1 Introduction

This policy covers the basic principles for cleaning and disinfection of endoscopic equipment, which includes:

- Flexible gastrointestinal endoscopes
- Bronchoscopes
- Nasendoscopes/Rhinoscopes used in Ear, Nose & Throat (ENT) Outpatients
- Rigid sigmoidoscopes and proctoscopes
- Endoscopes inserted into sterile body sites (Choledochoscopes and Laparoscopes)
- Transoesophageal Echocardiography (TOE) Probes.

The decontamination procedures must comply with the guidelines produced by the British Society for Gastroenterology, the British Thoracic Society and British Society of Echocardiography (see Section 12 for References). There are currently no published guidelines specific to endoscopes used in the ENT environment.

Any patient undergoing endoscopy may be infected with potentially transmissible infections such as HIV, hepatitis B, hepatitis C, Salmonella or mycobacteria. The purpose of cleaning and disinfection therefore is to prevent the exposure of all individuals to potential pathogens.

Current methods of endoscope disinfection are unable to destroy the infecting agent in Creutzfeldt-Jakob disease (CJD/variant CJD) and therefore therapeutic endoscopy should be avoided wherever possible in patients with known/ suspected or at risk of transmissible spongiform encephalopathy (TSE) e.g. CJD, vCJD or UK Plasma recipients. If therapeutic endoscopy is essential, the Infection Prevention and Control Team and Endoscopy Matron must be contacted prior to treatment.

2 Scope

This policy applies to all members of staff, including locum/agency staff, involved in the cleaning and decontamination process of endoscopic equipment in all dedicated decontamination units and outreach services. Everyone who uses or handles any type of endoscope must be familiar with the procedures referred to in this policy, which therefore includes all satellite areas where endoscopes are used. The policy also includes guidance and recommendations on the safe and controlled storage of
all flexible endoscopes, using cabinets specifically designed for this purpose. The policy describes all of the processes for the correct cleaning and decontamination of endoscopes including traceability procedures.

3 Aims

The aim of the policy is to ensure that the cleaning and decontamination of all endoscopes follows recognised guidelines, and that the Trust is compliant with current national standards.

This policy is also to ensure that there is complete traceability for the use, maintenance and cleaning processes of endoscopes.

All of the processes included in this policy are there to protect the patient from potential harm that may be caused if the equipment used has not been decontaminated to the highest possible standards.

4 Duties (Roles and responsibilities)

The Choice Framework for local Policy and Procedures (CFPP) 01-06 provides detailed guidance on management and decontamination of flexible endoscopes. Part 1 of CFPP 01-06 (Operational Management) outlines the roles and responsibilities of key individuals, such as the Surgical Instrument Manager/Coordinator and the User, and these are included below. Other key roles and responsibilities, relevant to endoscope decontamination, are also outlined in the Decontamination of Reusable Medical Devices Policy (Section 4), over and above those stated in this section.

The roles and responsibilities of key Trust officers are clearly defined and outlined below:

4.1 Chief Executive

The Chief Executive is ultimately responsibility for ensuring effective decontamination processes are in place within the organisation and therefore supports Trust-wide implementation of this policy.

4.2 Director of Infection Prevention & Control (DIPC)

The DIPC is nominated as Decontamination Lead, with roles and responsibilities as defined in Choice Framework for local Policy and Procedures (CFPP) 01-01, and has responsibility for decontamination at Board level. This person is responsible for the effective and technically compliant provision of decontamination services, including cleaning and disinfection of endoscopes, 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 IPC Doctors for each hospital site, who are nominated as Microbiologist (Decontamination) for their respective site, with roles and responsibilities as defined in CFPP 01-01. Other Consultant Microbiologists support these officers in advising the User and Management on microbiological and infection prevention aspects of endoscope cleaning and disinfection.

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 **Head of Environmental Management**

The Head of Environmental Management, as senior Estates manager, is in charge of decontamination support and 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 support aspects of decontamination and is accountable to the Designated Person.

4.6 **Sterile Services Manager, Endoscopy Matron, ENT Matron and Theatre Matrons**

The above managers are nominated as Surgical Instrument Managers and Users, with roles and responsibilities as defined in CFPP 01-01 and CFPP 01-06. They manage the cleaning and disinfection of endoscopes and are responsible for the Operators. These managers are responsible for coordinating 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/IPC Doctor on infection control issues associated with cleaning and disinfection of endoscopes.

4.7 **Staff who operate Automated Endoscope Reprocessors (AERs)**

Staff with the authority to operate decontamination equipment, i.e. AERs, 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 Estates Officers

Estate 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 and CFPP 01-06. The CP(D) will be responsible for carrying out maintenance, validation and periodic testing of AERs. 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 01-06 Decontamination of Flexible Endoscopes: Validation and Verification

External contractors may be contracted to carry out some AER 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, including AERs, 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 any endoscopes within their area, including outreach areas. Managers must ensure that staff are aware of how to effectively decontaminate endoscopes 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 endoscope decontamination issues in their areas and refer concerns to their line managers to ensure endoscopes are effectively decontaminated. It is also their responsibility to comply with this 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 process of reduction in viable infectious agents to a safe level, e.g. by using chlorine dioxide (Tristel®) or peracetic acid (Gigasept®).

5.4 **Automated Endoscope Reprocessor (AER)** is a washer-disinfector machine capable of disinfection and rinsing to a reproducible standard and where the performance can be validated and verified.

5.5 **Endoscope Storage Cabinet (ESC)** is a cabinet which is specially designed to store endoscopes in a clean and dry environment, using High Efficiency Particulate Air (HEPA) filtration.

5.6 **Endoscope Drying Cabinet (EDC)** is a cabinet similar to an ESC with the additional benefit of warming the filtered air to achieve a quicker, more efficient drying of stored endoscopes.

5.7 **Satellite Area** refers to a ward or department on an acute hospital site, but not part of the main Endoscopy or central decontamination area.

5.8 **Outreach Clinics** are units where services are available off acute sites.

6 **Effective Cleaning and Disinfection of Endoscopes**

6.1 **Disinfectants and Manual Cleaning Agents**

Cleaning chemicals can be damaging to instruments and processing equipment, therefore external surfaces of flexible endoscopes and equipment must be examined daily prior to use. Any evidence of damage must be reported to the senior nurse and documented in the department’s own ‘Endoscope Log Book’ which is held in each of the Trust’s Central Decontamination Units and all satellite units.

The chemicals used in the AERs achieve high level disinfection. They have a role to play where autoclaving is not possible in the processing of flexible endoscopes (e.g. flexible Cystoscopes, Hysteroscopes etc), which are required to be ‘high-level disinfected’ before use.

*Water for rinsing*: AERs use reverse osmosis (RO) water systems or tap water filtered through a bacteria retaining filter, which is an alternative to the use of sterile water.

6.2 **Decontamination of Endoscopes**

It cannot be emphasised too strongly that thorough manual cleaning of an endoscope prior to disinfection is the most important means of removing potential pathogens. Satisfactory cleaning will remove the vast majority of microorganisms, plus organic matter that would otherwise protect bacteria and viruses against the action of a disinfectant. In addition if thorough manual cleaning does not take place prior to automated disinfection, blood, mucus
and other organic material is “fixed” in place by disinfectants, which makes future cleaning more difficult.

Cleaning & disinfection of endoscopic equipment correctly is essential and everyone involved in this process must be familiar with this policy, procedures and relevant national guidance, and strictly adhere to it.

Adhering to the set guidelines reduces the risk of cross infection to both patients and staff.

6.3 Types of Endoscopes

There are many different types of endoscopes, which have the common feature in that they are inserted into sterile and non-sterile areas of the body. They include:

6.3.1 Rigid Arthroscope and Rigid Laparoscope

These instruments must be sterile and therefore must be autoclaved.

6.3.2 Rigid Hysteroscope

These instruments must be sterile and therefore must be autoclaved.

6.3.3 Flexible Hysteroscope

These instruments will not withstand autoclaving. After thorough manual cleaning, they should be processed in a suitable AER.

6.3.4 Flexible Choledochoscopes and laparoscopes

These instruments must be sterile and will not withstand autoclaving. After thorough manual cleaning, they should be processed by gas sterilisation, as recommended by the manufacturer.

6.3.5 Cardio Telescopes

These instruments are used in conjunction with a rigid bronchoscope therefore must be autoclaved.

6.3.6 Mediastinoscopes

These instruments must be sterile and must therefore be autoclaved.

6.3.7 Rigid Cystoscope

These instruments must be sterile and must therefore be autoclaved.

6.3.8 Flexible Cystoscope
These instruments will not withstand autoclaving. After thorough manual cleaning, they should be processed in a suitable AER.

6.3.9 Nasendoscopes

These instruments will not withstand autoclaving. After thorough manual cleaning, they should be processed using an AER. If there is no access to an AER the Tristel® 3 Wipe System must be used, as described in section 6.5.2.

6.3.10 Rhinoscopes

These are rigid scopes used in ENT and are autoclaved.

6.3.11 Transoesophageal Echocardiography (TOE) Probes

These instruments will not withstand autoclaving. TOE probes are routinely manually decontaminated using the Tristel® 3-Wipe System. After thorough manual cleaning, they should be processed using an AER.

6.3.12 Rigid uteroscopes

These instruments must be sterile and must therefore be autoclaved.

6.3.13 Flexible uteroscopes

These instruments will not withstand autoclaving. After thorough manual cleaning, they should be processed in a suitable AER.

6.4 Cleaning and Disinfection of Gastrointestinal Endoscopes

The use of AERs is not a substitute for effective manual cleaning prior to disinfection. Standard Precautions must be adhered to at all times and Personal Protective Equipment (PPE) including gloves, apron, goggles / face protection must be worn. During manual cleaning phase, forearms should be protected.

6.4.1 Procedure Room (immediately after removal from the patient and whilst still connected to the light source)

- Wipe down insertion tube with gauze swab in warm water (between 24°C – 30°C) and enzymatic cleaner
- For GI endoscopes, remove air/water (blue) valve and replace with flushing valve, depress for 10-15 seconds to eject any refluxed debris. If blockage noted, use appropriate blockage removal device immediately
• If endoscope has a suction channel, depress suction valve for 10-15 seconds, with insertion end of endoscope under level of water to remove debris from suction/biopsy channel
• Disconnect from the light source
• If video endoscope, attach video cap – *this is essential and must be attached*
• Transport dirty endoscope to cleaning room in the appropriate covered tray.

6.4.2 Cleaning Room – Leak Testing

• Fill the sink to the marked level with warm water and a pre-measured dose of enzymatic cleaner as per instructions
• If video endoscope, check the water resistant video cap is attached, as the videoscope must not be put in water without the water resistant video cap attached
• Attach leak tester and switch on
• Immerse endoscope in sink of warm water and perform leak test
• If endoscope shows a leak (bubbles in the water) – dry, wipe down with alcohol wipe, do not proceed any further. Do not place in the AER. The endoscope needs to be sent for repair (follow the process for sending for repair)
• If no leak apparent – proceed with cleaning process.

6.4.3 Cleaning Room – External Cleaning Process

• Remove all valves and discard disposable biopsy cap
• Clean air/water and suction valves with the disposable cleaning brush – these must be kept as a unique set with the particular endoscope
• Use 5ml syringe & connector to flush auxiliary channels (if applicable) wash outside of endoscope thoroughly with enzymatic cleaner
• Brush distal tip paying particular attention to the air/water nozzle
• If endoscope has no internal channels - Wash outside of endoscope thoroughly and brush distal tip.

6.4.4 Cleaning Room – Internal Cleaning Process

• A disposable cleaning brush must be used (sets of brushes are specific to the type of scope).
• Fully immerse the endoscope, brush through each of the following three channels *at least* three times or until brush emerges clean (remember to clean the end of the brush each time it emerges from the end before pulling it back through the channel):
  i) Channel 1 - from biopsy port through insertion tube emerging at distal end
ii) Channel 2 - from suction port through insertion tube emerging at distal end
ii) Channel 3 - from suction port through umbilicus emerging from suction connector

6.4.5 Cleaning Room – Flushing the Internal Channels

Gastrointestinal endoscope channels should be flushed using an all channel irrigator. Attach irrigator to endoscope and flush; check water is seen to emerge from the air/water nozzle at the end of the insertion tube and out of the water and suction connectors on the light guide.
All other endoscopes should have any channels flushed with a syringe.

6.4.6 Cleaning Room – Loading Cleaned Endoscopes into AER

After the channels have been thoroughly brushed & flushed place the endoscope and the unique set of valves (valves, including flushing valves and removable parts, must be kept with the endoscope to form a unique set of equipment) into the AER to complete cleaning and disinfection.

Discard the used cleaning brushes and contaminated PPE into the appropriate waste stream, as per Waste Policy.

6.4.7 Out of Hours – Cleaning and Disinfection

Endoscopes used out of hours must be decontaminated in accordance with this policy.

6.4.8 Transportation of Endoscopes

All endoscopes must be transported in approved endoscope trays with the hard lid fitted, on Cleanascope trolleys or a similar method of transport agreed by the Infection Prevention and Control Team.

6.4.9 Compatibility of Chemical Disinfectant and Endoscope

It is important to ensure that the endoscope manufacturer has approved the chosen disinfectant for use in decontaminating their product, and that the disinfectant is also compatible with the AER in which it is being used.

6.5 Cleaning and Disinfection of Flexible Bronchoscopes

The cleaning and disinfection of bronchoscopes is identical to the procedures used for gastrointestinal endoscopes. The cleaning procedure should be manual cleaning followed by processing in an AER.
6.6 Nasendoscopes (ENT Department)

6.6.1 Procedure room (immediately after removal from the patient)

- The scope is placed into a transport bag and transferred to the dirty utility room

6.5.2 Dirty Utility room

- Carry out a leak test using the specified pressure gauge for the make of scope
- If a leak is detected, clean the scope using the Tristel® 3-Wipe System (refer to Section 6.5.3 for process) and send the scope for repair (follow the process for sending for repair)
- If no leak is detected, follow procedure for manual cleaning followed by automated reprocessing in AER
- Fill the sink to the marked level with warm water and a pre-measured dose of enzymatic cleaner as per instructions
- Immerse the endoscope in the sink and carry out manual cleaning of the scope
- Complete the cleaning process of the endoscope using the AER.

6.5.3 Decontaminating ENT scopes using the Tristel® 3-Wipe System (either following a detected leak in the ENT Department, or when an AER is unavailable in the ENT Department, or to decontaminate scopes in ENT Outreach Services)

- The Tristel® 3-Wipe must be used to clean the nasendoscope as soon as the scope has been removed from the patient. This system is routinely used in outreach clinics but could be used in the event that the AERs are out of use.
- Cleaning: The first step in this method of decontamination process is the thorough cleaning of the nasendoscope to remove soiling and organic matter, using the Tristel® Pre-Clean Wipe, prior to high-level decontamination.
- Disinfection: The second step in this method utilises the Tristel® Sporicidal Wipes and is the central part of the Tristel® Wipes System. The wipe needs to be activated with two squirts of foam activator and will be ready to use after a 15 second period. The nasendoscope is then wiped down for a minimum time period of 30 seconds. Every area of the nasendoscope must be wiped at least once.
- Rinse: The final step in the decontamination process is the rinsing of the nasendoscope that has been treated. The Tristel® Rinse Wipe is impregnated with de-ionised water and low-level of antioxidant which will remove residues form the nasendoscope that has been decontaminated with a Tristel® Sporicidal Wipe.
6.5.4 Traceability and Audit of this Procedure

The decontamination process, patient’s details, date and time of use and user details must be recorded in the Tristel® Log Book.

6.5.5 Storage of ENT Scopes

ENT scopes are currently stored in a wall-mounted cabinet rather than an Endoscope Storage Cabinet and scopes must therefore be cleaned at the start of every clinic and must be used within 3 hours of the cleaning process.

6.5.6 ENT Outreach Services

The NUTH Outreach Clinics have a nasendoscope supplied for each Doctor's use at that clinic. The scope is stored in its scope case, which meets the requirements of the Infection Prevention and Control agreed standards. This scope is only used on weekly clinics and must be cleaned by the 3 Tristel® Wipe System (as outlined in Section 6.5.3) prior to the first patient use, after each patient use and prior to storage. The scope is also pressure tested immediately before patient use, after patient use and prior to storage. All the scopes are traceable by their asset ID to each of the clinics. The staff using the Tristel® 3 Wipe System must be trained and this training must be recorded in their competencies. All of the appropriate Tristel® cleaning records must be maintained in the clinics by the nurse in charge.

6.6 Transoesophageal Echocardiography (TOE) Probes

All TOE probes must be used with a protective sheath to form a protective barrier to infection. There is one exception where a protective sheath is not used with the micro TOE probe in paediatrics. This is because the images produced through the sheath are not clinically satisfactory, as they are difficult to interpret. If there is evidence or suspicion that the sheath has been perforated the probe must be cleaned in an AER before it can be used again. The probe must also be cleaned in an AER if it has been used on an infected patient, even when a sheath has been used. Manual cleaning of TOE probes after every use, using the Tristel® wipe system, is currently acceptable. However, at the time of writing this policy, the decontamination of TOE probes is currently under review, and it is anticipated that all TOE probes will be cleaned using an automated system to provide the highest standard of decontamination with full traceability of the cleaning process.

6.6.1 Storage of TOE Probes

TOE Probes must not be stored in their delivery cases, as there is a high risk of recontamination from an incompletely decontaminated probe contaminating the case. TOE probes must therefore be stored in a clean and dry locked cupboard. The micro TOE probe is currently stored in a protective case and is decontaminated before and following
use due to the fragility of the probe. If the micro TOE probe was not stored in this way there would undoubtedly be significant damage to the probe. The case is not a transport case but a protective storage container.

6.7 Periodic Testing of AERs

Daily tests of the AERs must be carried out by the operator in accordance with CFPP 01-06 and the department’s own Standard Operating Procedures. The daily test includes observing a complete wash cycle (Automatic Control Test) to ensure that all of the processes of the wash cycle are carried out. Table 5 ‘Schedule of Periodic Tests’ in CFPP 01-06 explains this in more detail (reproduced in Appendix A).

Weekly testing, which includes final rinse water testing, will be carried out by the Trust’s Estates Officers or suitably qualified external contractor. Taking samples of the final rinse water must follow the AER manufacturer’s procedures and must be carried out by any competent person.

The Estates Department will receive the results of the final rinse water testing and are responsible for informing the Endoscopy Department and Site IPC Doctor/IPCN in a timely manner. Appropriate action must be taken on any microbiological results showing a colony count greater than 10cfu/100 ml, and is outlined in Table 1. The Estates Department are also responsible for maintaining comprehensive records of the rinse water results and any engineering remedial action taken.

(policy continues with table on next page)
<table>
<thead>
<tr>
<th>Aerobic colony count in 100mL</th>
<th>Interpretation</th>
<th>Action</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>Satisfactory</td>
<td>Use as normal</td>
<td>Green</td>
</tr>
<tr>
<td>1-9 on a regular basis</td>
<td>Acceptable</td>
<td>Use as normal - indicates that bacterial numbers are under a reasonable level of control</td>
<td>Green</td>
</tr>
<tr>
<td>10-100</td>
<td>Unsatisfactory</td>
<td>Carry out a risk assessment and investigations (it must be remembered that by default the machine will have been operating, potentially, for a further five days since the positive sample was taken): 1. If count is 10-50 and counts from the previous three weeks’ samples, from the AER, have been below 10, then carry out an additional self-disinfection on the AER, re-test the rinse water and proceed to use the AER for all scopes. 2. If the count is between 10-50 and a count from the previous three weeks’ samples, from the AER, have been 10 or above then carry out an additional self-disinfection on the AER, re-test the rinse water and do not use the AER to process high-risk scopes until re-samples show acceptable counts. 3. If the count is 51-100 then carry out an additional self-disinfection on the AER, re-test the rinse water, and do not use the AER to process high-risk scopes until re-samples show acceptable counts. In addition to the above, if trends develop with regular unsatisfactory results, in one or more AERs, then Estates should seek advice from Site IPC Doctor and IPCN, and advise users accordingly.</td>
<td>Orange</td>
</tr>
</tbody>
</table>

| Over 100                      | Unacceptable   | AER should be taken out of service until water quality has improved/issue resolved (it must be remembered that by default the machine will have been operating, potentially, for a further five days since the positive sample was taken): 1. Estates to inform Nurse-in-Charge Endoscopy, Site IPC Doctor/IPCN immediately on receipt of results. 2. Take AER out of service and carry out corrective maintenance to resolve the problem. 3. Machine to remain out of service until water quality problem has been resolved and final rinse water results are acceptable or satisfactory. | Red |

| *Pseudomonas aeruginosa* present | Unacceptable | As per “Over 100cfu/100ml” above: AER should be taken out of service until water quality has improved/issue resolved (it must be remembered that by default the machine will have been operating, potentially, for a further five days since the positive sample was taken): 1. Estates to inform Nurse-in-Charge Endoscopy, Site IPC Doctor/IPCN immediately on receipt of results. 2. Take AER out of service and carry out corrective maintenance to resolve the problem. 3. Machine to remain out of service until water quality problem has been resolved and final rinse water results are acceptable or satisfactory. | Red |
6.8 Record Keeping and Traceability

6.8.1 Within Decontamination Units (i.e. Endoscopy, ENT Outpatients and Cardio)

Every department with the responsibility of cleaning flexible endoscopes must keep a record of the procedures performed. This record should identify the patient, the nature of the procedure, the serial number of the instrument used, the machine used and the operator’s name and the name of the person responsible for the cleaning and disinfection of the instrument. Such a record is kept so that if it is thought that an endoscopy related infection may have occurred it will be possible to check the adequacy of disinfection and to trace any other patients who might have been exposed to the same risk. The nurse looking after the patient is the person responsible for ensuring this information is attached to the patient’s notes.

6.8.2 Satellite Areas (returning scopes to a decontamination unit)

It is the responsibility of the senior nurse, in each satellite area (i.e. critical care units, theatres and acute outpatient departments), to ensure that users complete the ‘Record of Use’ form (see Appendix B), which must accompany all endoscopes returned to the Centralised Decontamination Unit. This form records all of the information necessary for full traceability of individual patient usage.

6.9 Use of Accessory Equipment

Endoscopes can come with accessory attachments. Those which are disposable should be disposed of as per Trust Waste Policy. Reusable accessories should be washed in fresh detergent/enzymatic cleaner and where appropriate reprocessed in the Sterile Services Department (SSD).

Equipment that breaches the mucosa, and other equipment used for manipulation within the bile duct and pancreas should be disposable. In the instance of the Spy Glass, this is decontaminated through the AER as per manufacturer’s guidelines.

6.10 Endoscope Storage

Flexible endoscopes must be stored in an approved Endoscope Storage Cabinet, and can be stored for up to 5 days, depending upon the type of storage cabinet used. If the cabinet has not been designed/configured for 5 day storage, the storage time is limited to 72 hours. Endoscopes which have been in the storage cabinets for less than 5 days (or 72 hours) may be used for procedures directly from the cabinet without further processing. When an endoscope is removed from a storage cabinet it must be used within 3 hours and cannot, under any circumstances, be returned into a storage cabinet without being processed in an AER, even if it has not been used. The contents of each cabinet, the date and time the endoscope was put in, and
the expiry date and time must be recorded (i.e. clearly marked on the front of each cabinet where a manual process is required or using the automated electronic system in more advanced cabinets). All other endoscopes, not taken from a storage cabinet, must be cleaned and disinfected prior to use. It is the responsibility of the nurse in charge to report any breaches of this process to the matron.

6.11 Creutzfeldt-Jacob Disease (CJD/vCJD) and Tuberculosis

Current methods of endoscope disinfection are unable to destroy the abnormal prions that are the causative agents of transmissible spongiform encephalopathy (TSE) commonly known as CJD or vCJD.

Risk assessment and identification of those at risk is essential prior to the endoscopy procedure being undertaken. A single question of “have you ever been notified that you are at risk of CJD/vCJD?” should have been asked of all those undergoing endoscopic procedures. Additionally, all at risk plasma recipient cases known to the Newcastle Hospitals Trust have been identified as at risk within the Trust eRecord documentation.

In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes used in all patients with definite, probable or possible CJD/vCJD and in those identified as at risk of developing CJD/vCJD is required. Prior to proceeding with a procedure in these circumstances reference must be made to the Policy for the Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in the hospital and community and the departmental SOP for reprocessing of these scopes. The Infection Prevention and Control Team and Endoscopy Matron should be contacted prior to a procedure being undertaken wherever possible.

Known or suspected tuberculosis and other mycobacterial infections (excluding M Avium-intracellulare): these organisms are relatively resistant to the action of disinfectants.

6.12 Health and Safety Aspects

The infectious status of patients undergoing endoscopy may be unknown at the time of the procedure, and therefore standard precautions against the acquisition of infection should be applied. Staff must be compliant with standard precautions and appropriate PPE must be worn when there is a risk of exposure to contaminated endoscopic equipment, patient secretions, blood, urine or faeces. The use of aprons, gloves, masks, and eye protection is required when cleaning and performing procedures involving splashing or more extensive contact with blood or potentially infectious body fluids. In the case of a patient with pulmonary tuberculosis a FFP3 mask must be used.

Disinfectants are potentially toxic chemicals and may cause sensitivity reactions in the staff that use them. Such reactions include skin rashes, conjunctivitis, nasal irritation, sinusitis and asthma. Staff should report any
such reactions to their supervisor and must be referred to Occupational Health. Staff should also complete an annual health questionnaire provided by the Occupational Health Department. To avoid toxic reactions, staff should:

- Avoid skin, eye or mucous membrane contact with the disinfectant
- Wear protective gloves (note: ordinary latex rubber gloves are not adequate use nitrile rubber gloves)
- Eye protection must be worn where splashing might occur masks to prevent inhalation of fumes if a spillage occurs e.g. during the mixing of fresh solutions
- Avoid needle stick injuries during cleaning by using disposable endoscopic accessories where possible

The use of AERs provides the best protection by reducing exposure to disinfectant. There is a legal obligation under the Control of Substances Hazardous to Health Regulations to attain this level of control. The use of manual disinfection in troughs is no longer accepted by the Trust.

6.13 Maintenance

6.13.1 Automated Endoscope Reprocessors (AERs)

AERs are recommended for routine disinfection of endoscopy equipment. These machines must be regularly maintained and the disinfection process validated in accordance with the Department of Health Choice Framework for Local Policy and Procedures 01-06, Decontamination of Flexible Endoscopes: Validation and Verification Manual (CFPP 01-063). There must be documented evidence of a testing and validation regime, this will be done by the Trust’s Estates Department or by an outside contractor.

6.13.2 Endoscopes

All endoscopes are covered by a manufacturer’s service contract, which includes an annual inspection from both a mechanical and optical functionality perspective.

7 Training

Regular training of staff in the manual cleaning and disinfection of endoscopes is vital. The staff training programme and competency must be conducted at induction and at least annually thereafter and written training records must be maintained by the department. This competency named ‘Reprocessing and storage of Flexible Endoscopes and associated equipment’ has been adapted from the Skills for Health Workforce Endoscopy Competency END21 and covers the awareness of channel configuration of all endoscopes, cleaning,
reprocessing in AERs and storage of endoscopy equipment applicable to staff in all areas dealing with all types of flexible endoscopes before, during and after patient use.

Training is offered in relation to the competency by the staff of the Endoscopy Units at both Freeman and RVI. Peri-operative/Critical Care and Cardiothoracic directorates must have a training and competency programme for all relevant staff in satellite areas (Critical Care and Theatres), with associated records maintained. Evidence of training and competence assessment for the Tristel® 3 wipe system and endoscope audit trail for ENT scopes is maintained in ENT Outpatients.

8 Equality & Diversity

The Trust is committed to ensuring that, as far as 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 document has been appropriately assessed.

9 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>Cleaning and decontamination of endoscopes</td>
<td>Conduct audits in Endoscopy Departments and all other departments that clean, uses, reprocesses and or stores endoscopes.</td>
<td>Matrons</td>
<td>Decontamination Working Group</td>
<td>Six monthly (May &amp; November) report to DWG. Exceptions then reported to IPCC</td>
</tr>
<tr>
<td>Record of competency following induction and thereafter</td>
<td>Audit</td>
<td>Sister in charge</td>
<td>Relevant department</td>
<td>Annual report to DWG. Exceptions then reported to IPCC.</td>
</tr>
<tr>
<td>Final rinse water testing</td>
<td>Trend analysis</td>
<td>Estates</td>
<td>Decontamination Working Group</td>
<td>Bi-monthly report to DWG. Exceptions then reported to IPCC.</td>
</tr>
<tr>
<td>Compliance with national decontamination guidance</td>
<td>Audit by Independent Authorising Engineer (Decontamination)</td>
<td>AE(D)</td>
<td>Decontamination Working Group</td>
<td>Annual report presented to DWG. Exceptions then reported to IPCC.</td>
</tr>
</tbody>
</table>
10 Consultation & Review

This policy has been reviewed in consultation with the Decontamination Working Group and will be reviewed every three years by the Decontamination Working Group, or as and when significant changes make earlier review necessary.

11 Implementation (including raising awareness)

Following implementation a summary of key changes will be notified to all managers of departments where this policy applies. Further advice and guidance will be available from the Decontamination Working Group, Endoscopy, Infection Prevention and Control and the Estates Department.

12 References

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.

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


British Society of Echocardiography Guidelines for Transoesophageal Echocardiography Probe Cleaning and Disinfection


13 Associated Documentation

This policy relates to other Trust policies and strategies; see also the:

Decontamination of Reusable Medical Devices

Environmental and Cleanliness Strategy

Decontamination of Healthcare Equipment following Patient Use and Prior to Service or Repair

Decontamination of the Patient Environment (including Terminal & Deep Cleaning) Policy

Cleaning and Disinfection Procedure

Policy for the Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD) in the hospital and community setting
# Appendix A

## Table 5 Schedule of periodic tests

<table>
<thead>
<tr>
<th>Period</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Daily tests – User or operator</strong></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td><strong>Automatic control test</strong></td>
</tr>
<tr>
<td>2.</td>
<td>Remove and clean strainers and filters</td>
</tr>
<tr>
<td><strong>Weekly tests – User or operator, CP(D) or contractor</strong></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td><strong>Weekly safety checks</strong></td>
</tr>
<tr>
<td>2.</td>
<td>Carry out daily tests</td>
</tr>
<tr>
<td>3.</td>
<td><strong>Weekly safety checks</strong></td>
</tr>
<tr>
<td>4.</td>
<td><strong>Weekly tests including automatic control test</strong></td>
</tr>
<tr>
<td>5.</td>
<td><strong>Verification of calibration</strong></td>
</tr>
<tr>
<td>6.</td>
<td>Final rinse-water tests:</td>
</tr>
<tr>
<td></td>
<td>* appearance</td>
</tr>
<tr>
<td></td>
<td>* TOC</td>
</tr>
<tr>
<td></td>
<td>* total viable count</td>
</tr>
<tr>
<td></td>
<td>* environmental mycobacteria</td>
</tr>
<tr>
<td></td>
<td>* electrical conductivity</td>
</tr>
<tr>
<td></td>
<td>* water hardness</td>
</tr>
<tr>
<td>5.</td>
<td>Leak and patency testing:</td>
</tr>
<tr>
<td></td>
<td>* leak test</td>
</tr>
<tr>
<td></td>
<td>* lumen patency detection test</td>
</tr>
<tr>
<td></td>
<td>* lumen disconnection detection test</td>
</tr>
<tr>
<td>6.</td>
<td>Thermometric tests:</td>
</tr>
<tr>
<td></td>
<td>* chamber wall temperature for the self-disinfection cycle (if used)</td>
</tr>
<tr>
<td></td>
<td>* temperature during routine cycle</td>
</tr>
</tbody>
</table>

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

Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Validation and verification manual 9163:1.0:England
SCOPES RETURNED TO ENDOSCOPY FOR DECONTAMINATION

The information requested below is essential for audit and traceability purposes. We will be unable to process a scope unless this form is correctly completed.

Please tick appropriate boxes.

<table>
<thead>
<tr>
<th>SCOPE MODEL</th>
<th>SERIAL NUMBER</th>
</tr>
</thead>
</table>

ACCESSORIES INCLUDED WITH THIS SCOPE:

- [ ] Screen Bag
- [ ] Suction Valve
- [ ] Air/Water Valve
- [ ] Flush Valve
- [ ] Tray Lid
- [ ] Water Seal Cap
- [ ] Dilators
- [ ] Others

DEPARTMENT SENDING:

- [ ] RVI
- [ ] FH
- [ ] Leazes Theatre Suite
- [ ] New Vic Theatre Suite
- [ ] Children’s Theatre Suite
- [ ] ITU/HDU Leazes wing
- [ ] ITU/HDU New Vic Wing
- [ ] Max Fax Theatre
- [ ] Other

Has this Scope been Used on Patient?  

- [ ] YES
- [ ] NO

Have the patient details been entered into the theatre/critical care register, with the scope type, and has the scope ticket been placed into the patient’s notes?  

- [ ] Yes

Date used:  

Time Used:  

Endoscopist:  

Hospital Number  

Patient’s Name  

Date of Birth  

Ward  

Is the Patient Infected?  

- [ ] NO
- [ ] YES

Type of Infection  

Biopsies taken?  

- [ ] NO
- [ ] YES

Scope has been-  

- [ ] Manually
- [ ] Washed & Brushed
- [ ] Flushed

If the scope has not been used, state reason why:  

- [ ] Out of Time
- [ ] Damaged
- [ ] Other

If damaged or other, please describe:  

Person completing this form:  

[Signature]

Contact Number:  

Print Name
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:** 11.01.2016

2. **Name of policy / strategy / service:**
   Cleaning and Disinfection of Endoscopes Policy and Procedures

3. **Name and designation of Author:**
   James Dixon, Head of Environmental Management

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 ❑ Strategy ❑ Service ❑**

   **Is this:** New ❑ Revised ❑

   **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)*

   Effective cleaning and disinfection of reusable endoscopic 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 outlines both the Trust policy and procedures for the effective decontamination of this reusable equipment, used in both acute and community services.

7. **Does this policy, strategy, or service have any equality implications?** Yes ❑ No ❑

   **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 disproportionally 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>No</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>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

Date of completion: 
11/01/16

(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.)