. HSC 1999/178 1999

Spongiform Encephalopathy Advisory Committee (1998) “Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection” (Advisory Committee on Dangerous Pathogens (ACDP) Spongiform Encephalopathy Advisory Committee (SEAC)

## Appendix 9. Governance Information

<b>Document Title</b>	Decontamination Policy		
<b>Date Issued/Approved:</b>	9 <sup>th</sup> November 2015		
<b>Date Valid From:</b>	1 <sup>st</sup> December 2015		
<b>Date Valid To:</b>	30 <sup>th</sup> November 2018		
<b>Directorate / Department responsible (author/owner):</b>	Mark Lavery, Trustwide Decontamination Lead		
<b>Contact details:</b>	01872 252816		
<b>Brief summary of contents</b>	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		
<b>Suggested Keywords:</b>			
<b>Target Audience</b>	<i>RCHT</i>	<i>PCT</i>	<i>CFT</i>
	✓		
<b>Executive Director responsible for Policy:</b>	Chief Operating Officer		
<b>Date revised:</b>	October 2015		
<b>This document replaces (exact title of previous version):</b>	Decontamination Policy		
<b>Approval route (names of committees)/consultation:</b>	Decontamination Risk Assessment Group. Hospital Infection Control Committee. Infection Control Lead (Joint DIPC).		
<b>Divisional Manager confirming approval processes</b>	Louise Dickinson		
<b>Name and Post Title of additional signatories</b>	'Not Required'		
<b>Signature of Executive Director giving approval</b>	{Original Copy Signed}		
<b>Publication Location (refer to Policy on Policies – Approvals and Ratification):</b>	Internet & Intranet	✓	Intranet Only
<b>Document Library Folder/Sub Folder</b>	Clinical / Infection Prevention & Control		
<b>Links to key external standards</b>	Governance Team can advise		

<b>Related Documents:</b>	
<b>Training Need Identified?</b>	No

**Version Control Table**

<b>Date</b>	<b>Version No</b>	<b>Summary of Changes</b>	<b>Changes Made by (Name and Job Title)</b>
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 Oct15	V7	Revised and updated	Mark Lavery (Trust Decontamination Lead).

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

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

**Controlled Document**

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## Appendix 10. Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as <i>policy</i> ) to be assessed: Decontamination Policy	
Directorate and service area: Estates and Facilities	Is this a new or existing Procedure? New
Name of individual completing assessment: Mark Lavery	Telephone: 01872 252694
1. Policy Aim*	To set the overarching Decontamination strategy for RCHT
2. Policy Objectives*	To provide information and guidance to all staff in relation to Decontamination. To provide a rationale for all aspects of decontamination activity within RCHT.
3. Policy – intended Outcomes*	To provide assurance that all risks associated with decontamination activities are mitigated by effective planning, policies and actions
4. How will you measure the 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.
6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?	No
b. If yes, have these groups been consulted?	
c. Please list any groups who have been consulted about this procedure.	Decontamination Focus Group. Infection Prevention and Control Lead Nurse (Joint DIPC). Hospital Infection Control Committee Governance Department.

## 7. The Impact

Equality Group	Positive Impact	Negative Impact	No Impact	Reasons for decision
Age			x	
Disability			x	
Religion or belief			x	
Gender			x	
Transgender			x	
Pregnancy/ Maternity			x	
Race			x	
Sexual Orientation			x	
Marriage / Civil Partnership			x	

**You will need to continue to a full Equality Impact Assessment if the following have been highlighted:**

- **A negative impact and**
- **No consultation (this excludes any *policies* which have been identified as not requiring consultation).**

8. If there is no evidence that the <i>policy</i> promotes equality, equal opportunities or improved relations - could it be adapted so that it does? How?	Full statement of commitment to policy of equal opportunities is included in the policy
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**Keep one copy and send a copy to Matron, Equality, Diversity and Human Rights, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Chyvean House, Penventinnie Lane, Truro, Cornwall, TR1 3LJ**

A summary of the results will be published on the Trust's web site.

Signed:..... Mark Lavery

Date:..... 20.10.15

