

Title: Decontamination Policy				
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1.0 INTRODUCTION

This policy is issued and maintained by the Strategic Planning & Commercial Development Director (the sponsor) on behalf of Sherwood Forest Hospitals NHS Foundation Trust (The Trust), at the issue date defined on the front sheet, which supersedes and replaces all previous versions.

Decontamination is a term generally used to describe a range of processes, including cleaning, disinfection and sterilization, which render a medical device safe for further use, remove or destroy contamination and thereby prevent infectious agents or other contaminants reaching a susceptible site in sufficient quantities to cause infection or any other harmful response.

Sherwood Forest Hospitals NHS Foundation Trust (SFHFT) recognises its obligations to take necessary measures to ensure the effective decontamination of Reusable Medical Devices and Equipment to minimise risk of transmission of infectious agents.

This policy is primarily aimed at the processing of re-usable instruments and not general decontamination duties that are managed via site procedures, ward manual and the decontamination handbook.

The policy addresses the responsibility for the maintenance of standards during the life cycle of the instrument or equipment rests with all staff involved with these process and use, to prevent infections consistently high standards must be applied to all decontamination practices throughout the organisation.

The Trust and where applicable its PFI Partners and various services Providers must comply with the guidelines and standards that relate to decontamination of both the environment and of medical equipment, including UK MDR 2002, as amended and Health and Safety Legislation (HMSO 1974, 1992, 2002). For this reason, decontamination is a risk listed on the Trust risk register and as so the Trust Board needs to have assurance controls are in place and that these are effective.

2.0 POLICY STATEMENT

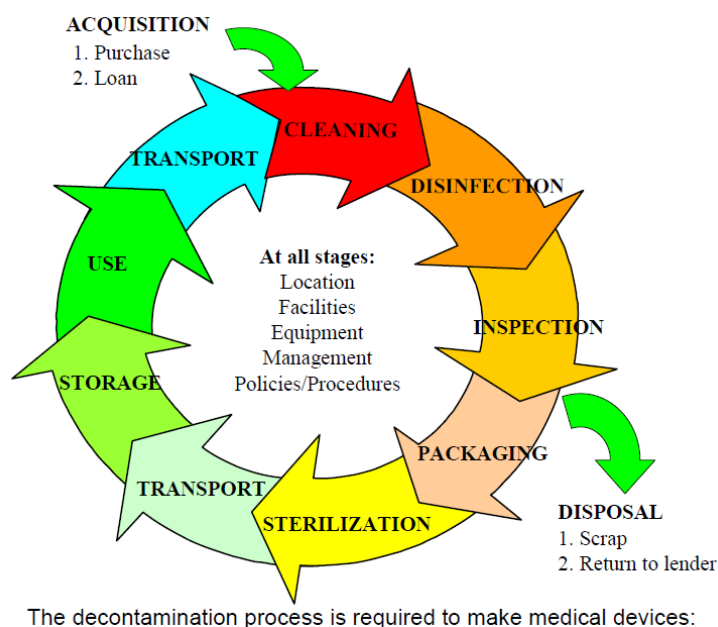
This policy sets out the management approach to be adopted by the Trust and their PFI Partners (Central Nottinghamshire Hospitals Plc (CNH)) and their Hard Facilities Management service providers (Skanska Facilities Services (SFS)) regarding the decontamination of medical devices and equipment associated with patient care.

The purpose of this policy is to define the terms of reference for decontamination of medical devices and equipment associated with patient care. This will allow the Trust and their partners to coordinate and implement effectively best practice in the management of decontamination. The terms of reference will reflect:

- Recognised industry best practice
- Statutory requirements, including UK MDR 2002, as amended.
- The Health and Social Care Act Code of Practice for the Prevention and Control of Health Care Associated Infections (The Hygiene Code)
- Other NHS guidelines

Compliance is required by all staff involved in decontamination which includes those directly involved in the reprocessing equipment as well as those involved in procurement, management, storage, and transportation.

Figure 1 The Decontamination Process:



- safe for users to handle
- safe for use on the patient

Source: NHS Estates

2.1 Statement of Intent

The Trust, as a major healthcare provider, is fully committed to maintaining an appropriate level of care and management in relation to the decontamination of equipment and instruments.

The Trust recognise that, although they outsource some of the delivery of maintenance and testing of decontamination process equipment to others (through their PFI Agreement, who primarily support the SSD), it still retains a duty of care to manage quality and check that appropriate decontamination controls and procedures are in place.

2.2 Key Points:

- Decontamination of equipment is the responsibility of the identified User as defined in the HTM 01-01/06.
- Most equipment will need cleaning and/or disinfection and/or sterilisation.
- The choice of decontamination method will depend on the risk of infection associated with the equipment.
- Regardless of use, any equipment must, as a minimum, be cleaned between patients.
- Cleaning is an essential pre-requisite of any disinfection or sterilisation process even when processing is undertaken via SSD. Detailed information relating to cleaning and the decontamination process is attached in '*Section 12: Cleaning – general*'.
- SSD is registered with MHRA for UK MDR 2002
- Moist heat with mechanical cleaning (e.g., using a washer-disinfector) is the preferred disinfection technique for instruments prior to sterilisation.
- The use of chemical disinfectants for medical and patient care equipment should be avoided wherever possible due to the inherent dangers of active chemical agents. Chemical disinfectants can also fail if not selected and used properly.
- Sterilization in SSD is the preferred sterilisation technique.
- All equipment must be appropriately decontaminated before inspection, service, or repair.

The Trust and its PFI partners have several policies and procedures currently in existence (see below) which relate to decontamination and this new policy serves to

augment these and to focus on the overview of decontamination of medical equipment.

- Trust Policy On Decontamination of Health Care Equipment Prior To Inspection, Service Or Repair
- Hydrogen Peroxide Training for Infection Control Update
- Emergency Decontamination policy
- Endoscopy Decontamination
- Ward manual

2.3 Policy Aims

Through implementation of this policy, the Trust aims to:

- Provide guidance to those responsible for the management of the decontamination.
- To provide terms of reference for decontamination between, The Trust, and their PFI Partners (Project Co) and other agencies
- To ensure that reusable medical devices are properly decontaminated in accordance with The Health and Social Care Act 2016 Code of Practice for the Prevention and Control of Healthcare Associated Infections (Department of Health, 2010)
- To set out responsibilities for the implementation of both statutory and mandatory HTM requirements
- Strive towards HTM compliance.
- Show compliance with CQC outcome 16 '*Assessing & Monitoring Quality*' in respect of Decontamination.
- Show compliance with JAG accreditation requirements.
- To ensure that the Trust has designated a lead manager for the decontamination of reusable medical devices (CQC Hygiene Code Duty 4b), for both SSD and Endoscopy

This policy DOES NOT cover

- Hand disinfection (see Infection Control Hand Hygiene policy).
- Transmissible Spongiform Encephalopathies (TSEs e.g., CJD)

Important note on single use instruments

All hospital equipment is either single-use or reusable. Single-use equipment should not be reused and should be discarded appropriately after use.

2.4 Equality Impact Assessment

The Trust is committed to ensuring that none of its policies, procedures and guidelines discriminate against individuals directly or indirectly on the basis of gender, colour, race, nationality, ethnic or national origins, age, sexual orientation, marital status, disability, religion, beliefs, political affiliation, trade union membership, and social and employment status.

An equality impact assessment (EIA) of this policy has been conducted by the author using the EIA tool developed by the diversity and inclusivity committee. The score of this policy when assessed by the tool was rated as 'low'.

3.0 DEFINITIONS

Definitions of specific terms used in the policy are as follows;

AE(D)	Authorising Engineer (Decontamination) is a person designated by Management to provide independent auditing and technical advice on decontamination procedures, washer disinfectors, sterilisers and sterilization and to review and witness documentation on validation
AER	Endoscope Washer Disinfector is a high-level disinfection method using a chemical washer disinfector specially for endoscopes
AP (D)	Authorised Person (Decontamination) is a person with sufficient technical qualifications and experience is responsible for the practical implementation and management of the organisations safety policy and procedures relating to the engineering aspects of decontamination equipment including the permit to work system
HTM	Hospital technical memorandum local Policies and Procedures is a document published by the DoH and forms a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.
CP(D)	Competent Person (Decontamination) is a person designated by Management to carry out maintenance, validation and periodic testing of washer disinfectors and sterilisers.
CSSD	Clinical Sterile Services Department registered with MHRA for UK MDR 2002, as amended.
DoH	Department of Health
EIA	Equality Impact Assessment is an assessment undertaken to score the policy on discrimination.
HCAI	Healthcare Associated Infections are infections that are acquired because of healthcare interventions. There are several factors that can increase the risk of acquiring an infection, but high standards of infection control practice minimise the risk of occurrence.
HTM	Health Technical Memorandum. Hospital specific engineering guidance published by NHS Estates.
IPCC	Infection Prevention & Control Committee which is chaired by the DIPC.

JAG	Joint Advisory Group is an external accreditation which ensures the quality and safety of patient care by defining and maintaining the standards by which Endoscopy is practiced.
MHRA	Medicines and Healthcare products Regulatory Agency
PA	Project Agreement. The agreement or contract between SFHFT and it's PFI partners (Project Co) for the building of the new hospital buildings and the provision of a facilities management services (see also Schedule 14).
PFI	Private Finance Initiative. The initiative under which, the Trust has entered into an agreement with its partners to build and provide certain services (such as Planned Preventative Maintenance) at its hospitals.
Project Co.	This is the term used to refer to Central Nottinghamshire Hospitals (CNH) PLC. It is the organisation appointed by the Trust to build the new hospital buildings and provide facilities services and then manage these facilities for the life of the contract, at which time they are then handed back to the Trust.
Schedule 14	Service Level Specification. The part of the PFI Project Agreement mainly concerned with the facilities management services provided by Project Co through their subcontract with Skanska Facilities Services (SFS).
SFS	Skanska Facilities Services. The organisation appointed by Project Co to provide certain facilities management services including estates and maintenance functions.
Staff	means all employees of the Trust including those managed by a third-party organisation on behalf of the Trust.
The Trust	means the Sherwood Forest Hospitals NHS Foundation Trust.

4.0 ROLES AND RESPONSIBILITIES

This section details the roles and responsibility of relevant persons and groups in the implementation of this policy as defined in HTM 01-01/06. Overall responsibility and more specifically, the duty of care within the Trust are vested in the Chief Executive, the Board of Directors, and its supporting structure, see appendix 1a.

A record should be kept of those appointed to carry out the functions listed below. The record should clearly state the extent of the post holder's duties and

responsibilities, and to whom they are to report. Substitute or replacement staff should be designated in order to cover for sickness, holidays and staff transfers.

Key persons such as Authorised Persons, Authorising Engineer and Competent Persons and Users should be appointed in writing and trained to provide that role and a record of the competence kept on file, which can be subject to audit.

A list of Trust named responsibilities is attached in appendix 2.

4.1 Trust Board

The Trust Board, through The Chief Executive (who is the Accountable Officer), has overall responsibility for Health and Safety within The Trust, carries ultimate responsibility for the decontamination process.

4.2 Collective Responsibilities (Policy & Procedures)

The Trust and its PFI partners all have responsibilities as duty holders to ensure they maintain the provision of the decontamination process. Each key party of the PFI scheme (Trust, Project Co and Skanska Facilities Services) has relevant responsibilities to develop, implement, manage and monitor within the decontamination process. This is undertaken through Policies and Procedures (reflecting each parties respective responsibilities as duty holders) as responsible partners.

The principal duties and responsibilities of the individual parties are highlighted below.

4.3 Project Co (CNH) Responsibilities

Day-to-day responsibility for inspection and maintenance of decontamination equipment (expecting AERs) in line with this policy is that of the Project Co (CNH Plc) who will comply with the requirements of HTM 01-01 and HTM 01-06 through the Project Agreement (PA). Project Co to discharge these duties will monitor and audit its service provider Skanska Facilities Services (SFS) compliance with their statutory and contractual obligations in line with HTM 01-01, HTM 01-06 HTM 03-01, ISO 14644 and this Policy (under the PFI Project Agreement).

Project Co will regularly provide statutory and mandatory compliance updates as part of the monthly PFI reporting function.

4.4 Skanska Facilities Services (SFS)

The day-to-day maintenance and validation of decontamination equipment (e.g. Washer Disinfectors and Sterilizers (currently excepting AERs)) is managed by SFS through the appropriate undertaking of regular Planned Preventative Maintenance (PPM) and validations. SFS will appoint persons who are suitably trained to fulfil the

role of Authorised Persons (Decontamination), Competent Person (Decontamination) and Competent Person (Pressure Systems).

SFS will also provide suitable monitoring regimes and record systems in order to comply with its contractual service delivery requirements (as defined in the PFI contract) and in line with the requirements of HTM 01-01, HTM 01-06, ISO 14644, HTM 01-03 and this Policy.

SFS will ensure that any areas of concern with regard to decontamination equipment deficiencies are brought to the immediate attention of Project Co who in turn will inform the Trust via the Designated Person for Decontamination.

4.5 Decontamination Lead

The Decontamination Lead is a Trust board member and is organisationally responsible for the effective and technically compliant provision of decontamination services.

The Decontamination Lead is responsible for the implementation of an operational policy for decontamination and for monitoring the implementation of the policy.

The Decontamination Lead may delegate specific responsibilities to key personnel.

The Decontamination Lead is the Chief Nurse.

Designated Person

The Designated Person provides the senior management link between the organisation and professional support and is accountable to the Decontamination Lead. The Designated Person should work closely with the Senior Operational Manager to ensure that provision is made to adequately support the decontamination process.

The Designated Person is the Head of Decontamination.

4.6 Senior Operational Manager

A Senior Operational Manager is technically, professionally, and managerially responsible for the engineering aspects of decontamination.

The Senior Operational Manager is the Senior Estates Manager – Hard FM for the Trust. For SFS (in relation to the roles they undertake) this will be the General Manager.

4.7 User (Sterile Services Department)

The User (Sterile Services Department) is defined as the person designated by Management to be responsible for the management of the relevant decontamination process.

The principal duties of the User (Sterile Services Department) are:

- To certify that the decontamination equipment is fit for use
- To hold all documentation relating to the decontamination equipment including the names of key personnel
- To ensure that decontamination equipment is subject to periodic maintenance.
- 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 control and safe working use are documented and adhered to in the light of statutory requirements and accepted best practice.

The User (Sterile Services Department) is the Head of Decontamination/Service Manager Decontamination

The User (Endoscopy)

The User (Endoscopy) is defined as the person designated by Management to be responsible for the management of the relevant decontamination process.

The principal duties of the User (Endoscopy) are:

- To certify that Endoscopy decontamination equipment is fit for use.
- To hold all documentation relating to the endoscopy decontamination equipment including the names of key personnel
- To ensure that Endoscopy decontamination equipment is subject to periodic maintenance.
- 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 control and safe working use are documented and adhered to in the light of statutory requirements and accepted best practice.

The User (Endoscopy) is the Head of Decontamination/Service Manager
Decontamination

4.8 Director of Infection Prevention and Control (DIPC)

The DIPC has Trust wide responsibility for the development of strategies and policies for the management of Infection Prevention and Control.

The DIPC is the Executive Chief Nurse

4.9 Nominated leads for Infection Prevention and Control Service Line Managers

Will ensure that the necessary management arrangements and structures are in place to allow all employees to fulfil their obligations in their roles in Infection Prevention and Control including decontamination where it applies (as defined in the ward manual).

4.10 Medical Staff

Are responsible for ensuring that their teams are aware of this policy and adhere to its statement. They will actively support all infection prevention and control measures and will have an active role in measuring outcomes and developing action plans for improvement.

4.11 Infection Prevention and Control Team (IPCT)

Will inform and support all staff at SFHFT of current and relevant information. These team members will also engage and support the decontamination committee as defined by this policy. This will ensure that all aspects of decontamination of instruments are considered throughout the operational processes.

4.12 Departmental/Ward Managers

Are responsible and accountable for Infection Prevention and Control within their sphere of responsibility. They will ensure that all staff are aware of all relevant Infection Prevention and Control measures.

4.13 Operator (SSD/Pathology)

This is any person with the authority to operate a washer disinfector or a steriliser (SSD/Pathology). Both the Trust and SFS staff undertake works on these items. These persons are trained and can be proven to be competent to undertake these roles.

4.14 Decontamination Technician (Endoscopy)

This is any person with the authority to operate an Endoscopy Washer. These persons are trained and can be proven to be competent to undertake these roles.

4.15 Authorising Engineer (Decontamination) (AE(D)) - External Appointment

The Authorising Engineer (Decontamination) (AE(D)) is the person designated by management (employed by either SFS or the Trust or both may have their own) to provide independent auditing and expert advice on washer disinfectors, sterilizers and sterilization and to review and witness documentation on validation.

Detailed role, responsibilities and qualifications are stated in HTM 01-01 and HTM 01-06.

4.16 Surgical Instrument Manager

The manager of surgical instruments is designated as the person assuming responsibility for coordinating activity between the theatre, decontamination, and supply / purchase teams. The person fulfilling that role should also ensure that the inventory of surgical instruments is proactively reviewed and managed in accordance with this guidance, clinical requirements, and industry best practice. The post holder will require close liaison with the Medical Device Coordinator.

The Surgical Instrument Manager is Jointly covered by ;

Service Manager Decontamination ,Specialist General Manager Theatres and Medicine (for Endoscopy)

4.17 Authorised Person (Decontamination)

The Authorised Person (Decontamination) (AP(D)) is the person responsible for the practical implementation and day to day operational management responsibility for the safety of the decontamination. Both SFS and the Trust will appoint their own AP (D) to manage their activities in respect of SSD and Endoscopy. Detailed role, responsibilities and qualifications are stated in HTM 01-01 and HTM 01-06.

4.18 The Competent Person (Decontamination)

The Competent Person (CP(D)) is the persons who are designated by Management (AP (D)) to carry out maintenance, validation and periodic testing of decontamination equipment such as washer disinfectors, AERs and sterilisers.

Detailed role, responsibilities and qualifications are stated in HTM 01-01 and HTM 01-06. These tests, inspections and validations should form a written scheme for the management of this equipment and be managed via a Planned Preventative Maintenance system.

4.19 Competent Person (Pressure Systems)

This role is defined in the Pressure Systems Safety Regulations and is a Chartered Engineer responsible for drawing up a written scheme or examination for the system. This is typically a specialist consultant/insurance inspector.

4.20 Microbiologist (Decontamination)

This is the person responsible for advising on the microbiological aspects of decontamination procedures for non-medicinal products, and to audit the documentation from all decontamination equipment that has been tested by microbiological methods (this may be an external appointment). Designated in writing by the Decontamination Lead Director, the Microbiologist will be responsible for:

- Providing advice to Service Managers/Users on microbiological aspects of sterilization and washing/disinfecting on non-medicinal products and Microbiological tests carried out on sterilisers and WDs
- Auditing the documentation from all steriliser/WDs which have been tested by microbiological methods.

4.21 Medical Device Co-ordinator

The Medical Devices Coordinator is the Medical Devices Lead who takes responsibility for coordination with the Service/Departmental manager(s) of device and equipment management, use and training matters including maintaining the medical devices inventory.

The Medical Device Coordinator is the Medical Physics Manager

4.22 Infection Control Team (ICT)

The Trust ICT are responsible for:

- Providing advice prior to the purchase of new equipment to ensure it can be decontaminated within the organisation.
- Approving decontamination procedures in specialist areas for specialist equipment
- Providing generic decontamination training as part of induction and infection control updates
- Implementation of a comprehensive decontamination programme
- Reporting to the decontamination committee

4.23 Decontamination Committee

This group/committee will monitor and oversee all aspects of decontamination within the organisation and ensure compliance with external standards. The chair of the committee is the Designated Person who can, through the Decontamination Lead, report to the Trust Board. Appendix 1A detail the reporting mechanism for the Decontamination Committee.

5.0 SCOPE OF POLICY

5.1 Limitations

This policy applies to hospital staff, Project Co, SFS and contractors employed by any of these parties. The policy complements the Department of Health Policies and Principles in the Health Technical Memorandum series and does not detract from other estates guidance.

The policy applies to all Trust and non-Trust staff involved in the procurement of medical devices or of the decontamination of medical equipment and the environment at any stage in the process. It also applies to those who manage these processes directly.

The policy does not include hand hygiene or decontamination of skin, wounds etc.

Refer to the Infection Control Policy for information about these

6.0 CONSULTATION

Consultation of this policy, prior to approval of the IPCC, was.

- Through distribution of the draft policy to all individuals named on the policy distributed list
- An agenda item on the Decontamination Committee agenda June 2024

7.0 NARRATIVE

7.1 Requirements

Due to the safety-critical nature decontamination it is highly regulated. A range of guides and requirements are provided in addition to the relevant HTMs that in some cases provide very specific recommendations and requirements within decontamination such as vCJD etc. These are listed in Appendix 2.

Where there may be variances in the guidance documents, associated with operational management, standards, monitoring and/or maintenance frequencies, the more detailed healthcare specific guidance contained within the HTMs shall be applied.

7.2 Maintenance of Sterilizers and Washer Disinfectors

The procedures (undertaken via SFS and audited via Project Co) will be prepared and reviewed (annually) by a suitably qualified person or persons. These procedures will include, where appropriate:

- Check sheets for recording purposes.
- Pressure systems written scheme.
- Operating and performance standards allowing monitoring of systems and plant.
- Permit to work log books.
- Clearly defined reporting procedures for any remedial action required following maintenance & monitoring procedures.
- Management arrangement for works by any sub- contractors.
- Record Keeping and Record Management Protocols
- Cleaning and disinfection procedures
- Commissioning and De-Commissioning procedures for all appropriate systems and plant
- Isolation procedures

After initial commissioning, testing and validation, decontamination equipment will be passed into service where they are subject to periodic inspection, verification and revalidation. These tests are the shared responsibility of the Trust User and SFS. The general frequency of inspections, verification and revalidation of decontamination equipment shall consist of the following:

- Washer Disinfectors and associated water plant
 - Daily (Trust/SFS)
 - Weekly (SFS/Trust)
 - Quarterly (SFS/Trust)
 - Yearly and Revalidation (SFS/Trust/AED)
- Sterilisers

- Daily (Trust)
- Weekly (SFS)
- Quarterly (SFS/Trust)
- Yearly and Revalidation (SFS/Trust/AED)
- Steam Quality
 - Yearly (SFS)
- Automatic Endoscope Reprocessors Endoscope Washer Disinfector and associated water plant
 - Daily (Trust)
 - Weekly (Trust)
 - Quarterly (Trust appointed contractor)
 - Yearly and Revalidation (Trust appointed contractor /AED)

Revalidation of decontamination equipment will typically also be required when engineering work has been undertaken which may affect the current validation. HTM 01-01 and HTM 01-06 provide guidance on this. Records shall include documentary evidence that can stand up to internal and external challenge.

7.3 Decontamination Method Selection

The method of decontamination required is dependent on the risk of infection i.e. the level of contamination and the extent of contact with susceptible sites on the patient. The risk of infection is classed as either high intermediate or low. Table 1 provides definitions of each infection risk classification and the suitable decontamination processes.

Table 1

RISK CATEGORY	FUNCTION	EXAMPLE	LEVEL OF DECONTAMINATION	METHOD
High Risk	A medical device that will be used for an invasive procedure, or medical device/equipment that will penetrate skin or mucous	Surgical instruments	Sterilisation	Cleaning and sterilisation conducted in the central SSD. For difficult to clean medical devices/equipment a disposable single use option should

	membrane			be used where possible e.g narrow lumen devices.
Intermediate Risk	Medical devices/equipment that have contact with mucous membranes or that are contaminated by microbes that are readily transmitted	Flexible endoscopes, and non invasive medical equipment	Disinfection or sterilisation	Cleaning, disinfection or sterilisation conducted in the central Decontamination Unit. Decontamination of flexible endoscopes are managed and decontaminated by EDU.
Low Risk	Medical devices and equipment that has a topical function	Incubators, Cots	Disinfection or clean	Automated disinfection or Manual clean with detergent and warm water. Dry thoroughly.

The ward manual gives guidance on the most suitable decontamination process for a range of equipment and devices in common use within the Trust.

- For specialist equipment e.g., flexible endoscopes, there must be local written protocols which have been agreed with the Infection Control Team
- An effective quality management system must be in place to cover all aspects of the decontamination life cycle for high and intermediate risk equipment.

7.4 Surgical Instruments and Invasive Medical Devices

Decontamination of surgical instruments must be conducted as soon as possible after patient use in accordance with the manufacturer's' decontamination and reprocessing instructions.

Once instruments arrive in the reprocessing department, they are prepared for washing and split into those sets that require only automated washing and those that require the additional manual wash step. On completion of any manual clean (if necessary) and after opening of any closed joints or dismantling, the instruments will be placed in an Automatic thermal Washer-Disinfector and exposed to the disinfection cycle for which a validated record is available.

Once cleaned the instruments exit into the Inspection, Assembly and Packing (IAP) are for inspection and packing. Once packed, sets and individual instruments are

loaded onto sterilizer trolleys and processed through a steam sterilizer before being placed onto cooling and storage racks.

Sets and instruments are then delivered to the relevant store area within the hospital and may be stored for a maximum of 12 months.

The Sterile Services Department is responsible for processing all surgical instruments and invasive medical devices.

7.5 Flexible Endoscopes

Decontamination of a flexible endoscope with or without lumen channels must be conducted immediately after patient use in accordance with the scope manufacturer's decontamination and reprocessing instructions and the British Society of Gastroenterologists (BSG) Guidelines (if appropriate).

Flexible Endoscopes with lumens:

Decontamination should begin as soon as the endoscope has been removed from the patient. Before the endoscope is detached from the light source/videoprocessor a preliminary cleaning routine should be undertaken. Manual cleaning and rinsing of all exposed internal and external surfaces should then be undertaken within the reprocessing area. This will involve an operative dismantling the contaminated endoscope and cleaning with care with single use cleaning brushes. ALL lumen channels in a flexible endoscope must be cleaned. On completion of the manual clean and leak test the flexible endoscope will be placed in an Endoscope Washer Disinfector then exposed to the disinfection cycle for which a validated record is available.

When the scope has been disinfected the scope will be placed in a clean scope tray covered with a clean protective cover then placed in the endoscope transport trolley and taken to the procedure room ready for use or placed in a HEPA filtered storage cabinet where the scope can be stored for seventy-two hours when the scope storage time expires and is reprocessed again

Where practicable single use endoscopic accessories are used

The Endoscopy department is responsible for decontamination of flexible endoscopes for Bronchoscopy, Thoracotomy, Gastro, Interventional Radiology (ERCP) and Outpatient services.

Flexible Endoscopes without lumens

Nasal endoscopes are used for the examination of nasopharynx, larynx and hypopharynx. They are short flexible endoscopes, usually without lumens. Nasal endoscopy used in Ear Nose and Throat procedures are often decontaminated near the point of use using a manual method such as disinfectant wipes when insufficient scopes or excessive travel distance makes the use of a central endoscope disinfection unit impractical.

All manual methods should include efficient cleaning of the used nasendoscope followed by controlled wiping with, or immersion in, an effective, compatible disinfectant. If selective immersion is used, non-immersible components also need to be disinfected, for example by wiping. Cleaning and disinfection are required even if single use sheaths are used.

Transoesophageal Echocardiography, Transvaginal and Trans-rectal Ultrasound Probes

Transoesophageal echocardiography (TOE) allows real-time visualisation of the heart via the stomach and oesophagus using ultrasonic emission from the distal end of a flexible probe. These probes do not have lumens. Only the patient insertion tube can be immersed in liquid.

Trans-rectal ultrasound (TRUS) probes and transvaginal ultrasound (TVUS) probes are used to examine the prostate gland and female reproductive organs, respectively. These do not generally have lumens, but some TRUS probes have an internal lumen that allows passage of a biopsy needle through the probe and then into the prostate gland via the rectal wall.

The cleaning and decontamination of TOE, TVUS and TRUS probes that do not have internal lumens is normally carried out manually directly after they have been used. This includes wiping until clean with detergent-soaked cloths or sponges, followed by wiping with a disinfectant-soaked cloth or sponge several times. The probe is then rinsed with water or an appropriate rinse wipe and dried. The manufacturer's instructions should be followed carefully. A local policy should be drawn up to describe the decontamination procedure.

It is essential that the whole of the probe and not just the insertion tube is effectively decontaminated. Cleaning and disinfection are required even if single use sheaths are used.

7.6 Cleaning – general

Cleaning removes organic material and many, but not all, micro-organisms. General purpose detergent and water or detergent wipes is the preferred method of decontamination for most items such as furniture, fittings and general equipment for example, mattresses, bed frames, washing bowls etc. Trust staff and PFI Provider staff should refer to the following procedure:

1. Where possible immerse the item in a designated bowl or sink of warm water and detergent. If immersion is not possible surface clean with detergent wipes
2. If using detergent wipes, use a sufficient number to prevent drying out
3. Do not use wash-hand basins in ward areas for cleaning equipment. Use a designated sink or bowl

4. Dry thoroughly
5. Store items dry
6. When cleaning equipment check for signs of damage e.g. covers on mattresses, pillows, cushions. If there are signs of damage report this to the department manager who can initiate replacement or repair

7.7 Cleaning of Surgical Instruments before Sterilization

Effective cleaning to remove all organic material is an essential pre-requisite for sterilization or high-level disinfection. Automated cleaning in a washer disinfectant is the preferred option. However, some instruments cannot be processed in a washer disinfectant or may need manual cleaning prior to processing in a washer disinfectant. However, manual cleaning of devices should be restricted to those items or those components of an overall decontamination process deemed incompatible with automated processes by the device's manufacturer. Trust staff and SFS should refer to the following procedure:

1. Fill the clean sink or container (not hand wash basin) with the appropriate amount of water and enzymatic detergent (refer to manufacturer's instructions)
2. Dismantle or open instrument.
3. Except for power tools, fully immerse the instrument in the solution for a minimum of 2 minutes.
4. Drain any excess detergent prior to rinsing with clean water.
5. Drain the item before drying with non linting clean cloth or paper towels.
6. Visually check to ensure organic material has been removed.
7. Complete any relevant documentation.
8. If cleaning solution or rinse water is obviously soiled or contaminated, replace immediately.

To minimise the contamination risk to personnel, splashing and the creation of aerosols must be always avoided. Always wear appropriate protective clothing when cleaning contaminated equipment - e.g., gloves, apron, and eye protection.

Power tools must not be immersed but should be surface cleaned only using a non linting cloth impregnated with an enzymatic detergent solution. This should be followed by a non linting cloth dampened with clean water and then dried using a dry non linting cloth. Alcohol impregnated wipes can be used following the manual cleaning procedure.

7.8 Disinfection

Disinfection reduces the number of micro-organisms to a safe level for a defined procedure but does not kill bacterial spores and does not necessarily inactivate all viruses.

The following disinfection methods and products are used locally and used by Trust staff . The use of alternative methods/products must be approved by the Infection Control Team prior to introduction.

7.9 Washer/Disinfectors

Washer disinfectors can be used to clean and disinfect equipment, such as bed pans, instruments and anaesthetic accessories that can withstand moist heat. The wash cycle with detergent, removes soiling. However, the wash cycle is unlikely to remove faeces and other body products that have been allowed to dry/congeal. Equipment in this state may need to be manually cleaned first with general purpose detergent and warm water. The disinfection cycle achieves disinfection at 90°C to 95°C for 1 minute. There may then be a heat assisted drying cycle.

7.10 Steam cleaners

Steam cleaners can be used to clean and disinfect fabric that cannot be laundered and surfaces that require surface disinfection. To achieve this a steam cleaner with a continuous vacuum extraction facility must be used.

The steam cleaner produces dry steam at temperatures exceeding 130°C. The water is turned into high temperature microfine vapour, the microscopic water particles penetrate the surface of the item being decontaminated and are subsequently removed by continuous vacuum extraction. The contaminated water then goes into a separate dirty water tank.

7.11 Chemical Methods

Chemical disinfectants are often irritant when allowed contact with skin and mucous membranes or when inhaled as vapour. They can also be corrosive and flammable.

A risk assessment, under the Control of Substances Hazardous to Health (COSHH) Regulations, must be undertaken before chemical disinfectants can be introduced.

There is a potential fire hazard associated with all chemical disinfectant products. It is advisable that these products are stored in appropriate sealed containers/cupboards.

Chemical disinfectants may also be damaging to equipment. It is vital, therefore, that equipment manufacturers' advice is sought to ascertain compatibility. This should be clarified prior to purchase of new equipment and a decontamination procedure written by the users and approved by the Infection Control Team.

7.12 Low level chemical disinfection - Alcohol

Usually in the form of ethyl or isopropyl alcohol this is most active at a concentration of 60 - 90%. It has good bactericidal and fungicidal activity but whilst ethyl alcohol is effective against most viruses, isopropyl alcohol is not.

Alcohol does not penetrate well into organic matter and must only be used on visibly clean surfaces. If an item is obviously contaminated with organic matter it must be cleaned before disinfection.

Alcohol is not an advocated method of disinfection.

Therefore should we remove

7.13 Low Level Chemical Disinfection - Chlorine Releasing Agents

This includes sodium hypochlorite and di-isochlorocyanurate (NaDcc).

- Wide range of bactericidal, virucidal and fungicidal activity
- Note: This is corrosive to some metals

This is inactivated by organic matter, particularly in low concentration, therefore pre-cleaning is essential. However, some chlorine releasing products e.g. Chlor-Clean and Actichlor-plus, combine a non-anionic surfactant and NaDCC and therefore pre-cleaning is unnecessary making them a practical product to use for terminal decontamination of the environment and equipment within isolation rooms.

Given the policy is for re-useable devices as per HTM 01 -01/06 should this be removed and added to the medical device/ipc policies?

7.14 Low Level Chemical Disinfection - Vaporised Hydrogen Peroxide

Vaporised hydrogen may be used to achieve thorough disinfection of the environment following outbreaks of infection such as Clostridium difficile and Norovirus. It will only be used with the agreement of the Infection Control team and operated by trained housekeeping supervisors. The area to be treated must be free of people when the vaporiser is in use.

This process must be preceded by thorough cleaning.

7.15 High Level Disinfection

High level disinfection in a chemical washer disinfector often referred to as an [automated washer disinfector](#). Endoscope Washer Disinfector is used for the decontamination of heat labile flexible endoscopes. Specialist units decontaminating flexible endoscopes and their accessories must adhere to written decontamination procedures produced by the User and agreed by the IPCC.

7.16 Sterilization

Sterilization removes or destroys all conventional infectious agents, including spores.

Instruments are received, cleaned, packed and sterilized in a controlled environment with validated procedures. In addition, a computerised tracking system is used to

provide evidence that each instrument or set has been through an appropriate decontamination process.

Porous load sterilizers, compliant with HTM01-01 are used to sterilize at 134°C to 137°C for 3 minutes. Porous load sterilizers can sterilize wrapped, lumened and hollow instruments. Instruments wrapped before sterilization remain sterile until the pack is opened or damaged and can therefore be stored whilst awaiting use.

7.17 Personal Protective Equipment (PPE)

Suitable safety equipment should be used wherever necessary, and staff should be trained in its use. Training in the use of safety equipment and a safe system of work will need to be repeated periodically in order to cater for changes in staff.

7.18 Local Reprocessing of Medical Devices

The Trust does not encourage local reprocessing and it is strongly discouraged.

7.19 Spillage Procedures

From time to time, spillages will occur; these must be dealt with as soon as is reasonably practicable. The location of the spill will dictate who has the responsibility to deal with the spill, however, some common sense and flexibility must be adopted with the priority being to remove the spill as soon as possible. The following should be used as a guide.

- 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 or department and the personnel available but this will typically be the responsibility of Housekeeping
- Estates staff (SFS) are responsible for cleaning of spills in the grounds of the hospital.

When dealing with the removal of blood and body fluid spills, the following procedure and precautions should be adhered too;

- Gloves and plastic aprons must be worn. If splashing is possible, eye protection must also be worn.
- Where the spillage may contain sharp material, forceps should be used to remove the sharp material, placing it in a sharp bin
- If the spillage is large, paper towels should be used to soak up the excess fluid. Used towels should be placed in yellow clinical waste bag

- Surfaces should be cleaned using warm water and detergent and a disposable cloth or mop
- Spill's on carpeted area's should be cleaned using a steam cleaner or wet extract carpet shampooer
- Spill's on curtains or loose fabric covers should be laundered or dry cleaned

7.20 Reporting of Incidents Relation to Equipment Operation

The User is responsible for the reporting of incidents that result in decontamination failure. Operators and others concerned with the operation of decontamination equipment should know what action to take in the event of an incident or failure. The User must ensure that a supply of incident reporting forms are available at all times.

Some types of defects should be reported to the Dept of Health and Social Care - these are usually defects where some central action may be required. Reporting defects and failures and disseminating estates and Facilities Alerts (EFA/2013/003)

If the item that fails or has a defect is also a medical device (such as a washer-disinfector) then it must also be reported to the MHRA in accordance with the MHRA on-line Yellow Card Scheme.

7.21 Single Use and Single Patient Use Devices

The expression '**single use**' on the packaging of medical devices means that the manufacturer intends the device to be used once and then discarded. This is typically because the manufacturer considers the device is not suitable for use on more than one occasion and/or has evidence to confirm that reuse would be unsafe. Typically this would be identified by the following;



There is no symbol for the expression '**single patient use**'. Instruction for this is given on the device packaging. This means the medical device is intended for more than one episode of use on one patient only, and may undergo some form of reprocessing between each use. If this is the case the manufacturer will include appropriate processing instructions to make it ready for reuse (on the same patient).

Reuse of 'single use' or 'single patient use' in contravention of the definitions above should be avoided.

7.22 Decontamination of Equipment Prior to Service or Repair

(See also Trust Policy, ICP12. *'Decontamination of Equipment Prior to Service or Repair'*)

Anyone who inspects, services, repairs or transports medical, dental or laboratory equipment, either on hospital premises or elsewhere, has a right to expect that medical devices and other equipment have been appropriately decontaminated; appropriate documentation must be provided to indicate the decontamination status of the item. Refer to MHRA guidance 'Managing Medical Devices' (April 2014) specifically Section 8 - 'Maintenance and Repair'. No maintenance or inspection will be conducted unless a suitable declaration of contamination status is attached to the item unless prior agreement has been made, such as during an equipment complaint or investigation. In this instance a risk assessment should be carried out and appropriate precautions taken to prevent cross contamination.

7.23 Records

It is a statutory requirement that appropriate records are kept. Accurate records of all assets relating to decontamination equipment and associated systems will be established and regularly maintained by the Trust and its PFI Partners as appropriate.

In order that equipment and associated systems can be correctly operated and maintained it is essential that as-fitted drawings, operating manuals, maintenance instructions and commissioning manuals are made available by the Trust. Log books should be kept for each item of decontamination equipment consisting of maintenance records, test and validation data.

Decontamination records such as testing and maintenance logbooks should be kept 21 years. The records for all maintenance, inspection and testing activities will be kept up to date, properly stored for at least 5 years before archiving for 24 Years and shall include as a minimum the following:

- The results and dates of any monitoring, inspection, test or checks carried out. This should include the state of operation of the system.
- Procedures for inspecting and checking the system & state of operation (In use /not in use)
- The findings and subsequent remedial and mitigation actions taken as part of risk assessments.
- The names and position of people responsible for carrying out the various roles as defined in this policy.

- Programme of planned maintenance for each item of equipment including details of tests and inspections carried out and work done, on what components, when and by whom with clear audit trails
- Details of ad-hoc / breakdown maintenance on any part of the equipment and/or system as above
- Records of inspecting and checking the system & state of operation (In use / not in use)
- Cleaning records including reports and certificates.
- A log detailing visits by contractors, consultants and other personnel
- Training records
- Up to date As Fitted Drawings, schematic layout drawings together with comprehensive Operation and Maintenance Manuals
- Asset register including all components of the decontamination systems, their service and maintenance history, records of inspection testing etc and dates of planned maintenance and inspection or testing.

7.24 Health & Safety

All operation and maintenance work shall be undertaken in accordance with the Trust's health and safety policies, Department of Health guidance, relevant Codes of Practice, Health and Safety Executive guidance and departmental health and safety procedures. Safe systems of work shall be used for all personnel operating and working on decontamination systems.

The means by which the system can be rendered safe for maintenance work should be determined, and a permit-to-work on the system implemented. This will typically involve decontamination of the equipment prior to maintenance being undertaken. All work processes should be subject to proper Risk Assessments and Method Statements. PPE should be provided as necessary to undertake the tasks safely and all notices should be provided.

Estates or visiting SFS contract staff requiring access to the SSD to conduct equipment maintenance may need induction training or to be accompanied when entering the SSD.

8.0 EVIDENCE BASE

This policy has been developed using guidance issued by the DoH '*Choices Framework Local Policies and Procedures*' and other associated guidance listed in appendix 3.

9.0 MONITORING COMPLIANCE

The Trust Designated Person is responsible for monitoring and auditing the effective implementation of this Policy. This may include, but not be limited to, Project Co's compliance with their contractual obligations, the relevant HTMs and best practices.

Maintenance performance shall be formally reported to the following:

- Monthly PFI Performance Meetings
- Infection Control Committee
- Decontamination Committee
- Financial Planning, Investment and Commercial Development Operational Governance Committee

10.0 TRAINING

Operation, inspection, and maintenance procedures can cause risks to the health of staff carrying out the work. All those involved should be trained appropriately to fulfil the task, be aware of the risks, and must work to the agreed safe systems of work. This may involve the Trust's PFI management team receiving training in awareness and refresher courses.

Training requirements in relation to decontamination processes or equipment will be regularly assessed by the line manager of the area responsible for the work to be undertaken and appropriate training undertaken and recorded, together with the date of delivery and topics covered. Any contractors involved in the installation, commissioning, modification or maintenance of decontamination equipment or systems shall be fully conversant with The Trust's decontamination Policy and shall be suitably qualified and trained.

Specific training requirements associated with the application of the policy will include, but not be limited to the following publications (that will form the basis of the Guidance Procedures to be adopted by the three parties).

- Health Technical Memorandum 01-01 Sterile Services
- Health Technical Memorandum 01-06 Endoscopy
- Health Technical Memorandum 01-05 *Decontamination in PC Dentistry*

- The equipment O&M records and manufactures instructions.
- Other relevant industry codes of practice

11.0 DISTRIBUTION

The policy will be made available to the following parties:

All Trust staff via the intranet

Decontamination committee

Decontamination Lead

Departmental Managers

Designated Person

Director for Infection Prevention and Control

Estates Governance Committee

Health and Safety Committee

Medical Physics Manager

Medirect

Project Co

Senior Operational Manager

Skanska Facilities Services

The Health and Safety Committee

Trust Board

Trust Risk Committee

User (CSSD)

User (Endoscopy)

12.0 COMMUNICATION

All new staff, as part of their induction, will be made aware of the Trust's policies and how to access these.

All policies will be easily accessible via the Trust's Intranet site under the relevant section.

Details of all new and reviewed policies will be included in the monthly team brief. The local team brief should be used to highlight the production of any local procedures or guidelines.

Additional training on the policy content will be provided if required.

Staff bulletins will also be used to raise awareness of new policies.

The Company Secretary will maintain a master set of all corporate policies.

An archive of superseded policies will be maintained as in line with the Trust's Retention and Destruction of Records Policy.

13.0 AUTHOR AND REVIEW DETAILS

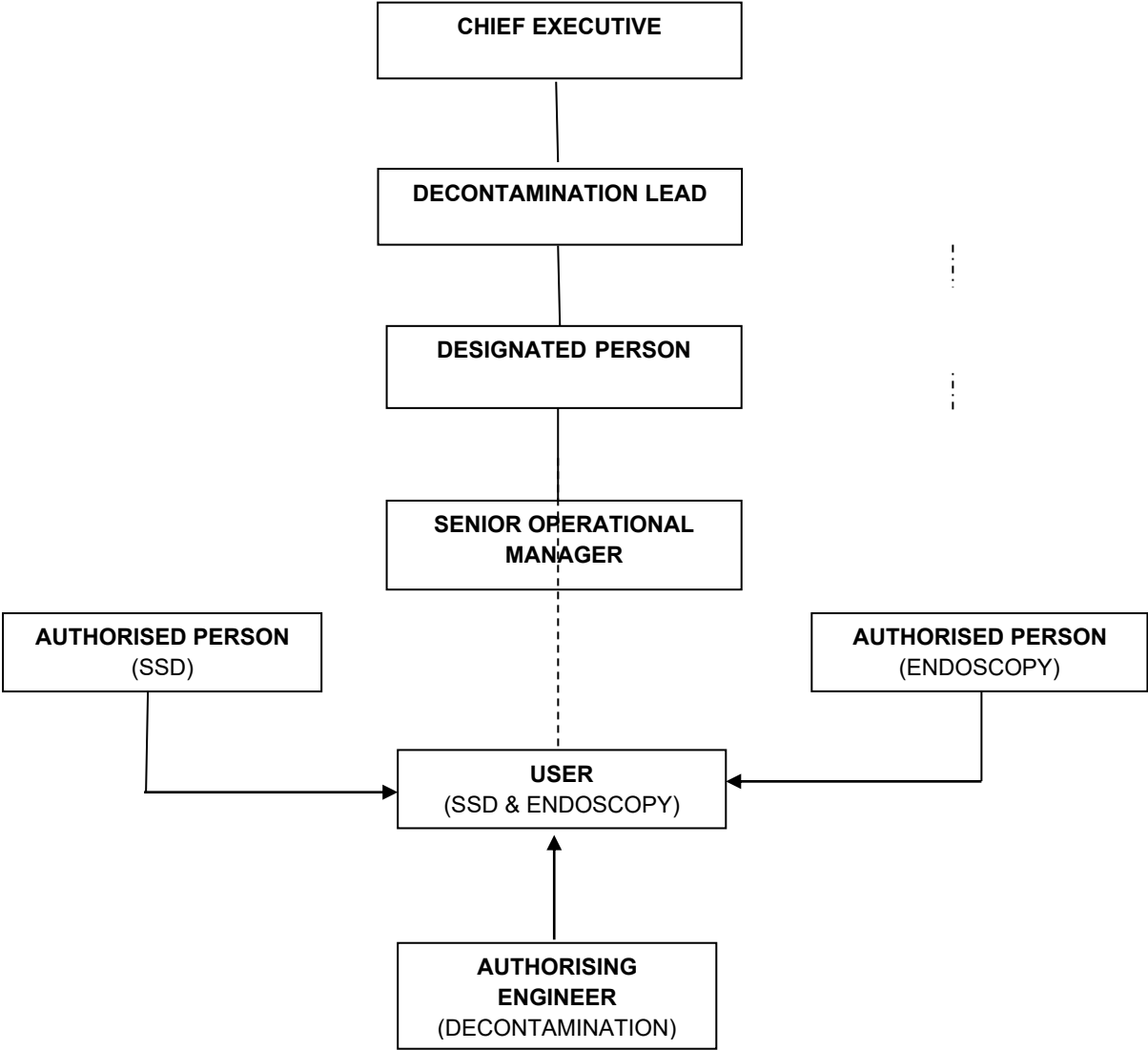
Date issued: February 2014

Date to be reviewed: February 2015

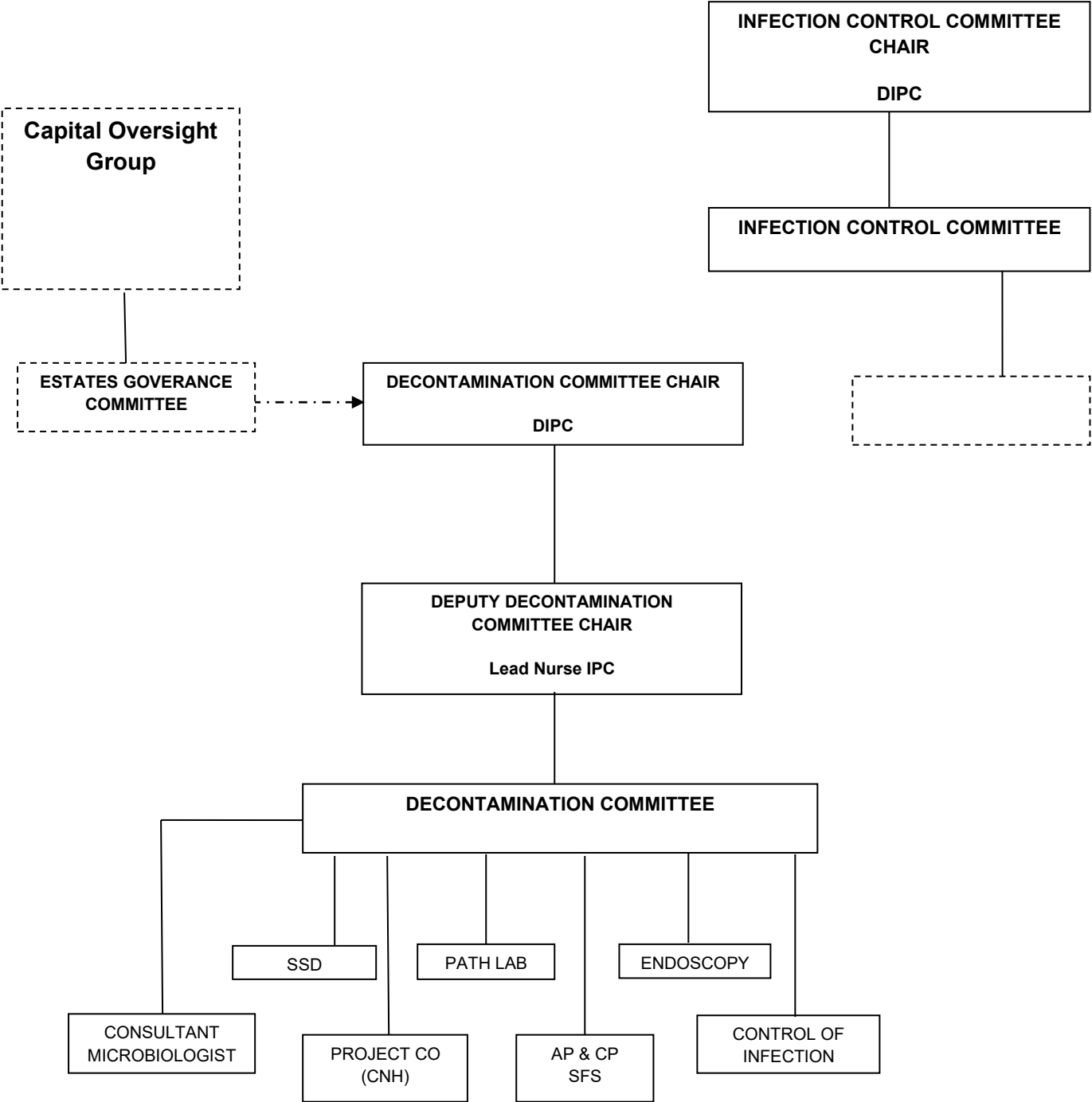
To be reviewed by: Kay Theaker Head of Decontamination

Executive Sponsor:

APPENDIX 1A: DECONTAMINATION MANAGEMENT STRUCTURE



APPENDIX 1B: DECONTAMINATION GOVERNANCE CHART



APPENDIX 2 – TRUST INDIVIDUAL NAMED RESPONSIBILITIES

Responsibility under this policy	Named individual	Role
Decontamination Lead	Phil Bolton	Executive Lead Nurse
Designated Person	Kay Theaker	Head of Decontamination
Senior Operational Manager	Vacant Stuart Locking	Associated Director of Estates Trust General Manager SKANSKA
User (CSSD)	Kay Theaker Julie White	Head Of Decontamination/ Service Manager decontamination
User (Endoscopy)	Kay Theaker Julie White	Head of Decontamination/ Service Manager Decontamination
Authorising Engineer (Decontamination)	Wayne Spencer	Spencer Nickson Ltd
Surgical Instruments Manager	Kay Theaker	Decontamination & Sterile Services Manager
Microbiologist (Decontamination)	Nikunj MAHIDA,	Microbiologist
Medical Device Coordinator	Peter Lee	Medical Physics Manager

APPENDIX 3 - REFERENCE DOCUMENTS

1. Advisory Committee on Dangerous Pathogens and Spongiform Encephalopathy Advisory Committee. Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection.
2. British Dental Association (2004) Advice sheet: Infection Control in Dentistry. DH London.
3. Coding for Success
4. DH (1993) Health Service Guidelines *HSG(93)26 - Decontamination of equipment prior to inspection, service or repair.*
5. EN 554 *Sterilization of Medical Devices – Validation and Routine Control of Sterilization by Moist Heat*
6. HBN 13 *Sterile Services Department*
7. Health & Safety at Work Act, 1974
8. Health and Safety Commission's *Approved Code of Practice and guidance document 'Legionnaires' disease; the control of Legionella bacteria in water systems' (L8)*
9. Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 - '*Ventilation in healthcare premises*'.
10. Health Technical Memorandum 04-01 '*The control of Legionella, hygiene, 'safe' hot water, cold water and drinking water systems*'
11. Health Technical Memorandum 01-01
12. Health Technical Memorandum 01-06
13. Heating and Ventilating Contractors' Association (HVCA), *SFG20*.
14. HSC 1999/123 *Risk Management and Organizational Controls*
15. HSC 1999/178 *Variant Creutzfeldt – Jakob Disease: Minimising the Risk of Transmission*
16. HSC 1999/179 *Controls Assurance in Infection Control. Decontamination of Medical Devices*
17. HSC 2000/32 *Decontamination of Medical Devices*
18. Institute of Decontamination Sciences (IDSC) Standards and Practice edition:2006 [superceded](#).

19. Matron's Charter for Cleaner Hospitals 2004
20. MDA (2002) *Bench top Steam Sterilizers - Guidance on The Purchase, Operation and Maintenance*. DB 2002(06)
21. UK MDR 2002, as amended.
22. Medicines and Healthcare Products Regulatory Agency (MDA2004/028 Flexible and rigid scopes)
23. MHRA DB2010(01) *'Reporting adverse incidents and disseminating medical device alerts*.
24. MHRA (2006) DB 2006(04) *Single-use Medical Devices: Implications and Consequences of Reuse*
25. MHRA DB 2002(05) *Decontamination of Endoscopes*
26. MHRA DB 2006 (04) V2.0 *Single-use Medical Devices: Implications and Consequences of Re-Use*.
27. MHRA (April 2014) *Managing Medical Devices*
28. Microbiology Advisory Committee to Department of Health, Medical Devices Agency (1993) *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination*. Updated 2010.
29. NHS Estates (2001) *A protocol for the local decontamination of surgical instruments*.
30. NHS Estates (2003) *A guide to the decontamination of reusable surgical instruments*.
31. NHS Estates National Decontamination Project Team (2003) *Strategy for Modernising the Provision of Decontamination Services*.
32. NHSE Estates Health Technical Memorandum 2025 *Ventilation*
33. Product Liability Directive 99/34 EEC
34. BS EN ISO 13485:2016 Medical devices – Quality management systems – requirements for regulatory purposes
35. Sherwood Forest Hospitals NHS Foundation Trust (2010) *'Policy on Decontamination of Healthcare Equipment Prior to Inspection, Service or Repair'*.
36. Sterilization, Disinfection and Cleaning of Medical Equipment: *Guidance on Decontamination from Microbiology Advisory Committee to Department of Health Medical Devices Agency* (MAC Manual)

- 37. The Control of Substances Hazardous to Health Regulations (COSHH)
- 38. The H&SC Approved Code of Practice & Guidance (L8)
- 39. The Health and Social Care Act 2008
- 40. The Health and Social Care Act 2008 – Code of Practice on Prevention and Control of Infections (Hygiene Code)
- 41. The Management of Health & Safety at Work Regulations, 1992
- 42. The O&M records and manufactures instructions for use
- 43. The Reporting of Injuries, Disease and Dangerous Occurrences (RIDDOR)
- 44. Winning Ways