Trust-wide Document

Great Western Hospitals NHS Foundation Trust

Decontamination of Flexible Endoscopes Policy

Document No	IP&C - 00008	**Version No**	2.0
Approved by	Policy Governance Group	**Date Approved**	30/06/2020
Ratified by	Infection Control Committee	**Date Ratified**	24/06/2020
Date implemented (made live for use)	14/07/2020	**Next Review Date**	24/06/2023
Status	LIVE		

Target Audience- who does the document apply to and <u>who should be using it</u>. - The target audience has the responsibility to ensure their compliance with this document by: • Ensuring any training required is attended and kept up to date. • Ensuring any competencies required are maintained. • Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.	Designated Decontamination Users
Special Cases	Definition of the user: • At the Great Western Hospital the user is the Sterile Services Manager. • In the community setting the user is the manager of the area using the Nasendoscope.
Accountable Director	Chief Nurse
Author/originator – Any Comments on this document should be addressed to the author	Sterile Services Manager
Division and Department	Decontamination Lead
Implementation Lead	Designated Decontamination Users
If developed in partnership with another agency ratification details of the relevant agency	N/A
Regulatory Position	Care Quality Commission (CQC) (Ref 12) The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (Ref 13)

Review period. This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust -wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.

Contents

1 Introduction & Purpose

1.1 Introduction & Purpose

This Policy and Procedure has been written as the Great Western Hospitals NHS Foundation Trust (the Trust) response to the Department of Health (DH) – Management and Decontamination of Flexible Endoscopes. Health Technical Memorandum (HTM) 01-06 (Ref 1). Its aim is to ensure the Trust demonstrates compliance with the expected decontamination standards for reprocessing and disinfection of flexible endoscopes.

In addition, the document will outline the intended sustainability programme to ensure that the decontamination standards are maintained, updated and continually improved in line with current research and technical advances.

For a full description of the decontamination processes and expected standards for automatic endoscope testing, reprocessing and recommended disinfection methods employees should refer to the HTM 01-06 (Ref 1) document series, the manufacturer's instruction and training manuals and the departments' local standard operating procedures.

This document outlines how the Trust will risk assess the use of various flexible endoscopes within the acute hospital and in the community setting. It identifies each site where flexible endoscopes are used, the type of scope used at the site, and if the sites meet Essential Quality Requirements (EQR) or Best Practice (BP). This document, also outlines how the Trust monitors and audits continual compliance with the standards, and ensures any shortfalls are supported by appropriate action plans for improvement.

1.2 Glossary/Definitions

The following terms and acronyms are used within the document:

BP	Best Practice
BS EN	British Standards European Norm
BSG	British Society of Gastroenterology
CJD	Cruetzfeldt-Jakob disease
COSHH	Control of Substances Hazardous to Health
CP (D)	Competent Person (Decontamination)
CQC	Care Quality Commission
DH	Department of Health
DIPC	Director of Infection Prevention and Control
DRG	Decontamination Risk Group
EIA	Equality Impact Assessment
ENT	Ear Nose Throat
EQR	Essential Quality Requirements
EWD	Endoscope Washer Disinfector
FD	Flexable scope Decontamination unit
GWH	Great Western Hospitals NHS Foundation Trust
HCAI	Health Care Associated Infections
HEPA	High-efficiency particulate air filtration system
HSDU	Hospital Sterilisation and Decontamination Unit
HTM	Health Technical Memorandum
ICU	Intensive Care Unit
IP&C	Infection Prevention and Control
ISO	International Organisation for Standardisation

JAG	Joint Advisory Group on GI Endoscopy
MAC	Microbiological Advisory Committee
MHRA	Medicines Healthcare products Regulatory Agency
NHS	National Health Service
PPE	Personal Protective Equipment
QMS	Quality Management system
RO	Reverse Osmosis
TOE	Transoesophageal Echocardiography Scopes
TSE	Transmissible Spongiform Encephalopathy Agents
USB	Universal Serial Bus
vCJD	Variant Creutzfeldt-Jakob disease

2 Main Document Requirements

2.1 The Decontamination Process

Employees should not use or decontaminate a flexible endoscope unless they have been specifically trained and deemed competent by the designated user as described in Ref 1.

2.2 The User

It is important that every area that uses flexible endoscopes identifies who the designated user is for their area and this is reflected in their Job Descriptions.

The "user" is defined in the Ref 1 as the person designated by Management to have overall operational responsibility for the process.

It also states that the user is responsible for the following:

- *The operators (Ref 1 p.13).*
- *The operation of endoscopy decontamination equipment that may be used on the endoscopes under their responsibility, but not off site (for example out-stationed drying cabinets).*
- *Reporting issues via telephone or email of concern regarding endoscope instruments or their reprocessing to the nominated surgical instrument manager and equipment owner.*
- *Compliance with the guidance contained in the HTM 01-06 Operational management documents (Ref 1).*

The principal responsibilities of the "user" are detailed in the Job Description.

1. To certify that the decontamination equipment is fit for use.
2. To hold all documentation relating to the decontamination equipment including the names of other key personnel.
3. To ensure that decontamination equipment is subject to periodic testing and maintenance and documents are available to evidence this.
4. To appoint operators where required and ensure that they are adequately trained.
5. To maintain production and track and trace records.
6. To have documented training records demonstrating that they are competent to undertake assigned responsibilities.
7. To establish procedures for product release in line with the quality management system.
8. To ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice. They will be available at point of use.
9. To develop a plan illustrating development from EQR to BP for the decontamination unit.

2.3 Risk Assessment for Reprocessing

Ref 1 page 8 (the need for guidance) states:

"Patients deserve to be investigated and treated in a safe and clean environment with consistent standards every time care is given. It is essential that the risk of person to person transmission of infections be minimised as far as reasonably possible."

The person designated as having the role of Director of Infection Prevention and Control (DIPC) or equivalent will have ultimate responsibility for the risk assessments.

In order to assess the risk associated with person to person risk of transmission of infections via the use of flexible endoscopes the DIPC has identified nominated persons as leads for this initial risk assessment. These are the Lead Nurse for infection control and Senior Operational Lead in HSDU.

Any purchase of new or replacement flexible scopes must be agreed by the following individuals before a case of need can be accepted by the Trust Equipment Manager via the minor equipment request form (under 5k) or the case of need form (over 5k)**.** Equipment Purchasing Procedure (Ref 2).

Any scope purchases will be discussed at the quarterly Decontamination Risk Group (DRG) meeting (to ensure departments can demonstrate decontamination risks are being effectively controlled once the equipment is in place.

- The DIPC or their designated appointee – Trust Decontamination Lead.
- Representative(s) from the Infection Control Team.
- Representative(s) from the clinical device users.
- The user or person(s) who have overall responsibility for the decontamination of the endoscopes on a day-to-day basis.
- Authorised Person (Decontamination) (AP(D)).
- Competent Person (Decontamination) (CP(D)).
- Microbiologist (Decontamination).
- Head of Service, Hospital Sterilisation and Decontamination Unit (HSDU)
- The Trust Equipment Manager.

When making any risk assessments relating to flexible endoscopes the Group will use the HTM 01-06 framework to measure current practice against, and agree any improvements required.

2.3.1 Trust Assessment of Risk and Compliance for Decontamination of Flexible Endoscopes

An initial Trust assessment of risk and compliance is as follows:

- For all channelled Flexible scopes; in the event of an inability to provide a fully functional and compliant automated endoscope reprocessor (AER) the endoscopy activity must cease and the fault reported to the decontamination maintenance s
again until the AER is verified as fully compliant and fit f
- Non Channelled scopes will continue to be disinfected u
EQR.

The Trust has one scope in this high risk category Choledochoscope
The users send this to be sterilised following on site decontamination after use.

2.3.2 Assessing Essential Quality Requirements (EQR) and Best Practice (BP)

The overall aim is to ensure the processess used within the
device (Flexible Endoscope) that is fully compliant with the "E
Devices Regulations 2002 (Ref 3). This implies that the endos

- Clean and high level disinfected at the end of the decor
- Maintained in a clinically satisfactory condition up to the

The Trust decontaminates and disinfects all channelled Cystoscopes and endoscopes in a certificated central decontamination unit with separated clean and dirty area. The Automated Endoscope Reprocessor (AER) and rinse water used, meet the higher standards of very low bacterial contamination. This therefore meets Best Practice requirements.

Following the guidance laid out in the HTM (Ref 1) the user
against known risks to establish if a satisfactory level of risk c
the regulations is evident.

A copy of the Top 10 tips for Endoscope Management and Decontamination (see Appendix B) must be displayed in every area where scopes are to be decontaminated.

Annual internal audits of mechanised decontamination areas certificated to ISO 13485 will be conducted by the HSDU Quality Representative and clinical areas using the Tristel wipe method of disinfection by the Infection Prevention and Control Team to ensure standards are met, maintained and improved.

2.4 Design of the Endoscopy Reprocessing Unit

The central endoscopy reprocessing unit at the Great Western Hospital (GWH) was designed in 2009 to comply with best practice and is audited against International Organisation for Standardisation (ISO) 13485 yearly by an external auditor (Ref 4). The unit also meets the requirements expected from the Joint Advisory Groups on GI Endoscopes (JAG) accreditation system.

The 'users' of flexible endoscope facilities outside the central decontamination facility must assess their compliance against the HTM 01-06 guidance (Ref 1) and clearly document how they can demonstrate they meet EQR for the design and layout of their decontamination facility as compliance may be assessed by the Care Quality Commission (CQC). Any shortfalls must be documented by the manager as a risk assessment, accompanied by an action plan and financial assessment which identifies how they intend to meet the minimum EQR within the next 12 months. The risk assessment and action plan must be sent to their Divisional Director.

The above diagram (Ref 1) forms part of the risk assessment criteria for deciding the method of Decontamination and advice must be sought from infection control and the Sterile Services Manager before the introduction of a any new device.

2.5 Transportation

The central Flexible Decontamination Suite (FD) uses the "Cleanascope System" for the transportation of scopes and identification of clean and dirty scopes. It is essential that any transport system used can clearly identify a used scope from a clean scope. Separated designated areas must be identified for the storage of clean and dirty scopes. Any scopes transported outside of the Flexi Decontamination Suite or satellite decontamination facilities should be protected from damage and enclosed using a hard lid. All scopes must be accompanied by a full track and trace label to identify their decontamination and disinfection status.

Unless the user has clear evidence via a signed Automated Endoscope Reprocessor (AER) print out that the scope has been fully decontaminated and disinfected after its last use and complies with the agreed storage time limits **it must not be used** and must be sent back to HSDU for reprocessing.

2.6 Storage and Drying of Channelled Endoscopes

After auto-processing, and if not required immediately the endoscopes are transferred for storage in drying cabinets or vacuum packed using a validated system.

In the drying cabinet the endoscope's internal channels are connected to the filtrated drying system by endoscope specific connectors. Once placed in the drying cabinet the channelled endoscopes need to have completed the drying stage before being suitable for use, Endoscopes are then immediately ready for use without the need for further re-processing for up to 720 hours.

A control system monitors the compressed air supply to the various channels of the endoscope during the drying process; each channel has a 0.2µ filter to prevent contamination of the lumens. An air blanket is blown down over the scopes and is provided through a high-efficiency particulate air (HEPA) filtration system which is 99.97% efficient at removing airborne particulates. The flow of air prevents outside air entering the cabinet when the door is opened.

The vacuum packing system is validated for 100 days.

The cleaning manuals for all endoscopes are kept in the HSDU, the department responsible for cleaning the endoscope.

2.7 Storage and Drying of Non- Channelled Endoscopes

Non channelled scopes such as Nasendoscopes or TOE scopes should be stored in a secure clean area in a purpose built cupboard or cabinet made of non- porous material that is easy to clean. Non channelled scopes do not need to be stored in a drying cabinet. Bacterial contamination on their surface will not replicate in the absence of liquid water. Therefore, as long as direct or indirect recontamination with patients' body fluids does not occur no maximum time of storage before reprocessing can be specified.

2.8 Maintenance Provision

All equipment associated with the decontamination of flexible scopes are controlled and supervised by the Sterile Services Manager including, AER's, Drying Cabinets, reverse osmosis RO units. Compressors and the vacuum packing system which are subject to maintenance scheduling as described in Ref 1 and in conjunction with Manufacturers specifications.

2.9 Testing and Validation

The testing and validation of the AER's, Drying cabinets and RO Plant are to be carried out as outlined in HTM 01 01 (Ref 5) and 01 06 (Ref 1). These periodic tests and annual tests will be carried out by Trust engineer(s) and appointed service level provider. Any deviations from test specifications are to be notified immediately to the HSDU Manager and the AP(D) who will take appropriate,

documented remedial actions which may include seeking advice from the AE(D). Machine test status is reported to the decontamination risk group meeting which meets quarterly.

2.10 Track and Traceability

All flexible endoscopes are individually numbered and barcoded. They are scanned throughout the mechanical decontamination process. Each AER and Drying Cabinet is connected to a central management system located on a local PC within the unit at records the cycle data. All cycle data is backed up daily via the Trust network.

At the end of each AER and Drying Cabinet cycle both the AER and Drying cabinets produce two identical tickets detailing: Scope ID, scope serial number, cycle number, date, cycle start and end times, cycle parameters, and operator identification. A copy of each ticket is placed in the patient's medical record.

If the endoscopes are unused after a period of 720 hours in the drying cabinets, then they must be re-processed prior to use.

The vacuum packing system generates a traceable printout for use within patient medical records Following vacuuming, if the endoscopes are unused after a period of 100 days, then they must be reprocessed prior to use.

A calibrated and validated dosing system is used in the cleaning room; the system allows enzymatic solution usage data to be collected to help validate the manual cleaning protocols. There is a provision to download this data via USB.

Within the cleaning room the water line sticker in the sink and thermometer ensure that the correct amount of water and enzymatic solution is used and is within the recommended temperature parameters.

The track and traceability of the TOE scopes and nasendoscopes is manual and is kept by the users within their department.

2.11 Health and Safety

All employees appointed to re-process endoscopes must have an understanding of Health and Safety protocols within the Trust including Control of Substances Hazardous to Health (COSHH) Policy (Ref 16) and Personal Protective Equipment (PPE) as per Standard Infection Control Precautions Policy (Ref 7) and Safe Handling & Disposal of Sharps Policy (Ref 8). Failure to comply with this legislation may result in disciplinary action as per Trust Conduct Management Policy (Ref 9).

Disinfectants are potentially hazardous and may cause sensitivity reactions in some employees. Such reactions may include skin rashes, conjunctivitis, nasal irritation, sinusitis and asthma Employees should consult Occupational Health should any of these conditions arise.

All employees must demonstrate that they have read the chemical datasheets which are available in the COSHH file in Endoscopy unit this should be reflected in their personal Endoscopy Training portfolio. This will be monitored during the employee members annual performance review (appraisal).

Annual environmental testing is arranged by the Health and Safety Department – copies of the results are kept in the department by the designated user.

2.12 Control of Substances Hazardous to Health (COSHH)

Control of Substances Hazardous to Health (COSHH) guidelines and data sheets for the chemicals used within the department must be kept in the COSHH files held by the designated user for the department.

Chemicals used in decontamination must only be used by employees trained in their use.

2.12.1 Disposal of Chemicals

Please refer to the "materials safety data sheet" for the specific chemical. A risk assessment must be undertaken by the designated user, recorded and kept within the department.

2.12.2 In the Event of a Spillage

All employees working within the decontamination suite must be aware of guidance regarding actions to be taken in the event of a spillage. Laminated guidelines must be displayed within the decontamination facility and next to Emergency Spillage kits.

All employees must be briefed about the procedure on induction to the Unit.

2.12.3 PPE in Endoscope Decontamination

When handling cleaning and disinfecting agents single-use gloves should be worn with forearm protectors and another pair of gloves on the top appropriate to the brand of disinfectant used. Top layer gloves and gauntlets are changed after manual decontamination of each scope. Eye and face protection with a full face visor is mandatory. Disposable gowns and aprons are to be worn and changed as per work instruction within the department.

Employees must be trained in effective hand washing as per Hand Hygiene and Skin Care Policy (including scrubbing gowning and gloving) (Ref 10) and a hand basin must be provided in both clean and dirty areas.

2.13 Initial Cleaning

All flexible endoscopes must be cleaned and flushed immediately after use by the person using the scope and before it can be placed in the transport container and transported to The FD suite.
When the scope arrives at the designated automated cleaning facility it will then be manually decontaminated in designated cleaning sinks before placing the scopes in AER.

2.14 Cleaning and Disinfectants Validated for Use in the AER Machines

AER Machines are commissioned with specific chemicals. Managers cannot change the chemicals used without full revalidation – Contact the AP(D) for further advice if required.

Achieving the correct concentration is crucial to ensure optimal cleaning efficacy of any detergent solution therefore dosing system require yearly calibration.

2.15 Employee Training and Competence

Rigorous training, frequent assessment and re-assessment, predisposes rigorous decontamination. It is the responsibility of the designated user to ensure this take place and records of competency are maintained.

There must be a "named training coordinator/trainer" for employees within the designated Decontamination facility.

Endoscope decontamination must only be undertaken by trained and competent employees. All appropriate employees will achieve the required decontamination competencies required to operate competently in their designated area. AER Operator ID will be issued to employees in training; a log of the training allocation will be kept by the manager of the area.

The user must ensure that bi annual update study sessions are arranged with the scope manufacturers.

Employees annual performance review (appraisal) will be integrated with Flexi Decontamination Competency Framework aligned to Skills for Health. Any training needs identified will be accompanied by a personal action plan to be achieved within six months.

2.16 Out of Hours Decontamination for Flexible Endoscopes

The central Flexi Decontamination Suite is currently open on seven days a week - Monday - Friday from 6am to 10pm, Saturday, Sunday and bank holidays 8am to 5pm.

There is a trained decontamination technician on call outside of working hours available via switchboard.
The HSDU department will provide a full service for the decontamination of flexible scopes used on planned and emergency cases for use in Endoscopy, Urology, Theatres and ICU during normal opening hours.

There are a limited number of scopes which will on occasions be used out of hours for emergency procedures as listed below:

- Gastroscopes
- Intubating fibrescopes

Any emergency scope requiring decontamination before 6am and after 10pm Monday – Friday will be considered out of hours.

Any emergency scope used before 8am and after 5pm anytime on Saturday, Sunday and bank holidays will be considered out of hours.

If an emergency scope is used out of hours a preliminary clean is performed at the bedside by the practitioner and the clinical employee will then contact the on call Decontamination Technician who will collect the scope from the users, check the track and trace forms are completed by the clinical employees and reprocess the scope.

2.17 Transmissible Spongiform Encephalopathy Agents (TSE) – Variant Cruetzfeldt Jakob Disease (vCJD)

Endoscopy should be avoided whenever possible in patients with either suspected or confirmed Variant Creutzfeldt-Jakob disease (vCJD)

All patients undergoing an endoscopic procedure should be asked:-

- “Have you ever been notified that you are at increased risk of Creutzfeldt-Jakob disease (CJD) or Variant Creutzfeldt-Jakob disease (vCJD) for public health purposes?”

If the answer is YES, do not proceed to endoscopy, advice should be sought from the Infection Prevention and Control Team and the Trust Decontamination Lead.

Please refer to Trusts Policy on Infection Prevention and Control of CJD/vCJD and other Human Prion Diseases Policy (Ref 11).

When deemed essential either a dedicated endoscope or one nearing the end of its useful life is employed and subsequently quarantined and this endoscope must not be used on another patient.

All accessories, whether marketed as single use or reusable or should be disposed of after use with patients at risk of CJD or vCJD.

3 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	Monitoring or audit method	Monitoring responsibility (individual, group or committee)	Frequency of monitoring	Reporting arrangements (committee or group the monitoring results is presented to)	What action will be taken if gaps are identified
Central Decontamination facility should be registered with the Medicines & Healthcare products Regulatory Agency MHRA and be certificated to ISO 13485	Internal audit program measuring performance against the Quality Management system (QMS) Yearly external audit by SGS UK Ltd to retain certification.	The HSDU Quality Representative is responsible for conducting the internal audits and reports to the HSDU Manager Any significant risks will be identified immediately to the directorate via the risk register.	This is defined in the documented yearly internally audit program which systematically reviews all aspects of the Quality Management System.	A monthly progress report is produced by the HSDU Quality Representative. This is sent to the HSDU Manager who reports to the Divisional Director and The Trust Decontamination Lead as appropriate.	If a gap is identified the HSDU Quality Representative and HSDU Manager will provide an action plan identifying the controls needed to address the shortfalls
Community and local decontamination against ISO 13485 and HTM 0106	Self assessment must be completed annually and the designated internal quality manager visits yearly to conduct an onsite audit in accordance with HTM - 0101 and 0106	Internal Decontamination Quality Representative and the nominated user	Annually	Any significant risks to be recorded on the planned care risk register and an action plan in place to reduce risk Progress on actions is monitored at the monthly directorate risk review meeting	The nominated user will be responsible for development of the action plan and the Decontamination Quality Representative will re audit the area within six months to ensure actions have been addressed.

4 Duties and Responsibilities of Individuals and Groups

4.1 Chief Executive

The Chief Executive is ultimately responsible for the implementation of this document.

4.2 Ward Managers, Matrons and Managers for Non Clinical Services

All Ward Managers, Matrons and Managers for Non Clinical Services must ensure that employees within their area are aware of this document; able to implement the document and that any superseded documents are destroyed.

4.3 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

4.4 Target Audience

The target audience has the responsibility to ensure their compliance with this document by:

- Ensuring any training required is attended and kept up to date.
- Ensuring any competencies required are maintained.
- Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.

4.5 The User

As defined in Ref 1 the user is the person designated by management to have operational responsibility of the process.

The user is responsible for the following:

- The operators
- The operation of endoscope decontamination equipment that may be used on the endoscopes under their responsibility, but not on site (for example, out stationed drying cabinets)
- Reporting issues of concern regarding endoscope instruments or their reprocessing to the surgical instrument manager
- Compliance with the policy
- At GWH the user is the Sterile Services Manager. In the community setting the user is the manager of the area using the Nasendoscope as they have responsibility for ensuring all of the above.
- For principle responsibilities of the user that should be included in their job description please refer to Ref 1.

4.6 Authorised Person Decontamination (AP(D))

As defined in HTM01-01 The AP(D) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the AE(D)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of decontamination equipment.
The AP(D) should be able to undertake the safe and effective management aspects of the service.

The role of AP(D) is intended to provide the organisation with an individual who, as part of the management infrastructure, will provide day-to-day operational management responsibility for the safety of the system and decontamination equipment.

The AP(D) will also be responsible for:

- The engineering management of decontamination equipment;
- Line management and/or appointment of the CP(D);
- The safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility;
- The acceptance criteria for operational and performance testing of all installed decontamination equipment;
- Liaison with the AE(D), Decontamination Lead and other interested professionals;
- Authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests.

4.7 Competent Person Decontamination (CP(D))

The CP(D) is defined in HTM01-01 (Ref 1) as a person designated by Management to carry out maintenance, validation and periodic testing of washer-disinfectors and sterilisers (This includes AER's). The CP(D) should report directly to an appropriate member of the estates department (for example AP(D)) or should be subcontracted by them.

The principal responsibilities of a CP(D) are:

- To carry out maintenance tasks.
- To carry out repair work.
- To conduct validation tests as given in HTM 01-01 (Ref 5) Parts B, C and D & HTM01-06 (Ref 1).
- To conduct periodic tests as given in HTM 01-01 (Ref 5) Parts B, C and D & HTM01-06 (Ref 1).

4.8 The Decontamination Risk Group

This Group will meet on a quarterly basis to review compliance with the policy, consider outcomes from internal and external audits and agree what needs to be identified on the Trust Risk Register under decontamination services heading. Any significant risks are added to the Risk Register and those scoring above 12 will be immediately escalated the Trust Board for consideration. This Group also provides a summary report of compliance to the Infection Control Committee which meets every six months.

5 Further Reading, Consultation and Glossary

5.1 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	HealthTechnical memorandum 01-06 Management and Decontamination of Flexible scopes.	*https://www.gov.uk*
2	Equipment Purchasing Procedure	T:\Trust-wide Documents

Ref. No.	Document Title	Document Location
3	Medical Devices Regulations 2002	http://www.legislation.gov.uk
4	International Organisation for Standardisation (ISO) 13485	Available on request from HSDU manager
5	HealthTechnical Memorandum 01-01	*https://www.gov.uk*
6	Control of Substances Hazardous to Health (COSHH) Policy	T:\Trust-wide Documents
7	Standard Infection Control Precautions Policy	T:\Trust-wide Documents
8	Safe Handling & Disposal of Sharps Policy	T:\Trust-wide Documents
9	Conduct Management Policy	T:\Trust-wide Documents
10	Hand Hygiene and Skin Care Policy (including scrubbing gowning and gloving) (Ref 22)	T:\Trust-wide Documents
11	Infection Prevention and Control of CJD/vCJD and other Human Prion Diseases Policy	T:\Trust-wide Documents
12	Care Quality Commission (CQC)	https://cqc.org.uk/
13	The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance	*www.legislation.gov.uk*

5.2 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

Job Title / Department	Date Consultee Agreed Document Contents
Clinical Lead - Theatres	19/06/2020
End User	19/06/2020
Production Manager - HSDU	19/06/2020
Authorised Person Decontamination	19/06/2020

6 Equality Impact Assessment

An Equality Impact Assessment (EIA) has been completed for this document and can be found at Appendix A.

Appendix A - STAGE 1: Initial Screening For Equality Impact Assessment

At this stage, the following questions need to be considered:			
1	What is the name of the policy, strategy or project? Decontamination of Flexible Endoscopes Policy		
2.	Briefly describe the aim of the policy, strategy, and project. What needs or duty is it designed to meet? This Policy and Procedure has been written as the Great Western Hospitals NHS Foundation Trust (the Trust) response to the Department of Health (DH) – Management and Decontamination of Flexible Endoscopes.		
3.	Is there any evidence or reason to believe that the policy, strategy or project could have an adverse or negative impact on any of the nine protected characteristics (as per Appendix A)?		**No**
4.	Is there evidence or other reason to believe that anyone with one or more of the nine protected characteristics have different needs and experiences that this policy is likely to assist i.e. there might be a *relative* adverse effect on other groups?		**No**
5.	Has prior consultation taken place with organisations or groups of persons with one or more of the nine protected characteristics of which has indicated a pre-existing problem which this policy, strategy, service redesign or project is likely to address?		**No**

Signed by the manager undertaking the assessment	Traci Parfect
Date completed	22/06/2020
Job Title	Head of Sterile Services

On completion of Stage 1 required if you have answered YES to one or more of questions 3, 4 and 5 above you need to complete a STAGE 2 - Full Equality Impact Assessment

Equality Impact Assessment

Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

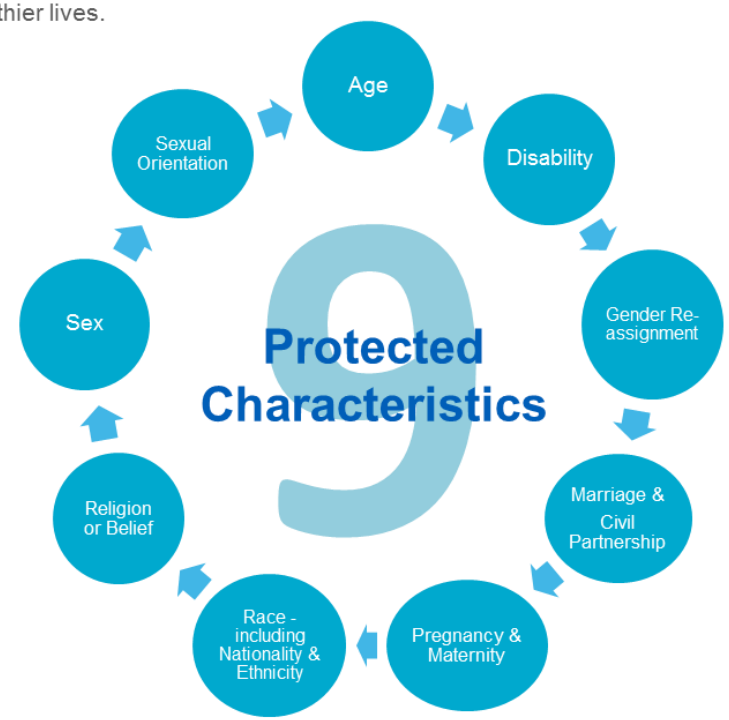
If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

Trust Equality and Diversity Objectives

Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels

Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



Appendix B – Management and Decontamination 01-06 Top Ten Tips

1. **COMPATIBILITY** - Ensure compatibility with the existing decontamination processes, including the automated endoscope reprocessor (AER), when purchasing any new endoscopes.

2. **INSTRUCTIONS** - Ensure that all equipment is operated and controlled in accordance with the manufacturer's instructions, local endoscope decontamination policy and associated risk assessments.

3. **TRACK AND TRACE** - Auto-identification and associated data capture should be used to track and trace all endoscopes, reusable accessories and AER's to ensure appropriate maintenance, correct decontamination and traceability to associated patients.

4. **LUMEN CONNECTION** - Check that all lumens in each endoscope can be connected to the EWD using the correct connectors/connection sets provided.

5. **MANUAL CLEANING** - Ensure endoscopes and reusable accessories are manually cleaned immediately after use, including the flushing of all lumens – even if they have not been used during the procedure.

6. **CHEMICAL COMPATIBILITY** - Only use chemicals that are compatible with the endoscope and its reusable accessories, and observe the correct process parameters that have been validated and demonstrated to be effective.

7. **ESSENTIAL QUALITY REQUIREMENTS AND BEST PRACTICE (AS DESCRIBED IN HTM 01-06) -**Endoscopes should always be decontaminated and maintained to a level specified in Essential Quality Requirements. A continuous process of evaluation and improvement should be in place to progress towards locally determined Best Practice.

8. **PLANNED PREVENTATIVE MAINTENANCE** - Have planned preventative maintenance and associated record-keeping in place to ensure all parts of the endoscope decontamination and management systems are optimally effective.

9. **STAFF TRAINING** - Ensure all staff, including new appointees, involved in the decontamination process are specifically trained in their role and in the broad context of endoscope management, decontamination and recontamination prevention, and that this training is kept up-to-date.

10. **INCIDENT REPORTING** - Report any potential failure in the management and decontamination of endoscopes, including equipment problems relating to endoscopes, AER's or process chemicals, to a line manager.

These Top Ten Tips take into account the broad approach taken in MHRA's Device Bulletin MDA DB2002(05) –'Decontamination of endoscopes'.