## POLICY FOR DECONTAMINATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Page(s)</th>
<th>Comments</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>December 2012</td>
<td>New Policy</td>
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Compiled by: Paul Cooper, Head of Estates & Facilities Infrastructure  
Approved by: Decontamination Group  
Ratified by: Clinical Governance Committee  
Date: April 2007  
Review Date: December 2012  
Review due: December 2015  
Target Audience: All Clinical Staff  
Contact Name for Comments: Paul Cooper, Head of Estates & Facilities Infrastructure  
Impact assessment carried out by: Paul Cooper, Head of Estates & Facilities Infrastructure
See also:
- Policy for Single-Use, Single Patient Use and Limited Use Medical Devices.
- Policy for the Management, Use and Disposal of Medical Devices
- Policy for Cleaning and Disinfection Policy
- Policy for Precautions During Clinical Procedures/Surgery for known or Suspected CJD Patients

1. INTRODUCTION

The Code of Practice Health and Social Care Act 2008 on the prevention and control of infections and related guidance, provides the standard for this aspect of patient care. Complementing this is the Department of Health guidance Choice Framework for local Policy and Procedures (CFPP), which assist Trust’s in complying with the decontamination guidance set out in the above Code of Practice and in meeting the Care Quality Commission (CQC) registration requirement on hygiene and infection control.

For the purpose of this policy the main focus is on reusable surgical instruments and that they are properly decontaminated prior to use or repair and that the risk associated with decontamination facilities, are well managed ensuring the safety of patients, staff and visitors. This policy should be read in conjunction with the above referenced Trust policies.

2. PURPOSE

The purpose of this policy is:

2.1 To increase the awareness of staff involved in handling of medical devices in procedures and bring to their attention the suite of guidance documents from Department of Health “Choice Framework for local Policy and Procedures” (CFPP).

2.2 To ensure that managers and individual members of staff are aware of their responsibilities in relation to decontamination of medical devices.

2.3 To assure that safe, managed and effective decontamination processes are adopted for all re-usable medical devices/equipment after and between patient use. This is an essential element of routine infection control practice and the monitoring process for this is outlined in section 11.

3. CHOICE FRAMEWORK FOR LOCAL POLICY AND PROCEDURES (CFPP) OVERVIEW

CFPP 01-01 supports local decision-making in the commissioning, regulation, management, use and decontamination of surgical instruments used in acute care. The guidance is designed to support continuous improvements in efficiency and outcomes in terms of safety, clinical effectiveness and patient experience by:

3.1 Guiding care commissioners and regulators in assessing the local policies and practices of a provider in terms of their approach to the management and decontamination of surgical instruments. Clear definitions of Essential Quality Requirements (EQR) and Best Practice are provided in CFPP, to help with this assessment.

3.2 Providing the evidence base and standards for use by providers of care and those decontaminating surgical instruments within the NHS to support them in their decision-making process.
3.3 Contributing to the effective management of surgical instruments through all parts of the use and reprocessing cycle including management practices related to surgical instruments in the theatre environment.

The implementation of CFPP guidance recommends that all providers of surgical care work with their decontamination specialists are to achieve “Essential Quality Requirements” (EQR) and to produce a plan with locally risk-assessed progression to “Best Practice” (BP).

4. THE HOSPITAL STERILE SERVICES DEPARTMENT (SSD)

The role of SSD is to:
4.1 Carry out cleaning, disinfection and sterilisation of reusable instruments for the Trust and other customers.

4.2 Comply with a number of regulations and codes of Practice:
- e.g. Medical Devices Directive 93/42/EEC (European Legislation)
- Standards - e.g. Medicines and Healthcare Products Regulatory Agency (MHRA) and Care Quality Commission (CQC)
- Policy & Guidance – National Institute for Health and Clinical Excellence (NICE), Department of Health CFPPs and Health Building Notes such as HBN 13.

4.3 Operate a Quality Management System (QMS) which would be accredited to ISO 9001:2008, ISO13485:2003 and Medical Devices Directive 93/42 Annex V which is the expected accreditation for departments that provide services outside their own organisation.

4.4 Process flexible endoscopes using the dedicated centralised Endoscopy decontamination service within SSD.

5. PROCEDURAL REQUIREMENTS

Some key decontamination procedural requirements are:
5.1 Medical devices should be decontaminated and stored in accordance with legislative, manufacturers’ and best practice requirements. Where appropriate decontamination should always be carried out in dedicated facilities, for example:
- endoscopes – endoscopy decontamination processing suite within SSD
- surgical instruments – SSD
- Individual Departmental managers and Directorates have responsibility for formulating a written decontamination Standard Operating Procedure (SOP) for any aspects of decontamination within their department. The SOP must include the minimum standards outlined in the Trust's “Cleaning and Disinfection Policy”.

5.2 Local SOPs are also required for management and safe transport of medical equipment from the point of use to the decontamination facility. For surgical instruments this must conform to the guidance given by SSD.

1 The Endoscopy service currently only processes Trust scopes. MDD 93/42 Annex V accreditation is to be obtained in 2013.
5.3 Decontamination requirements must be considered before reusable medical devices are acquired / purchased to ensure they are compatible with the decontamination equipment available.

5.4 Re-usable equipment that requires sterilisation must be adequately decontaminated between patients. This is best achieved centrally in the Trust’s SSD, where sterilisation processes are compliant and controlled.

5.5 Pre-cleaning of equipment prior to sterilisation/disinfection is vitally important for achieving adequate levels of decontamination. This is best achieved in automated washer-disinfectors, as found in the Trust’s central SSD, rather than by hand washing of equipment. Staff must not hand wash equipment prior to transfer to SSD.

5.6 Decontamination processes must not themselves pose a cross-contamination/infection risk to those staff undertaking the decontamination or to the environment in which the process is carried out. Staff handling used medical equipment should assume that it is contaminated and through training and correct use of personal protective equipment (PPE) take precautions to reduce the risk to themselves and others.

5.7 The decontamination method must be based upon a risk assessment, whereby the greater the level of risk involved the greater the level of decontamination undertaken. Differing levels of decontamination are used depending on the device and the procedure involved.

The levels and categories of decontamination are outlined in the tables 1 and 2 below.: 

Table 1: Levels of Decontamination

<table>
<thead>
<tr>
<th>Method</th>
<th>Process</th>
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<tbody>
<tr>
<td>Cleaning</td>
<td>Physical removal of contamination (blood, faeces, etc.) and many micro-organisms by use of hot water and detergent.</td>
</tr>
<tr>
<td>Disinfection</td>
<td>A reduction in the number of micro-organisms to a level at which they are not harmful, however, bacterial spores are not usually destroyed. Disinfection may be achieved by the use of heat or chemical disinfectants.</td>
</tr>
<tr>
<td>Sterilisation</td>
<td>Total removal or destruction of all micro-organisms, including bacterial spores. Sterilisation may be achieved by the use of steam under pressure, dry heat or radiation.</td>
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Table 2: Categories of Decontamination

<table>
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<th>RISK</th>
<th>APPLICATION OF ITEM</th>
<th>RECOMMENDATION</th>
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<tbody>
<tr>
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Managers’ guidance must also be followed when deciding upon an appropriate method of decontamination.

5.8 All medical devices, decontamination equipment, and surfaces should be appropriately dealt with after use on patients known to have, or who are in a risk category for, CJD. Refer to Policy for Precautions During Clinical Procedures/Surgery for known or Suspected CJD Patients

6. WHEN TO DECONTAMINATE

The 3 main categories for when to carry out decontamination are:

6.1 **Reusable items in routine use** which need to be used sterile at the point of use must be decontaminated following use and made sterile before re-use. They must be processed in a way which maintains sterility before re-use e.g. wrapped.

6.2 **Instruments which do not require to be sterile at point of use e.g. endoscopes** must be decontaminated after use and kept under clean storage conditions before re-use. Instruments which are prone to becoming recontaminated in storage, such as endoscopes, require further reprocessing immediately (or within 3 hours) before use.

6.3 **Loaned instruments and repair, inspection or disposal of instruments** subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer’s or agent’s premises, should be decontaminated before transit. This also applies to items returned to manufacturers. Once decontamination has been completed the items are packaged complete with a “Declaration of Decontamination Status” form.

Devices intended for single-use only must not be either decontaminated or re-used. Refer to Policy for Single-Use, Single Patient Use and Limited Use Medical Devices

7. TRACEABILITY OF INSTRUMENTS

It is important to have a clear traceability system in place for all re-useable instruments, including flexible and rigid endoscopes, in order to be able to trace back instruments used on a patient(s) in the event of suspected cross-infection or other incident. The traceability system used must allow...
for identification of instruments or endoscopes used for an individual patient and these details must be entered into the individual patient notes, as well as details regarding the decontamination process undertaken. In addition, a record of the instrument/endoscope reprocessing must be kept within the department where the reprocessing is undertaken. Currently, reprocessing traceability can only be undertaken for trays of instruments rather than individual items. Each stage of the reprocessing cycle, i.e. cleaning, disinfection and sterilisation must be recorded to allow for full traceability, including details of the washer-disinfector and steriliser used and the member of staff undertaking each stage of the reprocessing cycle.

8. TRAINING

All staff that undertake decontamination of instruments, whether in SSD or using equipment locally will undergo training. This training will include:

- Instruction in why decontamination and sterilisation is necessary
- Instruction in how to decontaminate equipment safely and effectively
- Instruction in the checking and use of the equipment
- Instruction in the handling of sterile and dirty instruments

Maintenance and testing of washer disinfection equipment and autoclaves will be undertaken by fully trained estates or contracted staff e.g. “Competent Person” (Decontamination)

9. DUTIES/RESPONSIBILITIES

The safe management and decontamination of surgical instruments as set out in the Choice Framework for local Policy and Procedures (CFPP) 01-01, Identifies the following roles (Appendix 2 identifies Trust job titles undertaking those roles):

9.1 EXECUTIVE MANAGER (EM)
The person with ultimate responsibility for an organisation in terms of allocating finances and appointing personnel.

9.2 DECONTAMINATION LEAD (DL)
Responsibility for decontamination and has access to the EM either directly or through a senior responsible person at that level. The Decontamination Lead is organisationally responsible for the effective, and technically compliant, provision of decontamination services. The Decontamination Lead is responsible for the implementation and monitoring of an operational policy for decontamination. They should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment.

9.3 DESIGNATED PERSON (DP)
Provides the senior management link between the organisation and professional support. The Designated Person should work closely with the Senior Operational Manager to ensure that provision is made to adequately support the decontamination system. The DL may also act as the DP.

9.4 USER
The User is defined as the person responsible for the management of the process. The User is also responsible for the Operators. In the acute sector, the User could be a sterile services manager.

The principal responsibilities of the User are as follows:
- to certify that the decontamination equipment is fit for use;
- 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;
- 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 are documented and adhered to in the light of statutory requirements and accepted best practice.

The User can seek the advice of the infection control team.

9.5 SURGICAL INSTRUMENT MANAGER/COORDINATOR
The manager of surgical instruments (medical devices) is designated as the person assuming responsibility for coordinating activity between the theatre, decontamination and supply / purchase teams. They 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. For a full listing of responsibilities refer to the CFPP 01-01.

9.6 AUTHORISING ENGINEER (DECONTAMINATION) AE(D)
The AE(D) is defined as a person designated to provide independent auditing and technical advice on decontamination procedures, washer disinfectors, sterilizers and sterilization and to review and witness documentation on validation.

9.7 AUTHORISED PERSON (DECONTAMINATION) AP(D)
Appropriately trained and appointed by the DP. Responsible for:
- engineering management of decontamination equipment;
- responsible for Competent Person (Decontamination);
- safe and effective systems of works for installed equipment;
- authorisation for use of equipment after testing /repair.

9.8 COMPETENT PERSON (DECONTAMINATION) CP(D)
Designated to carry out maintenance, validation and periodic testing of washer-disinfectors and sterilizers. The CP(D) should report directly to an appropriate member of the estates department (for example AP(D)) or should be subcontracted by them.

9.9 DIRECTOR OF INFECTION PREVENTION AND CONTROL (DIPC)
The DIPC is defined as the person responsible for the infection control aspects of decontamination. The designated person is accountable directly to the Chief Executive and to the Board.

9.10 OPERATOR
The Operator is defined as any person with the authority to operate decontamination equipment, including the noting of instrument readings and simple housekeeping duties. Operators should have their tasks defined in a standard operating procedure. Operators should also have documented training records to demonstrate that they are competent at undertaking their assigned tasks.
9.11 COMPETENT PERSON (PRESSURE SYSTEMS) CP(PS)
The CP(PS) as defined in the Pressure Systems Safety Regulations 2000 is responsible for
drawing up a written scheme of examination for the system. This service is provided by a technical
division within an Insurance company.

10. DISSEMINATION AND IMPLEMENTATION
The policy has been agreed by the Decontamination Committee, Control of Infection Committee
and ratified by the Clinical Governance Committee who will provide support to ensure
implementation. The policy will be available on the Trust web site.

11. MONITORING OF COMPLIANCE
To ensure that the guidelines are working effectively, an annual Trust wide decontamination
assessment will be conducted. Decontamination assessments (audits) will be conducted by the
Decontamination Lead, Infection Control and the Manager of the department being audited.

The Sterile Services Department (SSD) will undertake internal audits scheduled over 12 months
(see Appendix 3 for procedure) and the notified ISO accredited body will carry out an audit
annually.
The Trusts Authorising Engineer (Decontamination) will carry out an annual audit to provide
technical advice on validating decontamination equipment processes.

Audit outcomes are studied during the regular Management Review meetings where action plans
are agreed to address any areas of risk or improvement. All audit outcomes will be reported to the
Decontamination Group.

12. EQUALITY IMPACT ASSESSMENT
Ashford & St Peters Hospitals NHS Trust is committed to ensuring that, as far as is reasonably
practicable, the way we provide services to the public and the way we treat our staff reflects their
individual needs and does not discriminate against individuals or groups on any grounds. This
policy does not discriminate against individuals or groups on any grounds. See Appendix A for the
completed impact assessment tool.

13. ARCHIVING ARRANGEMENTS
This is a Trust-wide document and archiving arrangements are managed by Quality Department
who can be contacted to request master/archived copies.

14. REFERENCES AND BIBLIOGRAPHY
This policy was produced with reference to the following:

- Choice Framework for local Policy and Procedures 01-01 – Management and
decontamination of surgical instruments (medical devices) used in acute care. Part A: the
formulation of local policy and choices manual and Part B: Common Elements
Note: CFPP 01-01 Parts A to E supersedes Health Technical Memorandum and Health
Building Note 13 Supplement 1
- CFPP 01-06 suite (5 parts) – Flexible endoscopes:
- Policy for Single-Use, Single Patient Uses and Limited Use Medical Devices.
15. APPENDICES

APPENDIX 1: Equality Impact Assessment

APPENDIX 2: Personnel undertaking Duties and Responsibilities

APPENDIX 3: The procedure for Sterile Service Internal Audit.

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**APPENDIX 1**

**EQUALITY IMPACT ASSESSMENT TOOL**

**POLICY FOR SINGLE-USE, SINGLE PATIENT USE AND LIMITED USE MEDICAL DEVICES**

*Name:* Paul Cooper  
To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

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<tr>
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<th>Yes/No</th>
<th>Comments</th>
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<tr>
<td>1. <strong>Does the policy/guidance affect one group less or more favorably than another on the basis of:</strong></td>
<td>No</td>
<td>For each category describe how you have involved stakeholders including service users and employees</td>
</tr>
<tr>
<td>Race and Ethnic origin (include gypsies and travellers) (consider communication, access to information on services and employment, and ease of access to services and employment)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Disability (consider communication issues, access to employment and services, whether individual care needs are being met and whether the policy promotes the involvement of disabled people)</td>
<td>No</td>
<td></td>
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<tr>
<td>Gender (consider care needs and employment issues, identify and remove or justify terms which are gender specific)</td>
<td>No</td>
<td></td>
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<tr>
<td>Culture (consider dietary requirements and individual care needs)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Religion or belief (include dress, individual care needs and spiritual needs for consideration)</td>
<td>No</td>
<td></td>
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<tr>
<td>Sexual orientation including lesbian, gay and bisexual people (consider whether the policy/service promotes a culture of openness and takes account of individual needs)</td>
<td>No</td>
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<tr>
<td>Age (consider any barriers to accessing services or employment, identify and remove or justify terms which could be ageist)</td>
<td>No</td>
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2. Is there any evidence that some groups are affected differently?  
   | No |

3. If you have identified potential discrimination, for example, less than equal access, are any exceptions valid, legal and/or justifiable, for example a genuine occupational qualification?  
   | No |

4. Is the impact of the policy/guidance likely to be negative?  
   | No |

5. If so can the impact be avoided?  
   | N/A |

6. What alternatives are there to achieving the policy/guidance without the impact?  
   | N/A |

7. Can we reduce the impact by taking different action?  
   | N/A |

**APPENDIX 2**
## APPENDIX 3

### STERILE SERVICES INTERNAL AUDIT

#### OVERVIEW

Internal audit is designed to provide regular surveillance of the SSD Quality System to ensure that all procedures are adhered to and the system is working correctly. The objective is to determine the effectiveness of procedures in controlling the quality of services and to identify and monitor modification when required.

#### RESPONSIBILITY

The Sterile Services Manager is responsible for the operation of this procedure and ensuring that the complete quality system is audited once a year.

Staff trained as auditors are responsible for carrying out the audits as detailed in this procedure.
All staff are responsible for assisting the auditors carry out the audits and for carrying out any Corrective Actions determined for their areas.

PROCEDURE

The auditing of the Quality Management System is planned each year by the Sterile Services manager. An Internal Audit Plan is developed listing the processes to be audited with a suggested timescale for each.

Prior to each audit the auditor is briefed by the Sterile Services Manager on the process and the scope of the audit is defined. A copy of each relevant procedure and work instruction together with extracts from the quality manual are given to the Auditor.

The Auditor studies the procedure to be audited to establish a working knowledge of its content, associated Work Instructions and to plan the audit. The audit is then carried out to ensure the procedure is being complied with by following a series of ‘transactions’ through the procedure. Sufficient ‘transactions’ are followed and staff are observed and interviewed to assure the auditor that a true picture is obtained.

During the audit the auditor completes an Audit Report clearly identifying and recording the checks made, personnel interviewed and clearly identifying any non-conformances found. On completion of the audit the Audit Report is taken to the Sterile Services Manager who discusses the findings with the auditor. Suitable corrective actions are agreed and entered onto the Form. On completion of the corrective action the audit form is signed off and filed.

The results of audit shall be reviewed at the Management Review meetings.

The audit reports shall be subject to the controls of SSD/PM/01.

Issued by................................................   Designation..............................................................