Cleaning, Decontamination & Validation of Flexible Endoscopes

Department / Service:	Endoscopy Department
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Accountable Director:	Vicky Morris – Chief Nursing Officer
Approved by:	TIPCC
Date of Approval:	13th October 2017
Review Date: **This is the most current document and should be used until a revised version is in place**	13th October 2019
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All Endoscopy Departments within Worcestershire Acute NHS Trust
Target staff categories	All staff groups involved in the use and decontamination of all flexible endoscopes in all Endoscopy Units within Worcestershire Acute Hospitals.

Policy Overview:

- The aim of this policy is to provide a framework for the safe decontamination of all flexible endoscopic equipment (this includes duodenoscopes, gastroscopes, colonoscopes, bronchoscopes, cystoscopes, intubation scopes, ureteroscopes, Ultrasonic Endoscopes and Hysteroscopes).This version of the policy relates specifically to all Endoscopy Units within Worcestershire Acute Hospitals NHS Trust.
- For any other scopes used or processed outside the Trust endoscopy units please refer to WAHT-INF-026
- Decontamination is a general term that is used for the destruction or removal of microbial contamination to render an item safe. This will include methods of cleaning, disinfection and sterilisation, (Ayliffe 2009).

Key amendments to this Document:

Date	Amendment	By:
Nov 2010	**1.** Insertion of exclusions to this policy **B4.9.1** Insertion of instructions for reprocessing rigid nasendoscopes. **B4.13** Amendment to reduce frequency of final rinse water testing	H Gentry

	for mycobacterium from 6 months to every 12 months. Insertion of additional information on types of face mask usage information (Appendix 5)	
Nov 2010	**B4.13** Insertion of HTM2030 guidance on maintenance testing to the existing section on validation processes for Automatic washer disinfectors	S Steward
21/10/13	Document extended until the end of January 2014 whilst under review	TIPCC
21/07/14	Document extended for 3 months	Lindsey Webb
28/10/2014	Changes made to reflect current and up to date processes and equipment used in the Decontamination Room, Endoscopy, and Worcestershire Royal Hospital.	Karen Jeffries
14/08/15	Document re-written and amended to reflect current decontamination processes within Endoscopy Units.	
28/04/17	Document checked no changes required.	Heather Gentry

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1. Introduction

- To provide clear guidance for all Endoscopy staff taking part in the decontamination process.
- To act as reference material to inform members of staff to achieve the same standards, follow relevant guidelines and maintain a high quality decontamination service.
- To ensure patient and staff safety is paramount.

2. Scope of the policy

2.1 This policy applies to all staff involved in the decontamination process within the Endoscopy Units in the following hospitals: Alexandra Hospital, Redditch (ALX), Evesham Community Hospital (ECH), Kidderminster Treatment Centre (KTC), Malvern Community Hospital (MCH) and Worcestershire Royal Hospital (WRH).

2.2 This document relates to all flexible endoscopes used within the Endoscopy Department.

2.3 This policy supports standards set out by the BSG, JAG, MHRA (Appendix i) and CFPP01-06 guidance, aiming to continuously achieve high standards.

3. Definitions of key words

BSG	British Society of Gastroenterology
JAG	Joint Advisory Group
Flexible Endoscopes	Umbrella term for instruments used within Endoscopy that can move in various directions.
EWD's	Endoscopic Washer Disinfector
HTM	Health Technical Memorandum
MHRA	Medical & Healthcare products Regulatory Agency
TSSU	Sterile Services Unit
Unisoft	Electronic Endoscopy Reporting and Scheduling Tool
SOP	Standard Operating Procedure

4. Responsibilities & Duties

4.1 Endoscopy Staff
All Endoscopy staff are responsible for adhering to this policy.

4.2 Decontamination Team
Decontamination teams are responsible for compliance with BSG, CFPP01-06 and JAG standards. The team are responsible for adhering to the policy.

4.3 Trust Decontamination Lead
Responsible for implementing the policy and ensuring it is adhered to.

4.4 Unit Manager
Responsible for monitoring adherence to the policy and ensuring staff competencies are achieved and signed off.

4.5 Unit Manager & Decontamination Lead
Responsible for updating and ensuring the policy is valid and up to date.

5. Policy Detail

The following recommendations are made for cleaning and disinfection of all endoscopes (including bronchoscopes) and are based on current best practice guidance published by the British Society of Gastroenterologists (BSG 2014), Medicines and Healthcare Products Regulatory Agency (MHRA – formerly MDA) & NHS Estates CFPP01- 06.

5.1 Equipment

Details of key equipment:

Washer Disinfectors(EWD)
Drying Cabinets
Endoscopes
Single use cleaning brushes
Valves & Biopsy Bungs
Adjustable Endoscopy specific sinks
Irrigation pumps
Cleaning station

5.2 Key principles of Decontamination

- Decontamination of flexible endoscopes is undertaken in each of the Endoscopy Units.
- A specific area has been allocated and designed for this purpose.
- The dirty and clean areas are separated where possible.
- Endoscopes are decontaminated using an automated process.
- The tracking and traceability form for each contaminated scope must be completed throughout the decontamination process, not only to assist with assuring their quality, but also to enable the identification of patients on whom the medical devices have been used. The tracking and traceability form identifies the member of staff handling the endoscope at each part of the decontamination process. The tracking and traceability form is placed in the patient notes and scanned in with all other endoscopy documentation (Appendix ii).
- Decontamination is undertaken using guidelines and standards in order to protect both patients and staff.
- Decontamination equipment must be operated and maintained according to approved guidelines, CFPP01-06.
- Only suitably trained personnel who hold appropriate competencies for their role can carry out cleaning and disinfection of endoscopic equipment. Training should include an awareness of the channel configuration of all endoscopes and of the EWD and available irrigation adaptors.
- To achieve the standards set by the Medicines and Healthcare products Regulatory Agency (MHRA), staff must be trained and competent to use medical devices. A comprehensive training log must be maintained for all staff using this type of equipment.

- When using or processing endoscopes, appropriate personal protective equipment must be worn (Appendix iii).
- Rules for entry and exit from both clean and dirty decontamination rooms must be followed.
- Scopes must not be used for anything other than manufacturer's intended use.
- If an emergency endoscopic procedure is performed out-of-hours, trained personnel must be available and be responsible for cleaning and disinfecting the equipment (Staff must follow the out of hour's decontamination flowchart –Appendix iv). This should include scopes that might be used in departments other than the endoscopy units e.g. ITU and operating theatres.
- Records associated with decontamination processing of reusable medical devices or endoscopes to be retained for a minimum of 11 years.
- Reusable medical devices identification details are to be retained in individual patient case records for the life of those documents.
- A permanent record must be kept, detailing decontamination process information so as to allow identification and recall of reusable medical devices if required.
- All decontamination equipment maintenance records must be kept by the user.

5.3 Stage 1 (refer to Appendix v)

- At the beginning of each Endoscopy session, a trained member of staff checks all Endoscopes for faults. If a fault is found refer to section 5.10.
- Prior to first use of the day, the washer disinfector / EWD must have undergone a self-disinfection cycle. This process may be automatic or pre-set to occur at a designated time dependent on the make of the processor.
- The operator must then carry out the daily test according the manufacturer's instructions in order to comply with CFPP01-06.
- Any Endoscopes in a drying cabinet that have reached a storage time of seven days must be re-processed before use. Once Endoscopes have been re-processed they must be used within three hours or placed back in the drying cabinet, if they are not they must be re-processed again before use. (Appendix vi).
- Following removal from the drying cabinets or EWD and after checks to confirm the endoscope and valves are fit for purpose, the scope is placed in a tray with the traceability form and covered by a green tray liner in order to identify clean scopes or a red tray liner to identify a contaminated endoscope. If a traceability form is not present with the scope, the scope must not be used on a patient under any circumstances, until it has been re-processed.
- Endoscopes required for the endoscopy session are stored in a clean scope trolley for dispatch to the appropriate Endoscopy procedure room.
- Prior to use of the scope, the scope number is documented on the tracking & traceability form, the Endoscopy Procedure Report (using Unisoft GI Reporting Tool) and the Nursing Admission Assessment Form.

5.4 Stage 2

After each use, the insertion tube must be wiped down and the endoscope suctioned through with detergent, using the appropriate equipment, before being detached from the Endoscopy Stack. Flush the suction channel by immersing the distal tip of the endoscope in clean water and depressing the suction valve for at least 30 seconds. The air / water channel must then be flushed with water for at least 30 seconds to ensure that blood, mucus and other debris are expelled.

NB: The air / water valve MUST be replaced with a high pressure-flushing valve to flush the air / water channel.
The waterproof cap must be replaced and the scope coiled appropriately into a tray. The tray is covered with a red tray liner, highlighting contamination.
(For certain scopes) Where an auxiliary channel is present the auxiliary washing pipe should be connected to the auxiliary channel port. Using a new syringe, flush the suction channel with clean water until it runs clear. The distal tip of the scope should remain immersed to reduce the risk of aerosol production.
The tracking and traceability form is completed by the nurse carrying out the bed side endoscope clean.

5.5 Stage 3

AIM OF CLEANING – After flushing the scopes after every case, scopes are cleaned to ensure removal of all blood, secretions and other organic material prior to the surfaces coming into contact with the disinfectant.
MANUAL CLEANING of the instruments with a neutral or enzymatic DETERGENT is the most important aspect of the process. Manual cleaning is a pre-requisite (MDA July 2002) to further processing in an EWD approved washer disinfector.
All Endoscopes are tested for leaks, faults or damage before immersing it in a suitable neutral or enzymatic detergent.
(**NB:** enzymatic detergents are temperature dependent on the water, for activation and optimum cleaning).
If the leak test fails, the scope is packaged for repair as per departmental instructions (Appendix vii).
If the leak test is passed, continue with full manual cleaning before placing the scope in the EWD, as per guidelines.
Use the scope channel irrigator or a 20 ml syringe to flush all channels with water or a solution of neutral detergent (currently Lancer LND).

5.6 Stage 4

The fourth stage of decontamination is high level disinfection via a suitable EWD. Place the scope in the wash chamber as per manufacturer's instructions. Connect to the appropriate ports on the EWD to achieve high level disinfection.
Poorly maintained or inadequate decontamination equipment can result in inadvertent exposure to harmful micro-organisms or biological agents – which could be hazardous to health. Staff are encouraged to report any faults immediately. The Endoscopy Unit makes contact with relevant personnel to arrange repair and/or temporary replacement.
All Endoscopy staff are aware that any incidents are reported using the Trust's Incident Reporting Policy.
On completion of high level disinfection, endoscopes and valves are stored in a drying cabinet until required where available, or if for immediate patient use, stored in a hard based tray, with a green liner to identify ready for use, with the traceability document completed.
All stages of the disinfection process are recorded on the tracking and traceability form. All staff involved in the process are identified on this form, to enable traceability, should it be necessary.

5.7 Stage 5

All decontaminated Endoscopes should be stored hanging vertically and without valves or caps in a designated ventilated cupboard, where available, and not in their transit cases. Hangers are used in the drying cabinets to ensure scopes do not hang on the bottom of the cabinet and are

connected to the adapters continuously. Where possible, the ventilated cupboard should be HEPA filtered as this will considerably increase the hang time without need for re-processing, e.g. from hours to days. The Endoscopy Units use approved drying cabinets with a tracking system where available. Each endoscope should have an individual set of valves that are processed along with the scope and remain with it at all times.
All valves used during the list should be washed, brushed and placed in the EWD with the relevant scope to form a unique equipment set. They must not be placed in the scope case for storage.
All ultrasonic cleaning is currently integral to EWD processors used at KTC and ALX only.

5.8 Cleaning and Disinfection of Accessories

- Single use accessories are used where access for cleaning is difficult or the item is heat sensitive, e.g. biopsy forceps.

- Any accessories that are re-usable are manually cleaned and sent directly to TSSU (not endoscope valves).

- Disposable flexible cleaning brush and soft cleaning brush should be used for manual cleaning procedures.

5.9 Maintenance Testing and Validation

In order to ensure that any washer disinfector is fit for purpose it is necessary to have a control protocol in accordance with CFPP01-06. This is based on four key aspects to ensure that the required standards of performance and safety are met and sustained:

a). All EWD's are subjected to a planned programme of tests to validate their performance, that is, to provide experimental evidence that, when operated under the specified conditions, the EWD will reliably produce cleaned and disinfected items to the standard required.

b). All EWD's are subjected to a planned programme of tests to monitor their performance.

c). All EWD's are operated in accordance with an agreed procedure by staff trained in the use of the EWD's.

d). All EWD's have a quarterly and annual maintenance and testing regime check as part of the service package.

- **Weekly:**
  - ❖ **Endoscope Check for Residual Soil**

    1. Pass a sterile brush through internal channel of a randomly chosen endoscope following disinfection. The person sampling should use an aseptic technique and wear the appropriate PPE.

    2. Roll the brush gently onto a nutrient agar plate.

    3. Seal, date, label and send to Microbiology Laboratory for culture.

Results
Results can be accessed via ICE through EZ Notes, for all units.

Interpretation of Results
There should be no recovery of micro-organisms.

Action to be taken in the event of recovery of micro-organisms:
Remove scope from use, re-process and re-test. Discuss findings with Infection Control Team. Carry out immediate sampling of further selection of endoscopes.

- **Weekly/Quarterly**
  - **Final Rinse Water Check for Total Viable Count Weekly plus Mycobacterium 12 monthly (see Appendix viii).**

5.10 Breakdown of Machines / Spillages

In the event of breakdown or failure of the EWD's, the decontamination team report immediately to the appropriate service contract provider ie: Siemens (WRH only) and Cantel Medical **(Cantel Helpdesk - 01785 782420 / Siemens - WRH Only 30904).**

Any EWD not functioning correctly must be taken out of use immediately and the Unit Manager and Directorate Manager notified at the earliest opportunity, to sort endoscopy lists accordingly. If all EWD's are out of use, Endoscopy procedures must cease.

SOP's are in place to help deal with spillages and two emergency spillage kits are located within the Endoscopy sluice and one within the dirty decontamination area (Appendix ix/x/xi).

5.11 Special Precautions in Endoscopy for Patients with or at Risk of CJD or vCJD

Patients who fall into a risk category for CJD or vCJD should have been identified by screening questions pre-procedure. The additional precautions required for decontamination of endoscopes, are included in British Society of Gastroenterology (BSG) Guidance issued in 2014. This advises:

- Those involved in endoscopy ensure procedures are in place to minimise contamination and maximise cleaning
- Brushes and other purpose built catheters used to clean the channels of the endoscope are single use to ensure maximum efficiency of cleaning and reduce the risk of inoculating other endoscopes
- All accessories used during the endoscopic procedure are discarded and never re-used.

Type and Status of vCJD diagnosis	Management of the Endoscope
1. vCJD diagnosis confirmed	Destroy or decontaminate and store in quarantine for use on the same patient
2. Symptoms of CJD but awaiting diagnosis	Decontaminate and store in quarantine. If vCJD confirmed manage as above.
3. Asymptomatic patients at increased risk through receipt of labile blood	Destroy or decontaminate and store in quarantine for use on the same patient.

components (whole blood, red blood cells, white cells or platelets) from a donor who later developed vCJD	
4. At increased risk (e.g plasma product recipients) For details about the different types of at increased risk classification see the ACDP TSE guidance Part 4 (table 4a) http://www.dh.gov.uk/health/files/2012/11/Part-4-Infection-Control-Jan13.pdf.pdf	Decontaminate and reuse.

6. Audit Mechanism

Annual audit by Infection Control Nurse Link Staff within the departments using the DOH ICNA or HCC Audit Tool

- Weekly microbiological check as per sampling Programme
- Weekly microbiological check of final rinse water
- Infection Control Department to co-ordinate testing and monitor results
- Link nurse for infection control attends annual updates
- Annual water testing completed by the manufacturer
- Tracking & Traceability form audit – completed three monthly.

7. Implications of Non-Adherence

Non adherence to this policy may result in:

- Patients being put at risk
- Staff being put at risk
- Failure to comply with appropriate standards
- Damage to equipment / impact on the service leading to financial consequences
- Poor service

8. Implementation of the Policy

Plan:

- All appropriate staff to be trained according to relevant competencies. Records must be kept within the department.
- Policy to be disseminated to all Endoscopy staff.

Dissemination

- The policy will be placed on the Trust's Endoscopy Intranet page.

9. Monitoring and compliance

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	• Ensure all equipment is checked and in good working order prior to each list. • Identify any issues/problems and report through correct channels. • Ensure all Decontamination staff follow the correct training process and competencies.	• Completion of Daily/weekly Decontamination checklist. • Monitor breakdown of EWD's. • Monitor Datix submissions. • Training pack and PDR for all endoscopy Decontamination staff.	• 4 times per year • Continuous • Continuous • Yearly	• Decontamination leads on individual endoscopy sites. • Endoscopy unit manager. • Endoscopy unit managers/Matron/Directorate manager. • Decontamination unit lead /endoscopy manager/sister.	• Endoscopy directorate meetings. • Individual unit staff. • Decontamination leads on individual • Sites.	4 times per year.

Policy Review

This policy is due for review in one year, unless practice or equipment changes before.

10. References

- Ayliffe (2009) Ayliffe's Control of Healthcare-Associated Infection A practical handbook 5th edition, Published Edward Arnold Ltd, London
- British Society of Gastroenterology (2014) Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee (2008) BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy Available at: http://www.bsg.org.uk/images/stories/docs/clinical/guidelines/endoscopy/decontamination_2014.pdf [Accessed 27/04/2016]
- PHE (2014) Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex F Creutzfeldt-Jakob disease (CJD) biannual update (August 2014), with updated guidance on decontamination of gastrointestinal endoscopy equipment. Available at: https://www.gov.uk/government/publications/creutzfeldt-jakob-disease-cjd-surveillance-biannual-updates/creutzfeldt-jakob-disease-cjd-biannual-update-august-2014-with-updated-guidance-on-decontamination-of-gastrointestinal-endoscopy-equipment [Accessed 27/04/2016]
- ACDP TSE (2014) Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex F Available online: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470292/ACDP_TSE_Annex_F_Oct_2015.pdf [Accessed 27/04/2016]
- Department of Health (2013) CFPP 01-06: Choice Framework Policy & Procedures – Decontamination of Flexible Endoscopes. Available at: https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes [Accessed 27/04/2016]
- MDA (2002) Medicines and Healthcare products Regulatory Agency. Decontamination of Endoscopes July 2002 DB2002(05) Available at: http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/dts-bi/documents/publication/con007330.pdf [Accessed 27/04/2016]
- MHRA Medicines and Healthcare products Regulatory Agency.(2013) Top 10 Tips on Endoscope Decontamination . Available at: https://www.gov.uk/government/publications/top-10-tips-on-endoscope-decontamination [Accessed 27/04/2016]
- Health & Safety at Work Act 1974.
- Joint Advisory Group
- DATIX Incident Reporting Policy.

11. Background

11.1 Equality

The assessment conducted for this policy reveals no equality issues.

11.2 Financial Risk

Failure of JAG standards will lead to a 10% reduction Best Practice Tariff.

11.3 Health Risk

Failure to comply could result in Health Risk to both staff and patients.

11.4 Consultation

A broad selection of Endoscopy staff has been sought, along with review by the Infection Control Team.

11.5 Approval

This policy will be approved by the Endoscopy Directorate Meeting Group and Infection Control Team.

CONTRIBUTION LIST

Key individuals involved in developing the document

Name	Designation
Ian Little	HCA – Decontamination Lead, Alexandra Hospital
Sally Sykes	Unit Manager – Worcester Royal Hospital
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Circulated to the following individuals for comments

Name	Designation
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Dr Eftihia Yiannakis	Consultant Medical Microbiologist/Infection Control Doctor
Steve Steward	Decontamination Lead
Ray Cochrane	Head of Estates
Loraine Mahachi	JAG/Governance Sister (2017)
Endoscopy Directorate Group	
TIPCC Group	

Circulated to the chair of the following committees / groups for comments

Name	Committee / Group
Vicky Morris	Trust Infection Prevention & Control Committee and Director Infection Prevention and Control
Simon Noon	Trust Water Quality Committee
Martin Long	Trust Decontamination Committee

Appendices:

i	MHRA Top Ten Tips.pdf
ii	Tracking & Traceability Form.pdf
iii	PPE.docx
iv	Protocol for Procedures performe
v	Decontamination Process.docx
vi	Three Hour Rule.docx
vii	Scope Repair Instructions.docx
viii	Weekly & Quarterly Mycobacterium Testir
ix	SOP - Spillage Procedure.doc
x	SOP - Spillage Procedure External tc
xi	SOP - Procedure for Safe Disposal of Resi

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	Race	NO	
	Ethnic origins (including gypsies and travellers)	NO	
	Nationality	NO	
	Gender	NO	
	Culture	NO	
	Religion or belief	NO	
	Sexual orientation including lesbian, gay and bisexual people	NO	
	Age	NO	
2.	**Is there any evidence that some groups are affected differently?**	NO	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	NO	
4.	**Is the impact of the policy/guidance likely to be negative?**	NO	
5.	**If so can the impact be avoided?**	N/A	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources.

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	NO
2.	Does the implementation of this document require additional revenue	NO
3.	Does the implementation of this document require additional manpower	NO
4.	Does the implementation of this document release any manpower costs through a change in practice	NO
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	NO
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.