The Newcastle upon Tyne Hospitals NHS Foundation Trust

Decontamination of Reusable Medical Devices Policy

<table>
<thead>
<tr>
<th>Version No.</th>
<th>2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective From</td>
<td>12 February 2018</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>12 February 2021</td>
</tr>
<tr>
<td>Date Ratified</td>
<td>14 December 2017</td>
</tr>
<tr>
<td>Ratified By</td>
<td>Infection Prevention and Control Committee</td>
</tr>
</tbody>
</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/or 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, implemented, and seen through to timely completion.

2 Scope

This policy applies to all healthcare professionals working in both acute 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 Trustwide:

- Manufacturer’s instructions and national guidance must be adhered to;
- Equipment must be fit for its intended purpose;
- Decontamination processes must be validated and audited;
- Validated processes are independently monitored in accordance with national guidance;
- Planned/reactive maintenance of decontamination equipment must be undertaken and authorised by trained, competent, personnel;
- Relevant staff must be fully trained in decontamination practices;
- Records of decontamination processes are to be maintained;
- Any decontamination/reprocessing is 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 are required to undergo central processing through Trust Sterile Services Department;
- 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) is decontaminated by Trust Sterile Services Department;
- 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 cross infection/contamination;
- Single-use items can be considered as an alternative to re-processing, but a balanced judgement must be 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, are to be taken in accordance with Trust policy.

4 Duties (Roles and responsibilities)

Health Technical Memorandum (HTM) 01-01, 01-05 and 01-06 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 HTM 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 has site IPC Doctors acting as Microbiologist (Decontamination), with roles and responsibilities as defined in HTM 01-01. Other microbiologists support the IPC doctors in advising the User and Management on microbiological and infection prevention aspects of decontamination of reusable medical devices.

4.4 Director of Estates

The Director of Estates acts as Designated Person, with roles and responsibilities as defined in HTM 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
4.5 **Senior Estates Engineering Managers**

The Senior Estates Engineering Managers in charge of decontamination equipment maintenance and validation act as Senior Operational Manager, with roles and responsibilities as defined in HTM 01-01. The Senior Estates Engineering Managers are technically, professionally and managerially responsible for the Estates engineering aspects of decontamination and they are accountable to the Designated Person.

4.6 **Surgical Instrument Managers**

Sterile Services Managers, Endoscopy Matron, ENT Matron, Theatre Matrons and Dental Managers are Surgical Instrument Managers and Users, with roles and responsibilities as defined in HTM 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 Operators, with roles and responsibilities as defined in HTM 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 **Estates Engineering Officers**

Estates Engineering Officers with appropriate technical knowledge and relevant training are appointed, in writing, as an Authorised Person (Decontamination) (AP(D)) by the Designated Person, as per HTM 01-01. Competence of the AP(D)s will be assessed by the AE(D). The AP(D)s 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) are appointed, in writing, as Competent Persons (Decontamination) (CP(D)) by the AP(D), as per HTM 01-01. The CP(D) are 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 HTM 01-01 Parts B, C & D; and,
• Conducting periodic tests as stipulated in HTM 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 appointed 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 and competent in the safe use and handling of medical devices within their area. Managers must ensure that staff are aware of how to effectively decontaminate any reusable medical devices 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. All staff involved with reusable medical device decontamination must comply with this policy.

4.13 Decontamination Working Group

The Decontamination Working Group is the governance committee responsible for overseeing the management of reusable medical device decontamination across the Trust. A sub-group of the Infection Prevention Control Committee, the group will monitor and report on compliance with reusable medical device decontamination policies and procedures on behalf of the Trust Board.

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.

5.9 **Traceability** refers to the requirement for systems to be in place to ensure that reusable medical devices are tracked from usage through each phase of the decontamination process. Records of this must be maintained.

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
- NUTH @ Cramlington, Manor Walks

Decontamination for Dental Clinics in the community:

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

6.2 Procurement

Reusable medical devices, or decontamination equipment, that is new/hasn’t been used by the Trust must be discussed and agreed with the relevant Surgical Instrument Manager, User, IPC Doctor/Microbiologist and IPC Team before procurement.

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 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.

6.3 Resources

6.3.1 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.

6.3.2 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.

6.3.3 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 Sterile Services Technicians are required to train towards and complete NVQ Level 3 in Decontamination. With relevant knowledge of HTM 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.

7.2 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 HTM 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. This competency will be subjected to both internal and external (AE(D)) audit.

7.3 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. This competency will be subjected to both internal and external (AE(D)) audit.

7.4 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.

7.5 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.

7.6 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 appropriately educated and trained/competent, 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.
## Monitoring Compliance

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit 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 (May and November)</td>
</tr>
<tr>
<td>Community Dentistry (Infection Prevention Society audit tool)</td>
<td>Audit</td>
<td>Community Dentistry personnel</td>
<td>Decontamination Working Group</td>
<td>Twice per year (May and November)</td>
</tr>
<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>
</tr>
<tr>
<td>Estates Planned Preventative Maintenance, Testing and Validation of Trust Decontamination Equipment</td>
<td>Exception report</td>
<td>Estates Senior Operational Managers</td>
<td>Decontamination Working Group</td>
<td>Bi-monthly review of exceptions at each DWG</td>
</tr>
<tr>
<td>Competency Assessment of CP(D)s and AP(D)s</td>
<td>Audit</td>
<td>Authorising Engineer (Decontamination)</td>
<td>Decontamination Working Group</td>
<td>Annually</td>
</tr>
<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 water testing labs. Results sent to Users and Estates.</td>
<td>Decontamination Working Group</td>
<td>Weekly (sampling) Bi-monthly review of results at DWG</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>
</tr>
<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>
</tr>
<tr>
<td>JAG Report Scorecard</td>
<td>Internal Audit/Self-Assessment</td>
<td>Endoscopy Manager</td>
<td>Decontamination Working Group</td>
<td>Annually</td>
</tr>
<tr>
<td>Decontamination Incident Reporting</td>
<td>Incident Report Review</td>
<td>Head of Patient Safety &amp; Risk, CGARD</td>
<td>Decontamination Working Group</td>
<td>Bi-monthly review of incidents at DWG</td>
</tr>
<tr>
<td>Risk Register</td>
<td>Risk Register Review</td>
<td>Head of Patient Safety &amp; Risk, CGARD</td>
<td>Decontamination Working Group</td>
<td>Bi-monthly review of risks at DWG</td>
</tr>
<tr>
<td>Overall</td>
<td>External Audit</td>
<td>Independent AE(D)</td>
<td>Decontamination</td>
<td>Annually</td>
</tr>
</tbody>
</table>
10  Consultation and Review

Consultation for review of this policy was undertaken by the Decontamination Working Group before submission to IPCC for ratification. This policy is reviewed every three years by the Decontamination Working Group or as, and when, significant changes require earlier review necessary.

11  Implementation (including raising awareness)

Ward and Department managers must ensure that staff are aware of this policy and that it is available for staff to access via NUTH intranet. The Decontamination Working Group will assist in raising awareness of key issues regarding this policy.

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 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.

- Health Technical Memorandum (HTM) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part A: The formulation of local policy and choices
- Health Technical Memorandum (HTM) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part B: Common Elements
- Health Technical Memorandum (HTM) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part C: Steam Sterilization
- Health Technical Memorandum (HTM) 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part D: Washer-disinfectors
- Health Technical Memorandum (HTM) 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
- Health Technical Memorandum (HTM) 01-05 – Decontamination in Primary Care Dental Practices
- Health Technical Memorandum (HTM) 01-06 – Decontamination of flexible endoscopes. Part A: Policy and management
- Health Technical Memorandum (HTM) 01-06 – Decontamination of flexible endoscopes. Part B: Design and installation
• **Health Technical Memorandum (HTM) 01-06 – Decontamination of flexible endoscopes. Part C: Operational management**

• **Health Technical Memorandum (HTM) 01-06 – Decontamination of flexible endoscopes. Part D: Validation and verification**

• **Health Technical Memorandum (HTM) 01-06 – Decontamination of flexible endoscopes. Part E: Testing methods**

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)

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

Designated Person (Decontamination)
Director of Estates

Senior Operational Manager
Estates Engineering Manager (RVI/CAV) and Estates Engineering Manager (FH)

Authorised Persons (Decontamination)
Estates Engineering Officers

Competent Persons (Decontamination)
Steriliser Technicians and specialist contractors

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

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

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

Operators
Sterile Services staff, Endoscopy staff, ENT staff, Cardio Theatre staff, and Dentistry staff
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: 14.11.17

2. Name of policy / strategy / service:
   Decontamination of Reusable Medical Devices Policy

3. Name and designation of Author:
   Dr Lucia Pareja-Cebrian (DIPC and Chair of Decontamination Working Group)

4. Names & designations of those involved in the impact analysis screening process:
   Members of the Decontamination Working Group (inc.: Estates; IPC; Nursing; Peri-Op/Critical Care; Surgical Svs and CGARD)

5. Is this a:
   Policy X Strategy [ ] Service [ ]
   Is this: New [ ] Revised X
   Who is affected
   Employees [ ] Service Users [ ] Wider Community [ ]

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)
   This policy covers the decontamination of reusable medical devices such as surgical instruments and flexible endoscopes. 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. This policy offers best practice guidance on the management and decontamination of such devices 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.
### 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 as well as patient 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</td>
<td>No</td>
<td>No</td>
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<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>No</td>
<td>No</td>
</tr>
</tbody>
</table>

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?)
PART 2

Name: James Dixon (Head of Environmental Management, Estates) on behalf of the Decontamination Working Group

Date of completion: 14/11/17

(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.)