

## Decontamination of Reusable Medical Devices

Author:	David Biggins - Head of Medical Engineering
Owner:	Brian Golding
Publisher:	Healthcare Governance
Version:	5.0
Date of version issue:	20 <sup>th</sup> March 2015
Approved by:	Hospital Infection Control Group
Date approved:	21 <sup>st</sup> April 2015
Review date:	20 <sup>th</sup> March 2017
Target audience:	All Trust staff
Relevant Regulations and Standards	Health and Social Care Act 2008 Health & Social Care Act (Regulated Activities) Regulations (2014) Part 3
Links to Organisational/Service Objectives, business plans or strategies	Infection Prevention & Control strategy
<b>Executive Summary</b> This policy describes the arrangements for safe effective decontamination of high and medium risk reusable medical devices with York Teaching Hospital NHS Foundation Trust	

**This is a controlled document. Whilst this document may be printed, the electronic version is maintained on the Q-Pulse system under version and configuration control. Please consider the resource and environmental implications before printing this document.**

## Version History Log

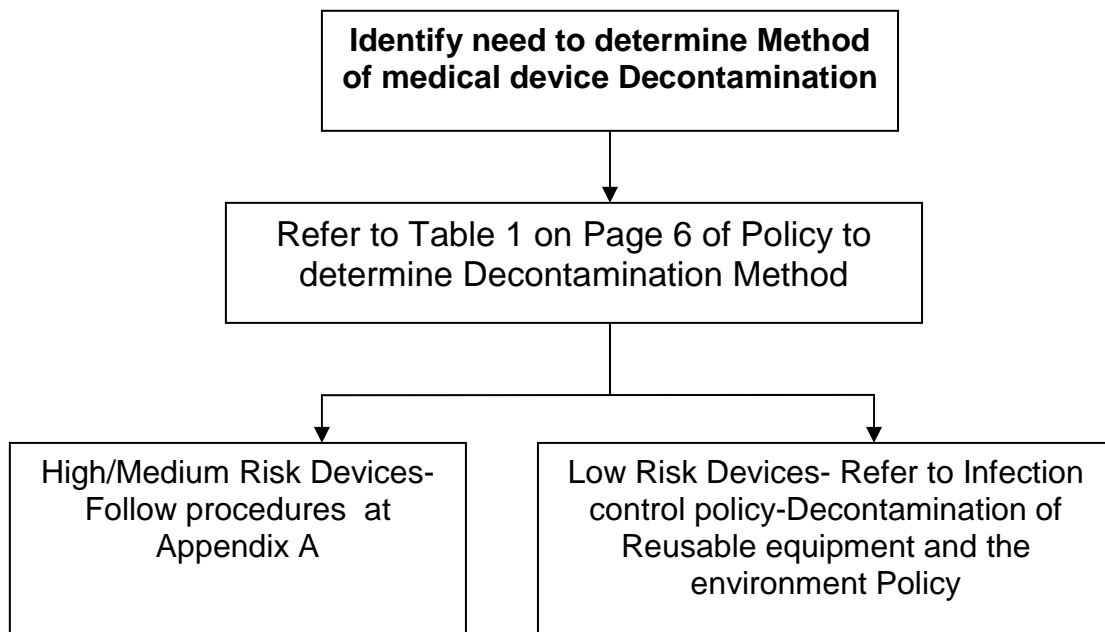
This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Approved	Version Author	Status & location	Details of significant changes
<b>3.0</b>	<b>10-01-13</b>	<b>D Biggins</b>	<b>Policy archive</b>	
<b>4.0</b>	<b>17-03-2014</b>	<b>D Biggins</b>	<b>Staffroom</b>	<b>Policy adapted to new policy format</b>
<b>5.0</b>	<b>21-04-2015</b>	<b>D Biggins</b>	<b>Staffroom</b>	<b>Policy adapted to new policy format</b>

## Contents

Number	Heading	Page
	Process flowchart	4
1	Introduction & Scope	5
2	Definitions / Terms used in policy	5
3	Policy Statement	6
4	Accountability	7
Appendix 1	Appendices Principles of Decontamination of Reusable Medical Device Procedures	13
Appendix 2	Decontamination of Reusable Surgical Instruments	16
Appendix 3	Decontamination Of Flexible Endoscopes & Invasive Probes	21
Appendix 4	Maintenance and Validation of Decontamination equipment	24
Appendix 5	Management of Decontamination Arrangements	26
Appendix 6	Definitions Of Terms & Abbreviations	27
Appendix 7	Policy Management	29

## Process flowchart



## 1 Introduction & Scope

The purpose of this policy is to describe arrangements for safe effective decontamination provision for all high and medium risk reusable medical devices for patient use ensuring that risks associated with decontamination are minimised and that the arrangements for effective decontamination are embedded across York Teaching Hospital NHS Foundation Trust.

## 2 Definitions / Terms used in policy

Decontamination is defined as a combination of processes used to render a reusable medical device safe for re use.

High and medium risk reusable medical devices are defined as any medical device that either comes into close contact with a break in skin or mucous membrane or is designed with the purpose of being introduced into sterile body cavities or those devices which come into contact with intact mucous membrane or membranes which may be contaminated with virulent organisms.

Table 1 gives examples:

Risk	Application of item	Example	Recommendation
High	<ul style="list-style-type: none"><li>• in close contact with a break in the skin or mucous membrane</li><li>• introduced into sterile body areas.</li></ul>	Surgical instruments Rigid Endoscopes	Sterilization.
Intermediate	<ul style="list-style-type: none"><li>• in contact with mucous membranes</li><li>• contaminated with particularly virulent or readily transmissible organisms</li><li>• Prior to use on immuno compromised patients.</li></ul>	Flexible endoscopes TOE/TV/TA Probes	Sterilization or disinfection required. Cleaning may be acceptable in some agreed evidence based situations and with appropriate local risk assessment
Low	<ul style="list-style-type: none"><li>• in contact with healthy skin</li><li>• Not in contact with patient.</li></ul>	Blood pressure cuffs	Cleaning.

### **3 Policy Statement**

The Trust recognises and will fulfil its duties to ensure that all reusable medical devices are introduced into, decontaminated, transported, stored and disposed of in accordance with recommendations for essential requirements as defined by Department of Health, (England), Care Quality commission standards and in compliance with the Health and Safety at Work etc Act (1974).

### **4 Impact Upon Individuals with Protected Characteristics**

The Policy Author has considered the following in the development of this document

- Current legislation with regards to safe decontamination of medical devices (Health & Social Care Act 2012),
- Department of Health Best practice & Essential quality requirement choice framework for policy and procedure documents,(CFPP 01-01 & CFPP 01-06).
- British standards & European Norms BS EN 285-Large Steam sterilizers, BS EN 15883 – Washer Disinfectors
- Medicines & Health Regulatory Agency (MHRA) publications: MDA SN 1999(32)
- Storage of sterile medical devices, MHRA DB 2006(04)
- Single use Medical Devices, consequences and implications of reuse.
- Decontamination of Medical Devices (2000/032)
- Equality Act 2010

Consultation has taken place by circulation of this document to the Policy Manager, Decontamination Steering group membership, Director of Infection Prevention and control, Hospital infection prevention committee and the Trust Decontamination Lead. The policy author believes that this document is fully inclusive and does not discriminate against any individuals with protected characteristics.

## **5 Accountability**

The success of this policy is dependent on a range of individuals being involved in the implementation of this document. The responsibilities on individuals in ensuring compliance with this document are detailed below:-

**5.1** The Trust's Chief Executive is responsible for the implementation and compliance monitoring of this policy' However there are a number of key responsibilities placed on individuals within the organisation to ensure the effective implementation of this policy:-

### **5.2 Decontamination Lead**

The Trust will have a nominated decontamination lead with responsibility for decontamination.

The decontamination lead is responsible for the implementation of this policy.

He/She should ensure that the policy clearly defines the roles and responsibilities of personnel who may be involved in the procurement, use, installation and maintenance of decontamination equipment and reusable medical devices.

### **5.3 Designated Person (Decontamination)**

The Designated person (decontamination) will provide the essential senior management link between the organization and professional support; the designated person should provide an informed position at board level.

Main Duties of the Designated Person;

- Assist the decontamination lead in the execution of their duties including formulation of policy and monitoring and trust wide audit of compliance against this policy.
- Provide technical advice on decontamination to users and others as required.
- Manage the Trusts decontamination audit programme.
- Manage and disseminate MHRA alerts and field safety notices relating to decontamination of medical devices.

## **5.4 Senior Operational Manager**

The Senior Operational Manager is technically, professionally and managerially responsible for the engineering aspects of decontamination processes (for example decontamination equipment and environment). The Head of Estates will carry out this role.

The senior operational manager must complete training commensurate with their duties.

## **5.5 Authorised Person (Decontamination) AP (D)**

The AP (D) and any associated deputies will be nominated engineers within the Estates Department. The AP (D) will have completed suitable training to carry out this role and be appointed in writing by the Executive Manager

The AP (D) must be suitably qualified to undertake their role.

### **Role of the AP (D)**

The AP (D)s will undertake the safe and effective management of the engineering aspects of the service.

The AP (D) will provide the organisation with an individual who, as part of the management infrastructure, will provide day-to-day operational management responsibility for the safety of the system.

The AP (D)s will report professionally to the Senior Operational Manager.

The AP (D) will also be responsible for:

- The engineering management of decontamination equipment;
- Line management and appointment of CP(D)'s;
- The safe and effective systems of work for all installed decontamination equipment;
- The acceptance criteria for operational and performance testing of all installed decontamination equipment;
- Appointment of Trust AE(D).
- Liaison with the AE(D) and other interested professionals;
- Authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests;
- Ensuring the continued competence of the CP(D)s, records of this will be held

The AP (D) can perform the role of the CP (D) – subject to the necessary skills, education and experience.



## **5.6 Authorising Engineer (Decontamination) AE(D)**

The AE (D) will provide independent auditing and advice on decontamination equipment and its uses. The AE (D) will review and audit documentation on validation.

The Trust AE(D) must be a registered AE(D) as stated within the Institute of Healthcare Engineering and Estates Management authorized engineers register.

The AE (D) will liaise closely with other professionals in various disciplines and, consequently, the appointment will be made known in writing to all interested parties.

### **Role of the AE (D)**

- The AE (D) will have a reporting route to the Decontamination Lead and provide professional and technical advice to AP (D)s, CP (D)s, Users and other key personnel involved in the control of decontamination processes.
- The Institute of Healthcare Engineering and Estates Management (IHEEM) sets professional standards for their voluntary registration and for the accreditation of training courses of AE (D)'s The Trust will engage in three year contracts with a nominated individual from the approved register, to ensure a consistent and strong working relationship is developed.

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

- To provide to Management and others, general and impartial advice on all matters concerned with decontamination;
- To advise Management and others on programmes of validation;
- To audit reports on validation, revalidation and yearly tests submitted by the AP(D);
- To advise Management and others on programmes of periodic tests and periodic maintenance;
- To advise Management and others on operational procedures for routine production;
- To advise Management on the appointment of the AP (D).

## **5.7 Competent Person (Decontamination) CP (D)**

The trust will have multiple CP (D)'s they will each be appointed in writing by the AP (D). The CP (D) will report directly to the AP (D).

### **Role of the CP (D)**

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

- To carry out the maintenance tasks outlined in Health Technical Memorandum 01-01 Part B;
- To carry out additional maintenance and repair work at the request of the User;
- To conduct the validation tests specified in Choice Framework for Policy & procedure Guidance CFPP 01-01/01-06 and to prepare the validation report;
- To conduct the periodic tests specified in Choice Framework for Policy & procedure Guidance CFPP 01-01/01-06 and to prepare reports as required by the User;
- To conduct any additional tests at the request of the User. For those CP (D)s who carry out maintenance duties, they will be an engineering craftsman with evidence to demonstrate competence in the maintenance of one or more types of decontamination equipment. The CP (D) will be in a position to deal with breakdowns, and have the ability to diagnose faults and carry out repairs, or to arrange for repairs to be carried out by others.

## **5.8 Director of Infection Prevention and Control (DIPC)**

The role of the DIPC is to:-

- Oversee local control of infection policies and their implementation;
- Be a full member of the IPT and attend regularly its infection and control meetings;
- Report directly to the Chief Executive or equivalent (not through any other officer) and the board or other senior management committee;
- Have the authority to challenge inappropriate clinical hygiene practice and inappropriate antibiotic prescribing decisions;
- Assess the impact of all existing and new policies on HCAI and make recommendations for change;

- Be an integral member of the organisation's clinical governance and patient safety teams and structures

## **5.9 Users**

The User will be notified by the Authorised Person(s) and will be responsible for the management of the decontamination processes within their area. The User is also responsible for the Operators within their area.

Users should be suitably trained to undertake their role having attended appropriate user courses for either sterilizers, washer disinfectors or endoscope washer disinfectors as appropriate.

The principal responsibilities of the User are as follows:

- To certify that the decontamination equipment is fit for use following validation, repair or service.
- To hold all documentation relating to the decontamination equipment, including the names of other key personnel;
- To ensure that decontamination equipment is subject to periodic testing and maintenance; including sterilizers WDs, EWDs and Endoscope storage cabinets (ESCs)
- To appoint operators where required and ensure that they are adequately trained;
- To maintain production records;
- To establish procedures for product release in line with the quality management system;
- To ensure that procedures for production, quality and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.

The User may seek the advice of the DP(D), infection control teams and decontamination steering group which may consist of a Director of Infection Prevention and Control, Control of Infection Officer or Microbiologist (Decontamination).

## **5.10 Operator**

The Operator is defined as any person with the authority to operate a washer disinfectant, ultrasonic cleaner, endoscope washer, endoscope storage cabinet or sterilizer, including the noting of instrument readings and simple housekeeping duties.

### **5.11 Trust Decontamination Steering Group**

With The Decontamination Lead, advise the Trust on decontamination Standards, the decontamination steering group shall meet not less than 5 times annually with any significant decontamination issues reported to the Hospital Infection Control group meeting.

The Decontamination steering group shall operate within its defined terms of reference.

### **5.12 Infection Prevention and Control Team**

With the Designated Person and users with responsibility, oversee implementation of and compliance with this policy for decontamination.

### **5.13 Clinical Directors, Directorate managers and Matrons**

Responsible for monitoring decontamination audit results and for communicating these throughout all staff groups in their directorate.

Responsible for reporting results of audits to the Infection Prevention and Control Team.

Responsible for ensuring all staff comply with the policy and for developing and implementing action plans if standards are seen to be below that considered acceptable by the HIPCG.

Responsible for managing the performance of any staff responsible to them who do not comply with the policy.

### **5.14 All Trust Staff**

Responsible for ensuring that they are aware of the contents of the policy and that they comply with it at all times.

Responsible for reporting any failure to achieve the standards identified in this policy to their line manager.

Responsible for ensuring the updating of their own skills and knowledge pertaining to decontamination in accordance with Trust policy.

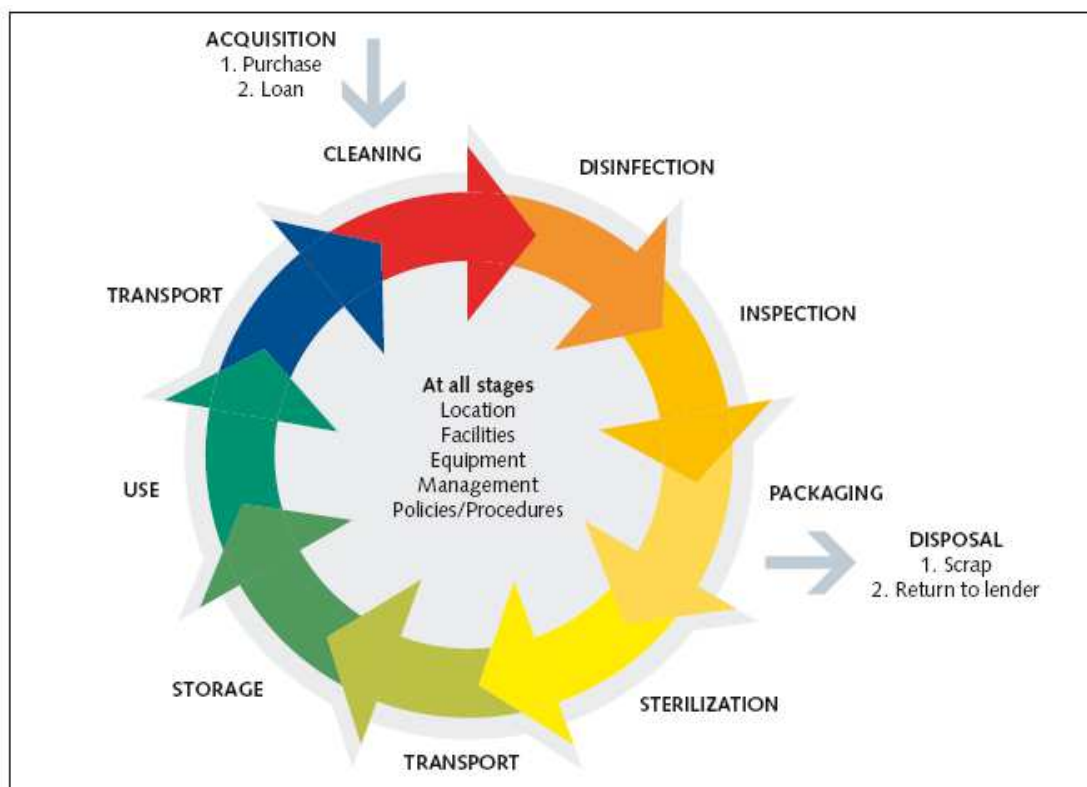
## Appendix 1

### Principles of Decontamination of Reusable Medical Device Procedures

#### Principals of decontamination

The diagram below highlights the life-cycle of a re-usable medical device.

Effective decontamination requires the attainment of acceptable standards at all stages of the life-cycle. Failure to address issues in any of these stages may result in inadequate decontamination.



Ref: CFPP 01-Management & Decontamination of Surgical instruments (medical devices) used in Acute care (Doh 2012)

#### Processing and reprocessing of medical devices intended for clinical re use.

It is essential to maintain adequate records demonstrating how a medical device was decontaminated. Current Department of Health guidance advises that cleaning is of the utmost importance in minimizing the potential risk of transmitting infectious agents between patients via surgical instruments but the general principles apply to any medical devices.

There should be clear instructions from the manufacturers regarding the appropriate method of decontamination. These methods must be locally achievable, and also be able to be fully validated.

It is therefore important that the procurement process for reusable devices includes confirmation that the Trust can successfully decontaminate the devices being purchased.

### **Single use Medical Devices**

Devices that are labeled by the manufacturer for 'single use only' must not be re-used under any circumstances. (MHRA DB 2006 (04) v2.0)

This will be clearly displayed on the packaging by the International Organisation for Standardisation symbol which is in the figure 2 with a diagonal line drawn through it;



Where possible and practical, single use items should be purchased but there may be clinical or other reasons where this is not possible and a risk assessment may be required to support the decision making process.

### **Single Patient Use Only Equipment.**

Certain devices, may be used a number of times on the same patient according to the manufacturer's guidance. Such equipment must not be re-used on other patients. For advice contact the Infection Prevention Team or Decontamination Designated Person.

### **Methods and Levels of Decontamination based on Risk of Infection.**

It is important to have a clear understanding of the terms and classification used in decontamination processes and to choose the most appropriate procedure for the items or surfaces in question.

## **Cleaning**

A process which physically removes infectious agents and the organic matter on which they thrive but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bio burden.

Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization can subsequently occur. Wherever practicable reusable medical device cleaning should be achieved by automated, validated processes unless contra indicated within device manufacturer's instructions.

Where manual cleaning processes need to take place specific SOPS and risk assessments for manual cleaning should be available locally.

## **Disinfection**

A process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores and prions.

Disinfection does not achieve the same reduction in microbial contamination levels as sterilization.

Disinfection of medical devices may be achieved via chemical or thermal methods in accordance with the disinfection guidance stated in BS EN 15883.

## **Sterilization**

A validated process used to render a product free from viable micro-organisms (BS EN ISO 14937:2009)

Note: In a sterilization process, the nature of microbial inactivation is exponential, and the survival of a micro-organism on an individual item can thus be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. Sterilization must therefore be defined as a process set by engineering parameters. These parameters need to be established during initial validation of a new piece of equipment and then periodically tested to ensure conformity. By this method the probability reduction mentioned can be consistently achieved.

## **APPENDIX 2 - Decontamination of Reusable Surgical Instruments**

### **Surgical Instruments**

For the purposes of this policy a surgical instrument is defined as 'any instrument that penetrates mucus membranes or intact skin or is introduced into a sterile body cavity`.

Such surgical instruments will be decontaminated using validated automated systems and will take place in appropriate facilities designed to minimise the risks that are present.

### **Sterile Services Department**

All reusable surgical instruments with the exception of flexible endoscopes and invasive and non invasive ultrasound probes will be reprocessed in the Sterile Services Department. (SSD/TSE).

Since June 1993 TSE York and 2007 (SSD Scarborough) have been bound by the Medical Devices Directive 93/42/EEC Article 12 Annex V (Sterility aspects only), and ISO 13485 which requires the department to have a quality management system.

### **Manufacturer's Instructions**

The SSD/TSE will only process surgical instruments which are **CE marked**, and where the manufacturers have provided the required information on the appropriate decontamination process to allow reuse. These include instructions for cleaning, disinfection, sterilization and packaging of the device.



The CE Mark

### **Limited use items.**

Sterile services Departments reprocessing limited use items need to have robust systems in place to ensure that the equipment is not used beyond its limited lifespan e.g. reusable laryngeal masks and diathermy forceps.



## **Tracking & Traceability of medical devices.**

The use of all surgical instrument sets on individual patients are required to be traced to the appropriate patient (HSC 2000/032). It is important to be able to trace medical devices through the decontamination process to which they have been subjected and to the patient on whom they have been used. The ability to track and trace medical devices and equipment enables corrective actions to be taken when necessary.

In the SSD surgical instruments are traced through the Meditrax traceability system. All items, trays and individual surgical instruments (supplementary items) when scanned into the system will produce a unique barcode label. When the instrument is used on a patient clinical staff must ensure one part of the label is attached to the patient's notes the other part of the label must be returned with the instruments to the SSD. Where a procedure tray has been used on a patient the patient number must also be written on the instrument check list and returned with the used instruments to SSD.

## **Transportation of contaminated instruments**

All used surgical instruments represent a risk of infection. To minimise this risk instruments other than those been used in main theatres, as the SSD is located in this area, must be transported in leak proof, easily cleanable rigid containers with a secure lid. This should happen as soon as possible after use. The users should ensure that all sharps, clinical waste, and fluids have been disposed of correctly and the correct paperwork completed before loading the transport containers.

The SSD will make dedicated trolleys and containers designed for purpose, available for this task such that the required standards for transport are met.

Instruments transported on both Scarborough and Bridlington sites must be transported in secure, leak proof easily cleanable containers.

Contaminated instruments and devices must also be accompanied by a decontamination status certificate.

## **Storage of Sterile Products**

Sterile products should be transported in containers or trolleys designated for the purpose. Packs should always be protected from the environment.

Containers and packs should be treated with care; they should not be tipped on their side or upside down to avoid damage to fragile components or the packaging. Staff should always lift instrument trays directly from and not dragged across shelving or cooling racks. Trays should never be pulled or lifted by their wrapping.

Storage should be on easily cleanable shelving and not packed too tightly. All packs should be stored above floor level away from direct sunlight and water. The room should be cool and well ventilated and kept secure at all times.

Sterility of single instrument packs, instrument trays and instrument containers must be ascertained by all staff prior to use and indicators to demonstrate sterility observed in accordance with sterile services local procedures.

The containers and packs should be rotated as normal practice and date checks carried out periodically with sterile items being returned to SSD for reprocessing where 1 year has elapsed since last sterilization episode.

## **Use of Sterile Products.**

It is the responsibility of the clinical staff to check the product prior to use on a patient. Ensure the product is in date, the “sterile” indicators on the packaging are correct, that no damage has occurred to the packaging which might suggest the sterility of the pack has been compromised.

See Appendix 6 Sterile Indicator Poster.

Always report to SSD Managers or supervisors any defects with the pack or contents, instruments which need repair or replacing. Always record the information on the instrument check list and mark the individual instrument an AIRs report must also be raised where any reusable medical device is found to be faulty, broken, dirty or inadequately sterilised either prior to use or in storage.

## Loan Instruments

In the event of use of loaned surgical instruments, these devices will require thorough and appropriate decontamination processes. (MDA SN 2002 (17) - Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals).

The responsibility for the management of loan instrumentation will be met by the sterile services department; the management of any other loaned reusable medical device must be met by the local ward or department requesting the loan.

Loaned surgical instruments must be managed in accordance with local sterile services procedures.

- Theatre staff should inform the SSD when loan instrumentation has been booked to arrive into the hospital. So that time is available to allow effective decontamination to be carried out prior to and after use
- Instruments should be decontaminated in accordance with the manufacture's recommendations and guidance in all instances and in an accredited Sterile services Department (SSD)
- Loaned instruments must be accompanied by a list of contents and relevant reprocessing instructions. If either the list of contents is missing or the SSD cannot perform the sterilization process required, the instruments must not be used.
- Theatre staff must check all loan instrumentation is correct prior to processing by the SSD. Theatre staff should also ensure the correct sterile implants have arrived with the instrumentation.
- Loaned instruments from other Sterilisation Units that do not hold CE approval must be re-sterilised in SSD before use. Except in emergency situations. If such emergency situations arise an AIR's form should be completed and information recorded in the patient's notes detailing the medical devices point of origin.
- Theatre staff must ensure that indemnity forms have been completed and those responsibilities for the instrumentation have been identified and documented.
- Following use and prior to return to the organisation from which the item was loaned, it should be decontaminated as per the manufacture's recommendations. A completed Decontamination Certificate must accompany the instrumentation.

- No surgical instrumentation or scopes can be removed by clinicians from the Trust without a formal contract and without informing SSD/Endoscopy Managers. To remove the equipment and use without traceability puts patients and the Trust at risk.

### **Disposal of Obsolete Surgical Instruments**

All surgical instruments that are for disposal must be adequately decontaminated, according to manufacturer's recommendations and where appropriate accompanied by a completed Decontamination Certificate for further information- see the Trust Waste Management Policy and Procedure.

## **APPENDIX 3 - Decontamination Of Flexible Endoscopes & Invasive Probes**

The endoscopy departments located at York, Scarborough & Bridlington sites are responsible for the decontamination of flexible endoscopes in accordance with relevant National Standards, guidance and local endoscope reprocessing procedures.

### **Cleaning & Disinfection of Flexible Endoscopes**

All flexible endoscopes and their accessories must be decontaminated in accordance with manufacturer's instructions and local endoscopy department procedures.

Flexible endoscope lumens must be flushed immediately after use, leak testing and manual cleaning must then take place in accordance with local endoscopy procedures.

Following Manual cleaning flexible endoscopes must then be chemically disinfected via a validated automated process and in accordance with local endoscopy department procedures.

### **Storage of Flexible Endoscopes.**

Flexible scopes must be stored suspended vertically in validated endoscope storage cabinets, to allow the circulation of air. They should not contact with other endoscopes or surfaces during the storage period.

Endoscopes may be stored for up to 31 days in a validated cabinet prior to reuse.

Where validated cabinets are not available endoscopes and probes must be stored in secure, clean, ventilated cabinets and reprocessed via EWD prior to reuse if needed within 3 hours of original decontamination process

## **Clinical Areas Using Trans vaginal, Trans rectal and TOE Probes**

Departments outside the Endoscopy Unit that use flexible endoscopes or invasive probes and transducers, such as X ray, and cardio respiratory departments will need to demonstrate safe systems of working and safe storage of TOE/TV and TA probes and transducers in accordance with the local Procedures and manufacturers instructions.

With specific regard to flexible nasal endoscope decontamination best practice requirements require reprocessing of flexible nasal endoscopes via a validated automated washer disinfectant.

However Flexible Endoscopes and probes such as those described may be cleaned and disinfected using a manual process as described in the essential quality requirements of CFPP-01-06 but must utilize carefully documented manual cleaning procedures and the use of appropriate sporicidal wipes approved by Infection Prevention & control team.

All cleaning and disinfection processes must also be traceable to patient.

## **Transmissible Spongiform Encephalopathies (TSE's) i.e. CJD/VCJD**

There are specific requirements for the decontamination of instruments in relation to TSE's. These requirements are necessary as routine sterilization practices do not destroy the prions that cause the disease. It is essential that if invasive procedures are carried out or planned for patients who are known or suspected to be at risk of TSE's that, appropriate arrangements are made to reprocess/dispose of or quarantine instruments in line with national recommendations and expert advice.

The Decontamination Lead and IPT must be informed of such cases.

Sterile services and endoscopy departments must have local risk assessments and procedures in place for the appropriate management of single and multiple instruments suspected of contact with TSEs.

## **Small Steam Sterilisers**

The Mortuary Manager is responsible for ensuring that daily housekeeping, testing and validation takes place of chemical decontamination processes for Mortuary located smalls team sterilizers.

Instruments sterilized via Mortuary sterilizer must be stored securely and be clearly identifiable as Mortuary use only and must not be reprocessed via sterile services units.

## **Pathology Sterilisers**

Infectious waste from the Pathology Department will be disposed of in accordance with local procedures in the Pathology Department. this will include decontamination via steriliser prior to disposal in the infectious clinical waste stream.

The steam sterilisers in the Pathology Departments at Scarborough & York sites must be operated maintained and validated in accordance with the relevant standards and operators must have completed appropriate documented training.

## **APPENDIX 4 - Maintenance and Validation of Decontamination equipment**

Management of the commissioning, maintenance, repair, service, period testing and Validation of decontamination equipment, (Sterilizers, Washer Disinfectors, Endoscope washer disinfectors, Endoscope storage cabinets), is the responsibility of the appointed users and Authorised Person (Decontamination) within the Estates Department.

The periodical tests will fall into four distinct sections.

1. Initial Validation & Commissioning on purchase of decontamination equipment
2. Weekly Testing
3. Quarterly Testing
4. Annual Re-validation

The Estates Department will store the hard copies of each set of test/validation reports in line with current guidance. Additionally the reports will be stored electronically on a shared trust drive.

Users, Authorised Persons, decontamination lead, designated person and executive managers should have access to on line reports.

It is essential that Users review and sign off validation, repair and test records for decontamination equipment they are responsible for.

The Authorising Engineer (Decontamination) will check each Initial Validation prior to first use of any new machine and annually will inspect the Quarterly and Annual tests. A representative proportion of the weekly test results will also be inspected at this time. During the annual visits The AE (D) and AP (D) will visit each decontamination area and produce a report that will be held on the shared trust drive and brought to the trust decontamination committee for discussion.



The CPD is responsible for inspection of the weekly tests carried out by maintenance persons across the site. This situation will continue until the final sections of the new HTM are issued at which time a review will be carried out by the AP (D).

All qualifications for in-house staff will be held within the estates department, a copy of each certificate for external contracts will be contained within each report produced by that contractor. Users should also retain copies of CPD Certificates relevant to their equipment locally.

The AP (D) will satisfy himself of the competence of each in-house engineer on an annual basis. Records of these evaluations will be held with the other training records.

The AE (D) will satisfy himself of the competence of the AP (D) and recommend in writing to the trust chief executive for appointment.

## APPENDIX 5 - Management of Decontamination Arrangements

<b>Executive Manager</b>	Patrick Crowley
<b>Decontamination Lead</b>	Brian Golding
<b>Designated Person (Decontamination)</b>	David Biggins
<b>Senior Operational Manager</b>	Andrew Fairgrieve
<b>Authorised Person (Decontamination)</b>	Andrew Betts
<b>Competent Persons (Decontamination)</b>	As designated by APDs
<b>Authorised Users</b>	Vincent North SSD/Endoscopy York Julie Jackson Endoscopy York Joan Ratcliffe Endoscopy SGH/BDH Marie Stephenson Endoscopy SGH Ian Scott SSD Scarborough Glenn Johnson SSD Scarborough Val Dixon, Endoscopy York
<b>Operators</b>	As appointed by users
<b>Director of Infection prevention and Control</b>	Dr Alistair Turnbull
<b>Microbiologist representative</b>	Dr Katrina Blackmore

## APPENDIX 6 - Definitions Of Terms & Abbreviations

<b>AE (D)</b>	Authorising Engineer (Decontamination)
<b>EWD</b>	An Endoscope washer disinfecter WD is equipment intended for the decontamination of flexible endoscopes.
<b>AIR</b>	Adverse Incident Reporting
<b>AP (D)</b>	Authorised Person (Decontamination)
<b>Audit</b>	Audit is a quality improvement process that aims to improve service user care and outcomes by carrying out a systematic review and implementing change.
<b>Bio burden</b>	The population of viable infectious agents contaminating a medical device.
<b>CJD vCJD</b>	Creutzfeld Jacob Disease variant CJD
<b>CP (D)</b>	Competent Person (Decontamination)
<b>Decontamination</b>	A process which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are used depending on the device and the procedure involved. The levels of decontamination are: <ul style="list-style-type: none"> <li>• cleaning</li> <li>• cleaning followed by disinfection</li> <li>• cleaning followed by sterilization.</li> </ul>
<b>Disinfection</b>	A process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilization.
<b>DIPc</b>	Director of Infection Prevention and Control
<b>DPd</b>	Designated Person (Decontamination)
<b>HIPCG</b>	Hospital Infection Prevention and Control Group
<b>HTM</b>	Health Technical Memorandum
<b>IPT</b>	Infection Prevention Team
<b>JAG</b>	Joint Accreditation Group for endoscopy

<b>Medical Device</b>	<p>Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:</p> <ul style="list-style-type: none"> <li>- diagnosis, prevention, monitoring, treatment or alleviation of disease,</li> <li>- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,</li> <li>- investigation, replacement or modification of the anatomy or of a physiological process,</li> <li>- control of conception,</li> </ul> <p>and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means</p>
<b>MHRA</b>	Medicines and Healthcare Products Regulatory Agency
<b>NHS</b>	National Health Service
<b>NICE</b>	National Institute for Health and Clinical Excellence
<b>Single-use device</b>	A medical device which is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be re-processed and used on another patient. The labelling identifies the device as disposable and not intended to be re-processed and used again.
<b>SSD/TSE</b>	<p>Sterile Services Department</p> <p>A centralised department specifically designed to reprocess re-usable medical devices.</p>
<b>Washer-disinfector</b>	An automated machine intended to clean and disinfect medical devices
<b>HPV Decontamination</b>	An automated room and equipment decontamination system used as part of the organisations c difficile management arrangements.
<b>ESC</b>	Endoscope Storage cabinet

=

## **Appendix 7**

### **Policy Management**

#### **1 Consultation, Quality Assurance and Approval Process**

##### **Consultation Process**

This Policy has been developed through a wide representation of the Decontamination Steering Group, Trust infection prevention specialists and other key stakeholders including Endoscopy and Sterile services departments.

##### **Quality Assurance Process**

The author has consulted with the following to ensure that the document is robust and accurate:-

- See above listing

The policy has also been proof read by the Policy Manager prior to being submitted for approval.

##### **Approval Process**

The approval process for this policy complies with that detailed in section 3.3 of the Policy Guidance.

It is the responsibility of the approving group/committee to ensure that they believe this policy is fit for purpose.

#### **2 Review and Revision Arrangements**

The Policy Author will be responsible for review of this policy in line with the timeline detailed on the cover sheet.

Subsequent changes to this policy will be detailed on the version control sheet at the front of the policy and a new version number applied. Subsequent reviews of this policy will continue to require the approval of the Hospital Infection Prevention and Control Group.

### **3 Dissemination and Implementation**

#### **Register/Library of Policies/Archiving Arrangements/ Retrieval of Archived Policies**

Please refer to the Policy Development Guideline for detail

### **4 Standards/Key Performance Indicators**

This policy conforms to the requirements identified in the Care Quality Commission Essential Standards of Quality and Safety and requirements of Code of Practice ,Criterion 2) and guidance from the Department of Health on the Management of, surgical instruments, flexible endoscopes and Reusable medical devices. See also the legislation and guidance annotated in Section 4 of the policy

### **5 Training**

Any training requirements identified within this policy that are of a 'Corporate Statutory or Mandatory nature will be outlined in the Statutory/Mandatory Training Brochure. This can be accessed via the link on Staff Room, the Q:\York Hospital Trust\Mandatory Training or the organisation's online learning platform.

If this training is deemed to be statutory or Mandatory and is not identified within the Statutory/Mandatory Training Brochure then application must be made by the Policy Author to the Corporate Learning and Development Team to have it added.

These training requirements are used to develop the customised profiles that can be viewed by learners when they access their personal online learning account. It is then the learner's responsibility to undertake this learning with the support of their line manager and the line manager's responsibility to review this at annual KSF appraisal.

The Corporate Statutory and Mandatory Training Identification Policy and Procedure document describes the processes relating to the identification, review, delivery and monitoring of statutory and mandatory training including non-attendance.

Engineering Maintenance, validation and testing of decontamination equipment must only be undertaken by appropriately trained personnel.

The Trust Authorised Persons (Decontamination) will maintain a register of appropriately trained engineering staff which will be audited on a yearly basis in accordance with the process for monitoring audit and compliance as stated in section 10.1 of this policy.

## 6 Trust Associated Documentation

- Decontamination Of Reusable Equipment And The Environment policy
- Central Alerts System Policy
- Medical Devices Management Policy
- Waste Management And Disposal policy
- Corporate Statutory And Mandatory Training Identification Policy

## 7 External References

- Choice Framework for Policy & Procedure – Management & Decontamination of Surgical Instruments –CFPP 01-01 (2012), Department of Health
- Choice Framework for Policy & Procedure –Decontamination of Flexible Endoscopes-CFPP 01-06 (2012), Department of Health
- Decontamination of Medical Devices, HSC 2000/032
- Medical Devices Agency (1999), MDA,SN 1999 (32) Storage of Sterile Medical Devices

## 8 Process for Monitoring Compliance and Effectiveness

In order to fully monitor compliance with this policy and ensure effective review, the policy will be monitored as follows:-

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results and monitoring of action plan	Responsible individual/ committee/ group for developing an action plan
Department of Health CFPP 01-01 Essential Quality Requirements (Sterile services)	Audit	Designated Person (Decontamination)	Annual	Decontamination Steering group	Sterile Services Manager
Health & Social Care Act- Code of practice for prevention and control of infections and related guidance (2011) Criterion 2	Audit	Designated Person (Decontamination)	Annual	Decontamination Steering group	Ward/dept Managers/ Sisters



## Dissemination and Implementation Plan

Title of document:	Decontamination of Reusable Medical Devices (Version 5.0)
Date finalised:	21 <sup>st</sup> April 2015
Previous document in use?	Decontamination of Reusable Medical Devices (Version 4.0)
Dissemination lead	David Biggins
Implementation lead	Policy Author
Which Strategy does it relate to?	Infection Prevention and Control

### Dissemination Plan

Method(s) of dissemination	Team Brief and via Staffroom
Who will do this	Policy author and Policy Manager
Date of dissemination	On approval
Format (i.e. paper or electronic)	Electronic

### Implementation Plan

Name of individual with responsibility for operational implementation, monitoring etc	Policy Author
Brief description of evidence to be collated to demonstrate compliance	<ul style="list-style-type: none"> <li>• Annual decontamination Audits</li> <li>• Decontamination steering group Terms of Reference agendas, minutes and papers</li> <li>• Training Record audits</li> <li>• AIRS Incident Review Records</li> </ul>