The Newcastle upon Tyne Hospitals NHS Foundation Trust

Decontamination of Reusable Medical Devices Policy

<table>
<thead>
<tr>
<th>Version No.:</th>
<th>1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective From:</td>
<td>30th December 2014</td>
</tr>
<tr>
<td>Expiry Date:</td>
<td>30th December 2017</td>
</tr>
<tr>
<td>Date Ratified:</td>
<td>9th October 2014</td>
</tr>
<tr>
<td>Ratified By:</td>
<td>Infection Prevention and Control Committee</td>
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</table>

1 Introduction

This policy covers the decontamination of reusable medical devices such as surgical instruments and flexible endoscopes and does not address issues of environmental cleanliness or the decontamination of other ‘near-patient’ reusable devices. For further advice refer to Environmental and Cleanliness Strategy, Decontamination of the Patient Environment (including Terminal & Deep Cleaning) Policy, Cleaning and Disinfection Procedure and Decontamination of Healthcare Equipment following Patient Use and Prior to Service or Repair.

Decontamination of reusable medical devices and equipment is a priority for the Trust and is essential to ensure the delivery of safe services to patients, staff and other service users. This policy offers best practice guidance on the management and decontamination of such devices used in acute and community services.

In order to be registered with the Care Quality Commission (CQC), the Trust is required to maintain appropriate levels of cleanliness and hygiene in relation to reusable medical devices. The Code of Practice provides guidance on how providers can meet this registration requirement, including key recommendations on the provision of a safe decontamination service that generates a clean and sterile product. The Trust has a responsibility to systematically identify, assess and monitor all decontamination processes relating to reusable medical devices, ensuring that they are compliant with required standards and processes.

This policy promotes a consistent and standardised approach and focuses on embedding and sustaining a culture of best practice across the organisation. Through this the Trust will ensure that a robust programme of audit and review is in place, in order to provide assurance that the required standards are being met at all levels in the organisation. When any deficiencies are identified, immediate remedial action will be taken and robust action plan will be developed and implemented.

This policy supersedes the previous Decontamination Strategy (version 1.0).
2 Scope

This policy applies to all healthcare professionals working in both acute and community services within The Trust’s Hospitals Outreach and Community Services and outlines responsibility of key individuals (roles) and describes the organisational structure to deliver this policy. This includes Estates and clinical staff, students, temporary staff, those working in the Trust from other organisations and contractors.

The policy focuses on all reusable medical devices and equipment which is:

- Reprocessed in Sterile Services Department (SSD);
- Processed through Endoscope Washer Disinfectors (EWDs); and
- Decontaminated manually, for example TOE/Nasendoscopes.

This policy focuses on reusable surgical instruments and flexible endoscopes and does not cover environmental cleanliness or the decontamination of other ‘near-patient’ reusable devices (please refer to Section 13 of this policy for further information).

3 Aims

The aim of this policy is to support the provision of the highest levels of patient care and staff safety in the most cost effective manner. All employees have a duty to consider patient safety and decontamination issues related to their work and the following principles underpin decontamination within the Trust:

- Manufacturer’s instructions and national guidance must be adhered to;
- Equipment will be fit for its intended purpose;
- Decontamination processes will be validated and audited;
- Validated processes will be independently monitored in accordance with national guidance;
- Planned/reactive maintenance of decontamination equipment will be undertaken and authorised by trained, competent, personnel;
- Relevant staff will be fully trained in decontamination practices;
- Records of decontamination processes will be maintained;
- Any decontamination/reprocessing will be a key consideration at the point of procurement to ensure standards can be met;
- Regular audit processes will be part of the on-going monitoring of the Trust decontamination arrangements;
- All surgical instruments, with the exception of those requiring decontamination by Ethylene Oxide (EO) sterilisation, are required to undergo central processing through Sterile Services Department;
- Flexible endoscopes, or surgical instruments, requiring decontamination by EO sterilisation must be cleaned as per the Cleaning & Disinfection of Endoscopes Policy and sent to an accredited EO facility for processing;
- The Trust employs a model of centralised decontamination of endoscopes;
- All Flexible Endoscopes are required to be cleaned through validated processes;
• A process of traceability must be maintained for all surgical instruments and flexible endoscopes;
• Community equipment (Sexual health and Podiatry) will be decontaminated by Sterile Services Department, Freeman Hospital;
• Community Dentistry will undertake local decontamination in accordance with national guidance;
• Single-use devices must be used in accordance with manufacturer’s instructions, and local policy, and disposed of appropriately to prevent contamination;
• Single-use items should always be considered as an alternative to re-processing and a balanced judgement achieved based on a range of factors including risk, cost effectiveness and sustainability; and,
• Where there is a risk of prion transmission during surgical or endoscopy procedures, specific precautions, including instrument quarantine, will be taken in accordance with Trust policy.

4 Duties (Roles and responsibilities)

The Choice Framework for local Policy and Procedures (CFPP) 01-01 and 01-06, and Health Technical Memorandum (HTM) 01-05, provide guidance on management and decontamination of reusable medical devices.

The reporting structure within the Trust, for decontamination, is outlined in Appendix 1.

The roles and responsibilities, for a range of key officers with responsibility for aspects of decontamination, are clearly defined and outlined below:

4.1 Chief Executive

The Chief Executive is the Executive Manager, with roles and responsibilities as defined in CFPP 01-01, and has ultimate management responsibility for allocation of resources and appointment of personnel for the organisation in which the decontamination equipment is installed.

4.2 Director of Infection Prevention & Control (DIPC)

The DIPC is nominated as Decontamination Lead, with roles and responsibilities as defined in CFPP 01-01, and has responsibility for decontamination at Board level and reports directly to the Chief Executive. This person is responsible for the effective and technically compliant provision of decontamination services, implementing and monitoring operational policy for decontamination and is responsible for clearly defining the roles and responsibilities of all personnel involved in the use, installation and maintenance of decontamination equipment. The DIPC also has responsibility for chairing the Trust’s Infection Prevention & Control Committee, which oversees the work of the Decontamination Working Group.
4.3 Infection Prevention & Control (IPC) Doctors and Microbiologists

The Trust have a site IPC Doctor nominated as **Microbiologist (Decontamination)**, with roles and responsibilities as defined in CFPP 01-01. Other site IPC Doctors and Microbiologists support the nominated Microbiologist (Decontamination) in advising the User and Management on microbiological and infection prevention aspects of decontamination of reusable medical devices.

4.4 Director of Estates & Facilities

The Director of Estates & Facilities is nominated as **Designated Person**, with roles and responsibilities as defined in CFPP 01-01, and provides the senior management link between the organisation and professional support, providing an informed position to Board and working with the Senior Operational Manager to ensure provision is made to support the decontamination system. The Director of Estates & Facilities will appoint, in writing, the independent Authorising Engineer (Decontamination) (AE(D)).

4.5 Senior Estates Manager

The Senior Estates Manager in charge of decontamination support is nominated as **Senior Operational Manager**, with roles and responsibilities as defined in CFPP 01-01, and is technically, professionally and managerially responsible for the Estates engineering aspects of decontamination and is accountable to the Designated Person.

4.6 Sterile Services Managers, Endoscopy Matron, ENT Matron, Theatre Matrons and Dental Managers

The above managers are nominated as **Surgical Instrument Managers** and **Users**, with roles and responsibilities as defined in CFPP 01-01. They manage the decontamination of medical device process and are responsible for the **Operators**. These managers are responsible for co-ordinating activity between theatres, clinics, central decontamination and Supplies; ensuring compliance with appropriate processing techniques throughout the decontamination cycle. The Users may seek advice from the DIPC or Microbiologist/Infection Prevention & Control Doctor on infection control issues associated with decontamination of medical devices. They are responsible for ensuring that any contraindications to staff working with decontamination chemicals are considered; for example pregnant staff and staff with asthma.

4.7 Staff who operate Decontamination Equipment

Staff with the authority to operate decontamination equipment are nominated as **Operators**, with roles and responsibilities as defined in CFPP 01-01. They must
be adequately trained and competent to carry out the task, under the management and supervision of the Surgical Instrument Managers and Users.

4.8 Engineering Officers

Engineering Officers with adequate technical knowledge and relevant training will be appointed, in writing, as an Authorised Person (Decontamination) (AP(D)) by the Designated Person, as per CFPP 01-01. The AP(D) will be responsible for:

- Engineering management of decontamination equipment;
- Line management and appointment of the Competent Person (Decontamination);
- Safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility;
- Acceptance criteria for operational and performance testing of all installed decontamination equipment;
- Liaison with the AE (D), Senior Operational Manager, Designated Person, Microbiologists, IPC Doctors and other interested professionals; and,
- Authorising the use of decontamination equipment after major repair, or refurbishment, and after quarterly or annual tests.

4.9 Engineering Technicians (Sterilisers)

The Engineering Technicians (Sterilisers) will be appointed, in writing, as Competent Persons (Decontamination) (CP(D)) by the AP(D), as per CFPP 01-01. The CP(D) will be responsible for carrying out maintenance, validation and periodic testing of washer-disinfectors and sterilisers. The CP(D) will report directly to the AP(D) and be principally responsible for:

- Carrying out maintenance tasks;
- Carrying out repair work;
- Conducting validation tests as stipulated in CFPP 01-01 Parts B, C & D; and,
- Conducting periodic tests as stipulated in CFPP 01-01 Parts B, C & D.

External contractors may be contracted to carry out some decontamination equipment maintenance and testing, thus carrying out some CP(D) duties.

4.10 External Independent Authorising Engineer (Decontamination) (AE(D))

The AE(D) is designated by management to provide independent auditing, validating and professional advice on all decontamination procedures, washer-disinfectors, sterilisers and sterilisation and to review and witness documentation on validation. The AE(D) will assist in the appointment of AP(D)s and their consequent annual assessments.

Principal responsibilities of the AE(D) are to:
• Provide management and others, general and impartial advice on all matters concerned with decontamination;
• Advise management and others on programmes of validation and testing;
• Provide audit reports on validation, revalidation and yearly tests submitted by the AP(D);
• Advise management and others on operational procedures for routine production;
• Advise management on the appointment of the AP(D);
• Provide technical advice on purchasing and selection of decontamination equipment for the users, and
• Provide technical advice on the relevant guidance on decontamination equipment and procedures.

The Trust currently employs the services of **Tracey Miller from AVM Services (Cambridge University Hospitals NHS Foundation Trust)** in this role.

4.11 Ward/Department Sisters/Charge Nurses/Managers

All ward and department managers are responsible for ensuring that their staff are trained in the safe use and handling of medical devices within their area. Managers must ensure that staff are aware of how to effectively decontaminate equipment used within their department and Managers must therefore ensure that all staff comply with this policy.

4.12 All staff

It is the responsibility of all staff to identify any reusable medical device decontamination issues in their areas and refer concerns to their line managers to ensure equipment is effectively decontaminated. Also their responsibility to comply with the policy.

5 Definitions

The following section lists the meaning of some terms used in the context of this document:

5.1 **Decontamination** is the combination of processes (including cleaning, disinfection and sterilisation) used to render reusable items safe for further use on patients and handling by staff. Effective decontamination is essential in reducing the risk of transmission of infectious agents.

5.2 **Cleaning** is the process that physically reduces the level of contamination (organic matter, dirt, grease) but does not destroy all organisms. The effectiveness of cleaning is as important as the agent used. It is important to emphasise that thorough physical cleaning must be the first step in
decontamination; if items are not appropriately cleaned, subsequent disinfection or sterilisation will be ineffective.

5.3 **Disinfection** is the partial removal or destruction of some, but not all organisms present. Heat disinfection is preferable to chemical disinfection and therefore should always be considered in the first instance.

5.4 **Sterilisation** is the process used to render an object free from all microorganisms including spores. Routinely sterilisation of most surgical instruments is achieved in autoclaves using steam under pressure.

5.5 **Medical devices** refer to all products, except medicines, used in healthcare for diagnosis, prevention, monitoring or treatment. This includes a range of products including surgical instruments to hospital beds.

5.6 **Single-patient use** items are any medical devices deemed unsuitable for re-processing as stated by the manufacturers. Equipment labelled as such may be used a number of times by the same patient only.

5.7 **Single-use/disposable** items are any medical devices deemed unsuitable for re-processing as stated by the manufacturers; these items must be disposed of after each use.

5.8 **Contamination** is the soiling or pollution of inanimate objects or living material with harmful, potentially infectious or unwanted material.

6 **Decontamination**

6.1 **The Trust’s Decontamination Facilities**

The Trust operates out of the two main acute hospital sites where decontamination of surgical instruments and flexible endoscopes occurs, and community bases where re-useable items requiring decontamination are used.

Facilities where decontamination is authorised to be carried out are outlined below. Decontamination activities are not permitted to take place in other areas without authorisation from the Decontamination Working Group (in consultation with the Authorising Engineer (Decontamination)).

6.1.1 **Acute**

- Sterile Services Department (SSD), Royal Victoria Infirmary
- SSD, Dental Hospital
- Endoscopy Department, Royal Victoria Infirmary (also reprocesses flexible endoscopes for all Theatres)
- SSD, Freeman
Endoscopy Department, Freeman Hospital (also reprocesses flexible endoscopes for all Theatres and Endourology at Freeman Hospital)

Ear, Nose and Throat (ENT) Department, Freeman Hospital

Cardiothoracic & Institute of Transplantation Screening Rooms, Freeman Hospital

6.1.2 Community

Decontamination for Sexual Health and Podiatry Services is carried out by Freeman SSD. Community bases where these services operate out of are:

- New Croft House
- Diabetes Centre, Campus for Ageing & Vitality
- Arthurs Hill Clinic
- Walker Resource Centre
- Gosforth Memorial Clinic
- Denton Park
- Geoffrey Rhodes Centre
- Throckley Primary Care Centre
- Benfield Park
- St. Nicholas Hospital
- Belsay Unit, Campus for Ageing & Vitality

Decontamination for Dental Clinics in the community:

- Walker Resource Centre
- Arthurs Hill Clinic
- Molineux Street Centre
- Kenton Resource Centre

6.2 Policy development

Key policies and procedures underpinning decontamination and cleanliness will be developed through the respective policy groups with input from key disciplines (Infection Prevention and Control, Nursing, other Clinicians etc.) as appropriate to the policy.

All policies will conform to the Trust’s defined format and will be formally ratified through the Trust’s Clinical Policy Group in accordance with policy.

Policy development is co-ordinated through the Decontamination Working Group and ratified by the Trust Infection Prevention and Control Committee.

Review, updating and replacement of existing Trust intranet policies will be managed through the Clinical Effectiveness Manager (CGARD).
6.3 Procurement

Before any new decontamination equipment, or reusable medical devices, are purchased they should be discussed and agreed with the relevant Surgical Instrument Manager, User, IPC Doctor/Microbiologist and IPC Team.

The Supplies Department, in supporting procurement of instrumentation, will ensure that purchasers are aware of the requirement to check manufacturer’s instructions to enable the product to be processed as required i.e. by sterilisation or disinfection.

All reusable surgical instruments purchased, except those requiring Ethylene Oxide sterilisation, will be required to undergo central processing through the Sterile Service Department and therefore managers must ensure that the equipment meets this requirement prior to purchase.

Reusable medical devices/equipment will be required to be capable of being cleaned and disinfected effectively to maintain the current and national standards. This will be verified through a review of Manufacturer’s instructions.

The method and suitability of the equipment and processing will be determined prior to purchase by the users and assessed with input from the relevant Trust advisors.

6.4 Resources

6.4.1 Financial

Directorate/Department budgets will be used to best effect to ensure that requirements in respect of decontamination are met, whether these are as a result of national or local initiatives.

Where additional resources are required a business case will be submitted to the appropriate committee for consideration and approval to ensure that any deficits in funding are addressed. Responsibility for developing business cases rests with the relevant Directorate/Department Manager.

National and Local initiatives may require additional resources to support implementation. Where there are designated funds available to support such initiatives, and funds can be acquired via a bidding process either to Clinical Commissioning Groups/Department of Health, the Trust will submit bids as appropriate to secure these funds.

Where resources are limited, decisions on investment will be based on sound evidence and be able to demonstrate efficiency and effectiveness can be achieved. Prioritisation of investments will be agreed through the
respective committee i.e. Decontamination Working Group, Infection Prevention and Control Committee, Capital Management Group, and their recommendations referred to the Trust's Executive Team for consideration.

6.4.2 Workforce

It is recognised that the introduction of new policy/procedures may have an impact on service delivery and therefore it will be essential to review requirements as changes are introduced to ensure appropriate resources.

Workforce planning will be essential to this, i.e. assessing current and future requirements.

6.4.3 Physical

It is essential that staff have access to equipment to enable them to perform the required task, which is ‘fit for purpose’ i.e. in good working condition and that the environment in which the equipment is used is in a good state of repair. This will ensure that the deployment of resources is to best effect, ensuring adequate Personal Protective Equipment (PPE) is available to enable them to carry out the task.

7 Training

7.1 All Trust staff are required to complete mandatory IPC training in which the basic principles of decontamination are covered.

7.2 All Sterile Services Technicians are required to train towards and complete NVQ Level 3 in Decontamination. With relevant knowledge of CFPP 01-01, including awareness of this policy and current European and National Legislation on the subject. This will be assessed for competency by Sterile Services management.

7.3 All Endoscopy staff carrying out decontamination activities will be competent for the decontamination tasks carried out. This will include formal training and experience, with relevant knowledge of CFPP 01-06, including awareness of this policy and current European and National legislation on the subject. This will be assessed for competency by Endoscopy management.

7.4 All Community Dental staff carrying out decontamination activities will be competent for the decontamination tasks carried out. This competency will include formal training and experience, with knowledge of HTM 01-05, including awareness of this policy and current European and National legislation on the subject. This will be assessed for competency by Community Dentistry management.
7.5 All staff involved in the maintenance, testing and validation of decontamination equipment (either internal Estates staff, or external contractors) will be competent for the task undertaken. Individuals adopting the role of CP(D) and AP(D) must have the necessary competencies before appointment. This competency will be a combination of formal training and experience, and will be subjected to both internal and external (AE(D)) audit. This will be assessed for competency by Estates management.

7.6 Higher levels of training by accredited external bodies will be facilitated, where considered appropriate to the needs of the organisation, and to ensure compliance with relevant standards.

7.7 In addition to assessment of the education and training requirements for staff identified through staff appraisal, line managers will be required to ensure that staff are adequately educated and trained, and able to support effective implementation of any policy/procedural changes associated with decontamination.

8 Equality and Diversity

The 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 has been appropriately assessed.

9 Monitoring Compliance

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
<th>Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traceability of flexible endoscopes (Endoscopy and satellite units)</td>
<td>Audit</td>
<td>Endoscopy, Theatre, ITU and ENT personnel</td>
<td>Decontamination Working Group</td>
<td>Twice per year (February and September)</td>
<td></td>
</tr>
<tr>
<td>Community Dentistry</td>
<td>Audit</td>
<td>Community Dentistry personnel</td>
<td>Decontamination Working Group</td>
<td>Twice per year (May and November)</td>
<td></td>
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<tr>
<td>SSD Quality Management System</td>
<td>Audit</td>
<td>Notified Body (SGS)</td>
<td>Decontamination Working Group</td>
<td>Twice per year</td>
<td></td>
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<tr>
<td>Estates Planned Preventative Maintenance, Testing and Validation of Trust Decontamination Equipment</td>
<td>Assurance report</td>
<td>Estates Senior Operational Manager</td>
<td>Decontamination Working Group</td>
<td>Bi-monthly review of report at each DWG</td>
<td></td>
</tr>
<tr>
<td>Competency Assessment of CP(D)s and AP(D)s</td>
<td>Audit</td>
<td>Estates Senior Operational Manager</td>
<td>Decontamination Working Group</td>
<td>Annually</td>
<td></td>
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<tr>
<td>Final Rinse Water Sampling (Endoscopy and ENT)</td>
<td>Weekly sample testing to national guidance, results distributed to Users and Estates each week for action. Summary report reviewed at each DWG.</td>
<td>Sampling carried out by CP(D)s. Samples sent to PHE labs. Results sent to Users and Estates.</td>
<td>Decontamination Working Group</td>
<td>Weekly (sampling) Bi-monthly review of results at DWG</td>
<td></td>
</tr>
<tr>
<td>Competency Assessment of Decontamination Equipment Operators</td>
<td>Audit</td>
<td>Endoscopy &amp; SSD Managers</td>
<td>Decontamination Working Group</td>
<td>Annually</td>
<td></td>
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<tr>
<td>Joint Advisory Group (JAG) on GI Endoscopy Accreditation</td>
<td>External Audit</td>
<td>JAG</td>
<td>Decontamination Working Group</td>
<td>Two yearly</td>
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<tr>
<td>JAG Report Scorecard</td>
<td>Internal Audit/Self-Assessment</td>
<td>Endoscopy Manager</td>
<td>Decontamination Working Group</td>
<td>Annually</td>
<td></td>
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<tr>
<td>Decontamination Incident Reporting</td>
<td>Incident Report Review</td>
<td>Quality &amp; Safety Lead, CGARD</td>
<td>Decontamination Working Group</td>
<td>Bi-monthly review of incidents at DWG</td>
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</tr>
<tr>
<td>Risk Register (Decontamination)</td>
<td>Risk Register Review</td>
<td>Quality &amp; Safety Lead, CGARD</td>
<td>Decontamination Working Group</td>
<td>Six monthly</td>
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<tr>
<td>Overall Decontamination of Reusable Medical Devices by the Trust</td>
<td>External Audit</td>
<td>Independent AE(D)</td>
<td>Decontamination Working Group</td>
<td>Annually</td>
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</tbody>
</table>

### 10 Consultation and Review

Consultation of this policy was undertaken by the Decontamination Working Group before submission to IPCC for final review and approval. This policy will be reviewed every two years by the Decontamination Working Group or as, and when, significant changes make earlier review necessary.

### 11 Implementation (including raising awareness)

Ward and Department managers should ensure that staff are aware of this policy and that it is available for staff to access via NUTH intranet.

### 12 References

- European Medical Devices Directive 93/42/EEC
- BS EN ISO 13485 – Quality Management System for Medical Devices
- BS EN ISO 14971 – Application of Risk Management to Medical Devices
- BS EN ISO 15883 – Washer-Disinfectors

The hyperlinks below go to national NHS guidance documents hosted online by [www.gov.uk](http://www.gov.uk) and may be subject to change. Should a link fail the full title of the
document can be copied and pasted into an internet search engine, and the up-to-date document found.

- **Choice Framework for local Policy and Procedures (CFPP) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part A: The formulation of local policy and choices**
- **Choice Framework for local Policy and Procedures (CFPP) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part B: Common Elements**
- **Choice Framework for local Policy and Procedures (CFPP) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part C: Steam Sterilization**
- **Choice Framework for local Policy and Procedures (CFPP) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part D: Washer-disinfectors**
- **Choice Framework for local Policy and Procedures (CFPP) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part E: Alternatives to steam for the sterilization of reusable medical devices**
- **Choice Framework for local Policy and Procedures (CFPP) 01-06 – Decontamination of flexible endoscopes: Operational management**
- **Choice Framework for local Policy and Procedures (CFPP) 01-06 – Decontamination of flexible endoscopes: Design and installation**
- **Choice Framework for local Policy and Procedures (CFPP) 01-06 – Decontamination of flexible endoscopes: Testing methods**
- **Choice Framework for local Policy and Procedures (CFPP) 01-06 – Decontamination of flexible endoscopes: Validation and verification**
- **Choice Framework for local Policy and Procedures (CFPP) 01-06 – Decontamination of flexible endoscopes: Policy and management**
- **Health Technical Memorandum (HTM) 01-05 – Decontamination in Primary Care Dental Practices**

13 **Associated documentation**

- **Environmental and Cleanliness Strategy**,  
- **Decontamination of the Patient Environment (including Terminal & Deep Cleaning) Policy**,  
- **Cleaning and Disinfection Procedure**  
- **Decontamination of Healthcare Equipment following Patient Use and Prior to Service or Repair**  
- **Policy for the Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD) in the hospital and community setting**
Appendix 1 – Reporting Structure

DECONTAMINATION OF REUSABLE MEDICAL DEVICES: REPORTING ARRANGEMENTS

Executive Manager
Chief Executive
(or nominated Executive Director)

Decontamination Lead
Director of Infection Prevention & Control (DIPC)

Designated Person (Decontamination)
Director of Estates and Facilities

Authorising Engineer (Decontamination)
T. Miller, AVM - Cambridge

Senior Operational Manager
Senior Estates Manager

Authorised Persons (Decontamination)
Engineering Officers

Competent Persons (Decontamination)
Steriliser Technicians

Surgical Instrument Managers & Users
Sterile Services Manager, Endoscopy Matron, ENT Matron, Theatre Matrons, and Dental Managers

Operators
Sterile Services staff, Endoscopy staff, ENT staff, Cardio Theatre staff, and Dentistry staff

Microbiologists & IPC Doctors
IPC Doctor (RVI), IPC Doctor (FH), and Consultant Microbiologists

Infection Prevention & Control (IPC)
IPC Matron (and IPC Nurses)

Independent PHE Advice
Professor K. Gould
The Newcastle upon Tyne Hospitals NHS Foundation Trust

**Equality Analysis Form A**

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

**PART 1**

1. **Assessment Date:** 10.10.2014

2. **Name of policy / strategy / service:**

   Decontamination of Reusable Medical Devices Policy

3. **Name and designation of Author:**

   James Dixon (Waste Officer)

4. **Names & designations of those involved in the impact analysis screening process:**

   Members of the Decontamination Working Group (DWG) and Infection Prevention & Control Committee (IPCC)

5. **Is this a:**

   - Policy [X]
   - Strategy [ ]
   - Service [ ]

   **Is this:**

   - New [ ]
   - Revised [X]

   **Who is affected**

   - Employees [X]
   - Service Users [X]
   - Wider Community [X]

6. **What are the main aims, objectives of the policy, strategy, or service and the intended outcomes?** *(These can be cut and pasted from your policy)*

   Decontamination of reusable medical devices and equipment is a priority for the Trust and is essential to ensure the delivery of safe services to patients, staff and other service users. This policy offers best practice guidance on the management and decontamination of such devices (i.e. surgical instruments and flexible endoscopes) used in acute and community services.

7. **Does this policy, strategy, or service have any equality implications?**

   Yes [ ]
   No [X]

   **If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:**

   The policy has considered the needs of all people including those who have protected characteristics and ensures any groups of people with protected characteristics are not disproportionately advantaged or disadvantaged.
## 8. Summary of evidence related to protected characteristics

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups</th>
<th>Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)</th>
<th>Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race / Ethnic origin (including gypsies and travellers)</td>
<td>The policy is designed to support the highest levels of patient care and staff safety.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sex (male/ female)</td>
<td>As above</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Religion and Belief</td>
<td>As above</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sexual orientation including lesbian, gay and bisexual people</td>
<td>As above</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Age</td>
<td>As above</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section</td>
<td>As above Only staff who have the capacity and capability will be asked to undertake these procedures</td>
<td>Need to clarify if there are any particular contraindications for staff with medical conditions such as asthma undertaking these procedures. If there are add a sentence to 4.5: They are responsible for ensuring that any contraindications to staff working with decontamination chemicals are considered; for example staff with asthma.</td>
<td>No</td>
</tr>
<tr>
<td>Gender Re-assignment</td>
<td>As above</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Marriage and Civil Partnership</td>
<td>As above</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Maternity / Pregnancy</td>
<td>As above</td>
<td>Need to clarify if there are any particular contraindications for pregnant women undertaking these procedures. If there are add a sentence to 4.5: They are responsible for ensuring that any contraindications to staff working with</td>
<td>No</td>
</tr>
</tbody>
</table>
decontamination chemicals are considered; for example pregnant staff.

9. Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

Do you require further engagement? Yes [ ] No [ X ]

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)

No

PART 2

Name: James Dixon

Date of completion: 10/10/14

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)