# POLICY FOR THE
DECONTAMINATION OF FLEXIBLE ENDOSCOPIES

<table>
<thead>
<tr>
<th>Name of Policy:</th>
<th>Policy for the Decontamination of Flexible Endoscopes</th>
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<tbody>
<tr>
<td>Purpose of Policy:</td>
<td>To provide guidance on the decontamination of all flexible endoscopes that are used throughout the SHSCT</td>
</tr>
<tr>
<td>Directorate responsible for Policy</td>
<td>Acute Services</td>
</tr>
<tr>
<td>Name &amp; Title of Author:</td>
<td>Mrs Sandra McLoughlin Head of Decontamination Services</td>
</tr>
<tr>
<td>Does this meet criteria of a Policy?</td>
<td>Yes</td>
</tr>
<tr>
<td>Trade Union consultation?</td>
<td>Yes</td>
</tr>
<tr>
<td>Equality Screened by:</td>
<td>Mrs Sandra McLoughlin Head of Decontamination Services</td>
</tr>
<tr>
<td>Date Policy submitted to Policy Scrutiny Committee:</td>
<td>12.06.2012 (originally approved 14/12/2009)</td>
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Members of Policy Scrutiny Committee in Attendance:
Vivienne Toal, Head of Employee Engagement & Relations (Chair), Claire Graham, Head of Corporate Records (for Siobhan Hanna), Carmel Harney, Assistant Director of Allied Health Professionals, Governance & Workforce Planning, Claudine McComiskey, Head of Domiciliary Care (for Melanie McClements), Danny McKeivitt, Head of Specialist Estate Services, Stephen McNally, Director of Finance & Procurement, Stephen Wallace, Infection Prevention Control Operational Assistant (for Anne Brennan)

Policy Approved/Rejected/Amended: Approved subject to point 5.2 should make reference to include the Director of Acute Services

Policy Implementation Plan included?: Place on Trust Intranet

Any other comments:

Date presented to SMT: 23rd December 2009

Director Responsible: Dr G Rankin

SMT Approved/Rejected/Amended: Approved

SMT Comments: Paragraph 6.11 to be amended – completed 5/1/2010

Date received by Employee Engagement & Relations for database/Intranet/Internet: 17 December 2012

Date for further review: August 2014
**POLICY DOCUMENT – VERSION CONTROL SHEET**

<table>
<thead>
<tr>
<th>Title</th>
<th>Policy for the Decontamination of Flexible Endoscopes Version: 2.0</th>
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<tbody>
<tr>
<td><strong>Supersedes</strong></td>
<td>Supersedes: Policy for the Decontamination of Flexible Endoscopes Version 1.2 Description of Amendments(s)/Previous Policy or Version:</td>
</tr>
<tr>
<td><strong>Originator</strong></td>
<td>Name of Author: Mrs Sandra McLoughlin Title: Head of Decontamination Services</td>
</tr>
<tr>
<td><strong>Scrutiny Committee &amp; SMT approval</strong></td>
<td>Referred for approval by: Dr G Rankin Date of Referral: Scrutiny Policy Committee Approval (Date): 12.06.2012 (originally approved 14/12/2009) SMT Approval (Date): 23rd December 2009</td>
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<tr>
<td><strong>Circulation</strong></td>
<td>Issue Date: Circulated By: Issued To: As per circulation List (details below)</td>
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<tr>
<td><strong>Review</strong></td>
<td>Review Date: August 2014 Responsibility of (Name): Mrs Sandra McLoughlin Title: Head of Decontamination Services</td>
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**Change Log**

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Notes on Revision/ Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Dec 2009</td>
<td>Sandra McLoughlin</td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Dec 2010</td>
<td>Sandra McLoughlin</td>
<td>Minor changes to wording</td>
</tr>
<tr>
<td>1.2</td>
<td>March 2012</td>
<td>Sandra McLoughlin</td>
<td>No changes</td>
</tr>
<tr>
<td>2.0</td>
<td>August 2012</td>
<td>Sandra McLoughlin</td>
<td>Review of roles and responsibilities Addition of new DHSSPS guidance</td>
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1.0 Introduction

1.1 The Southern Health & Social Care Trust (hereafter referred to as the “Trust”) Decontamination of Flexible Endoscopes Policy is based on the Controls Assurance Standards for Decontamination of Reusable Medical Devices Framework, 2006.

1.2 The Trust is committed to ensuring that robust integrated governance arrangements are in place. This policy sets out how the Trust will manage the decontamination of flexible endoscopes. It provides a simple, consistent approach for all staff involved in decontamination of this equipment.

1.3 This policy has been developed in accordance with the Trust’s key principles for policy development.

1.4 This policy has been developed in consultation with the appropriate internal stakeholders.

1.5 This policy should be read in conjunction with The NI Regional Infection Prevention and Control Manual.

2.0 Definitions

2.1 Decontamination is a combination of processes, including cleaning, disinfection and sterilisation, used to make reusable medical devices safe for further use on patients and handling by staff. The effective decontamination of reusable medical devices is essential to reduce the risk of transmission of infectious agents.

2.2 A medical device is any instrument, apparatus, appliance, material or other article whether used alone or in combination, intended by the manufacturer to be used on human beings for the purpose of:
- Diagnosis
- Prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
• Investigation, replacement or modification of the anatomy or physiological process
• Control of conception

2.3 Medical devices are classified into categories depending on the infection risk to the patient from contact with the medical device.

<table>
<thead>
<tr>
<th>RISK</th>
<th>APPLICATION OF MEDICAL DEVICE</th>
<th>TYPE OF DECONTAMINATION RECOMMENDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>• In close contact with a break in the skin or mucous membrane</td>
<td>Sterilisation</td>
</tr>
<tr>
<td></td>
<td>• Introduced into sterile body cavities</td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>• In contact with mucous membranes</td>
<td>Sterilisation or disinfection required</td>
</tr>
<tr>
<td></td>
<td>• Contaminated with particularly virulent or readily transmissible organisms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prior to use on immunocompromised patients</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>• In contact with healthy skin</td>
<td>Cleaning</td>
</tr>
<tr>
<td></td>
<td>• Not in contact with patient</td>
<td></td>
</tr>
</tbody>
</table>

2.4 Cleaning is a process that 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 on many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite to ensure effective disinfection or sterilization.

2.5 Disinfection is 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 sterilisation.
2.6 **Sterilisation** is a process used to render an object free from viable micro-organisms including viruses and bacterial spores.

2.7 Flexible endoscopes will melt if they are exposed to the sterilization process in Sterile Services. Endoscopes should be decontaminated by a combination of manual cleaning and high level disinfection in an Automated Endoscope Reprocessor.

2.8 Endoscopes that are introduced into a sterile body cavity e.g. choledochoscope must be sterilized after use by Ethylene Oxide sterilization.

### 3.0 Purpose and Aims

3.1 The purpose and aims of this policy are to:

   3.1.1 Minimize the risk of infection through transmission of infectious agents from the reuse of flexible endoscopes.

   3.1.2 Ensure the welfare of patients and staff.

   3.1.3 Ensure that the Trust has in place suitable and robust governance arrangements to support endoscope decontamination.

   3.1.4 Ensure that responsibility for endoscope decontamination is clearly defined and that there are clear lines of accountability throughout the Trust leading to the Board.

These will be achieved by ensuring that:

   3.1.5 All flexible endoscopes are handled, collected and delivered in a manner that reduces the risk of contamination to the product, patients, staff and any area within the Trust.
3.1.6 All flexible endoscopes are decontaminated and stored in accordance with legislative and best practice requirements.

3.1.7 All flexible endoscopes are tracked through the decontamination process and can be traced to individual patients.

3.1.8 Endoscope decontamination equipment is subject to validation, calibration, monitoring and maintenance by appropriately qualified persons.

3.1.9 All flexible endoscopes and endoscope decontamination equipment are dealt with as per Trust procedures after use on patients that are suspected / known to have CJD / vCJD.

3.1.10 All endoscope decontamination equipment that does not meet the requirements of current standards and test methods is upgraded or replaced as soon as practicable in accordance with a planned replacement programme.

3.1.11 All flexible endoscopes that cannot be easily cleaned and/or those in poor condition are identified and subject to a planned replacement programme.

3.1.12 All locations where the decontamination of flexible endoscopes is carried out are dedicated for the purpose, appropriately designed, maintained, controlled and meet the required standards.

3.1.13 The risk management process is applied to all aspects of decontamination of flexible endoscopes.

3.1.14 Education and training in appropriate aspects of endoscope decontamination practice is provided to all relevant staff.

3.1.15 All medical devices must not be modified or used for purposes not intended by the manufacturer.
3.1.16 All single use medical devices MUST NOT be reused.

4.0 Scope of the Policy

4.1 The scope of this policy extends to all Trust staff involved in the decontamination of flexible endoscopes.

5.0 Roles and Responsibilities

5.1 Executive Manager - Chief Executive

The Chief Executive in accordance with *Choice Framework for local Policy and Procedures 01-06 – Reprocessing of Flexible Endoscopes* is the Executive Manager and is defined as the person with ultimate management responsibility.

5.2 Decontamination Lead – Director of Acute Services

The Director of Acute Services in accordance with *Choice Framework for local Policy and Procedures 01-06 – Reprocessing of Flexible Endoscopes* is the nominated Decontamination Lead at Trust Board level with responsibility for Decontamination.

The Director of Acute Services will report to SMT Governance Committee and Trust Board on matters relating to the decontamination of flexible endoscopes.

5.3 The Assistant Director for Cancer and Clinical Services is responsible for the operational management of the endoscopy service and has responsibility for all aspects of flexible endoscope decontamination.

5.4 The Assistant Director of Acute Services, Functional Support Services has operational responsibility for the management of the decontamination service provided by Sterile Services Departments (SSDs). The Head of Decontamination Services has responsibility for the
provision of decontamination services within the Trust and is accountable to the Assistant Director of Acute Services, Functional Support Services.

5.4 **Senior Operational Manager** - Head of Medical Technical Services

The Head of Medical Technical Services is technically, professionally and managerially responsible for the engineering aspects of decontamination (e.g. decontamination equipment and environment).

5.5 **User** – Department Manager

The User is responsible for the management of the flexible endoscope decontamination process. The User also has responsibility to:
- Certify that the flexible endoscope decontamination equipment is fit for use
- Hold all documentation relating to the flexible endoscope decontamination equipment
- Ensure that that the flexible endoscope decontamination equipment is subject to periodic testing and maintenance
- Ensure that operators are adequately trained
- Maintain staff training records
- Maintain production records
- Establish procedures for product release
- Ensure that procedures for production, quality control and safe working are documented and adhered to

5.6 **Operator**

The operator is defined as any person with the authority to operate an Automated Endoscope Reprocessor.

5.7 **Authorising Engineer (Decontamination)** – Mr John Singh, HEIG DHSSPSNI

The AE(D) is defined as a person designated by the Trust to provide independent auditing and advice on washer-disinfectors (including Automated Endoscope Reprocessors), sterilizers and sterilization and to review
and witness documentation on validation of this equipment.

The AE (D) is fully independent of the Trust’s structure for maintenance, testing and management of the endoscope decontamination equipment.

The AE (D) has a reporting route to the Decontamination Lead and should provide professional and technical advice to the AP (D), CP (D), Users and other key personnel involved in the endoscope decontamination processes.

5.8 **Authorised Person (Decontamination)**

The AP (D) is responsible for the practical implementation and operation of the policy and procedures relating to the engineering aspects of endoscope decontamination equipment.

The AP (D) is responsible for the line management of the Competent Persons (Decontamination).

5.9 **Competent Person (Decontamination)**

The CP (D) is responsible for carrying out maintenance, validation and periodic testing of the endoscope decontamination equipment.

5.10 **Clinical Director of Infection Prevention and Control**

The Clinical Director of Infection Prevention and Control is responsible for infection control aspects of endoscope decontamination.

5.11 **Microbiologist (Decontamination)**

The Microbiologist (Decontamination) is responsible for advising the User on microbiological aspects of disinfecting and sterilizing non-medicinal products. He/she should also be defined as the person responsible for advising the User on the microbiological aspects of handling, washing, disinfecting and sterilizing flexible endoscopes.
5.12 **Trust Decontamination Committee**

The Trust Decontamination Committee is responsible for:

- The implementation of the Decontamination of Flexible Endoscopes Policy and the establishment and implementation of supporting procedures and guidelines.
- Ensuring a periodic review of compliance with the Decontamination of Reusable Medical Devices Controls Assurance Standard.
- Providing assurance to the Trust Senior Management Team on a regular basis in relation to compliance with the Decontamination of Reusable Medical Devices Controls Assurance Standard and any other DHSSPSNI guidance or recommendations.

5.13 Trust Directors, Assistant Directors, Heads of Service and Senior Managers including Ward / Departmental Managers are responsible for ensuring that decontamination procedures are fully implemented and monitored as part of the Trust’s integrated governance arrangements.

5.14 All Trust managers must ensure that their staff have access to this policy, understand its content, and are aware of its aims and purpose.

5.15 All Trust staff who are responsible for the decontamination of flexible endoscopes must comply with this policy.

6.0 **Legislative Compliance, Relevant Policies, Procedures and Guidance**

6.1 Staff must comply with relevant professional standards and guidance and other Department of Health, Social Services and Public Safety publications including, but not exclusively or exhaustively the following:-


6.1.4 DHSS Circular HSS (MD) 16/99, Controls assurance in infection control: decontamination of medical devices.

6.1.5 DHSS Circular HSS(MD)15/99, Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission

6.1.6 HSS (MD) 4/01 Decontamination of reusable medical devices

6.1.7 DB 9904 (NI) Medical Device and Equipment Management for Hospitals and Community-based Organisations NIAIC

6.1.8 DB 2002 (NI) (05) Decontamination of Endoscopes

6.1.9 Hine Review 2004

6.1.10 Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes


7.0 Equality and Human Rights Considerations

7.1 This policy has been screened for equality implications as required by Section 75, Schedule 9, of the Northern
Ireland Act, 1998. Equality Commission for Northern Ireland Guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be targeted at them.

7.2 Using the Equality Commission’s screening criteria; no significant equality implications have been identified. This policy will therefore not be subject to an equality impact assessment.

7.3 This policy has been considered under the terms of the Human Rights Act, 1998, and was deemed to be compatible with the European Convention Rights contained in that Act.

7.4 This policy will be included in the Trust’s register of screening documentation and maintained for inspection whilst it remains in force.

7.5 This document can be made available on request in alternative formats, e.g., Braille, disc, audio cassette and in other languages to meet the needs of those who are not fluent in English.

8.0 Review of Policy

8.1 The Trust is committed to ensuring that all policies are kept under review to ensure that they remain compliant with relevant legislation.

8.2 This policy will be reviewed by the Head of Decontamination Services in August 2014 or earlier if relevant guidance is issued. That review will be noted on a subsequent version of this policy, even where there are no substantive changes made or required.
9.0 Sources of Advice and Further Information

9.1 Further advice and information regarding this document can be obtained from the Head of Decontamination Services.