IHEEM Decontamination Technical Platform [DTP]
Annual review of flexible endoscope decontamination facilities

This decontamination review is designed to assess the suitability of decontamination facilities as part of a JAG accreditation assessment or annual review. It will determine if they are fit for purpose and meet the requirements of the NHS and independent healthcare sector in the UK.

The audit process of flexible endoscope decontamination requires knowledge of how the department operates and works and expertise in decontamination. This review is designed as part of an on-going quality control survey – internal or external audit processes. This should be reviewed in conjunction with the annual infection prevention quality improvement audit.

Notes on completion

- **The IHEEM audit process is to be carried out and signed by the appointed authorising engineer (decontamination) (AE(D)) for the site.**
  - **It is a requirement that the AE(D) must be currently registered with the Institute of Healthcare Engineering and Estates Management**
- The review will require evidence of the process – reports, documents, manuals, and correct responsible personnel signatures are to be produced for acceptance.
- **Any immediate concerns must be escalated by the AE(D) to the JAG team via the email – ask.jag@rcp.ac.uk**
- The completed report must be submitted to the endoscopy unit by the AE(D) in PDF format.

Site/hospital	
Auditors	
Date	
Department	
Department personnel	
AE(D) name and contact details	
AE(D) Registration Details (IHEEM)	
National guidance used for the audit (please ensure nation specific)	

Summary:

Review status

Red	Red/amber	Amber	Amber/green	Green

Executive Summary of Risks and Non-Conformances:

Section 1 - Personnel responsibilities

1.1	Unit/department manager	
1.2	Endoscopy unit manager - team leader	
1.3	Estates/facilities manager responsible for building management and	
1.4	Designated person responsible for decontamination procedures	
1.5	Infection prevention (include contact details of personnel involved)	
1.6	Decontamination lead for hospital, department, or unit (Strategic/Operational as applicable)	
1.7	Appointed AP(D) for unit/facility {as assessed by the AE(D). (include contact details of personnel involved)	Record of assessment required

Note - ***The review will require evidence of the process – reports, documents, manuals and correct responsible personnel signatures are to be produced for acceptance.***

Section 2 - Governance responsibilities

Does the organisation have the following in place?

		Name, job title and location
2.1	Endoscopy lead nurse for decontamination procedures	
2.2	Designated person responsible for local staff training and records	
2.3	Has the unit/department quality assurance [QA] procedures in place applicable for endoscope decontamination?	
2.4	EWD test engineers (contractors or in-house- give details)	
2.5	Endoscope storage cabinet test engineers (contractors or in-house)	
2.6	Other suppliers linked to the decontamination process e.g. pre-cleaning/elongated storage systems	

Section 3 - Operational management

The purpose of this section is to ensure that there are clear and robust governance arrangements in place to identify report and act on any decontamination issues.

	Criteria	Evidence	Comments
3.1	What is the structure for reporting decontamination? issues to the organisation's board/CEO? (Evidence of structure, reports/minutes/agenda of meetings etc.)		
3.3	What is the involvement from the infection prevention department/ microbiologist for advice, review of test data and subsequent continued use of an EWD in the event of a microbiological failure? Is there evidence of regular internal audits within the unit and action plans with timescales arising from these audits (state audit type and date of most recent)? It is recommended the audit undertaken is using the tool developed through the Infection Prevention Society.		
3.4	If the endoscope decontamination unit is supplying service to a third party, is it accredited to the medical device regulations, ISO 13485 or ISO 9001? Or has it plans to work towards any of these, or alternative audited QA systems in the future?		

3.5	If the unit/department has QA in place, who is responsible for the management of the system?		
3.6	Has the organisation, or unit, maintained competency certificates or information for the CP(D)s carrying out the testing or service work on the decontamination equipment? Are the certificates appropriate for the activity/equipment they are working on? Has the training been carried out over the last 3 years? Does the AP(D) or alternative responsible officer	*The estates or contractors may hold this information and assurance may be required*	

Section 4 - Policies and procedures

The purpose of this section is to ensure that local operational policies are in place and consistent with national guidance.

	Criteria	**Evidence and details**	**Comments**
4.1	What local written operating procedures are there available to cover the endoscope decontamination pathway? Is there evidence of regular review/updates?		
4.2	Do the local policies or practices followed on use of equipment and accessories differ from national guidelines or manufacturers' instructions? If yes, please give details, provide risk assessments, and identify risk risks.		
4.3	What is the policy and process for the out of hours/off site endoscope decontamination process		

4.4	Are timelines for the decontamination managed in accordance with HTM 01/06? This includes post reprocessing within the EWD and transportation back to the Decontamination facility after use? How does the organization mitigate any non-conformities to these timelines?		
4.5	Are there any endoscopes (such as Choledocoscopes) being sterilised for use? Provide details of the sterilisation units being used on site or off site and the process used. Has the sterilisation unit attained accreditation for the purpose?		

Added comments on the operational management and policies and procedures by the AE(D) because of carrying out the audit.

4.5	**General comments and recommendations**

Section 5 - Business planning for the decontamination facility

	Criteria	Evidence and details	Comments
5.1	Which of the following applies? 1) The facility is an interim solution with a new facility planned and built within one year/ alternative decontamination service planned within one year. 2) The facility meets current guidance and activity but will not support five-year projected decontamination activity to support the expected growth in service provision. 3) The facility meets current guidance, and current and five-year projected decontamination activity to support the expected growth in service provision. 4) A temporary solution or mobile unit to meet urgent service requirements?		
5.2	What are the replacement programmes in place for equipment reaching the end of their designated service lives? i.e. EWD's, CESC, ventilation, compressor and water systems.		
5.3	Are there any identified single points of failure within the unit? How are risks managed and are service continuity plans in place? Have these business continuity plans been tested periodically?		

Section 6 – details of the decontamination equipment for reference and records

This section looks for evidence of risk assessments.

	Criteria	Evidence	Comments
6.1	What records are kept for each EWD and cabinet/storage systems/automated flushing devices?		
6.2	Do the EWDs and cabinets have a maintenance contract in place?		
6.3	What type of storage/drying cabinets are in use? Have they been validated in accordance with BS EN 16442 /HTM01-06 /WHTM 01-06?		
6.4	If 'storage' cabinets are in use, what process is in place to dry the endoscopes being placed within? Are procedures covered under a formal SOP to manage the decontamination status of the endoscopes positioned within?		

EWD details - manufacturer	Model and type	Age and Serial Number	Details	Comments

Details of the decontamination equipment for reference and records

Storage / drying cabinets details - manufacturer	Model and type	Date of manufacture and serial number	Details	Comments

Sterilizer details - manufacturer	Model and type.	Age and Serial Number	Details	Comments

Additional technologies used- manufacturer	Model and type	Age and Serial Number	Details	Comments

Section 7 – Validation and test reports

	EWD(s)	Periodic Test Reports (including microbiological tests) reviewed by/date and who completes the details	Comments
7.1	Daily including self-disinfection		
7.2	Weekly including final rinse water samples		
7.3	Quarterly Evidence from HTM tables		
7.4	Annual Ensure that the reports are signed off and checked by the relevant people in each section i.e. CP(D), AP(D), and user		*Note: Provide comments on the suitability of those signing.*
7.5	Are laboratories, who undertake weekly, quarterly and the annual rinse water tests accredited for tests they complete?		
7.6	Are the annual test reports for all EWDs signed by the AE(D)?		

Evidence of testing reports to the NHS guidance to include, but not limited to, HTM 01.06, [WHTM 01.06 Compliant Endoscope Decontamination Unit] BS EN 15883 parts 1,2 and 4, 5, BS EN 16442, BS EN ISO 14971; 2007 Medical Devices –Application of risk management to medical devices

Section 8 - Equipment review

For the following tables where a risk element is required, the AE(D) should add in their own perceived risk level in the table for the following questions/survey using the following definitions: 1 – high; 2 – medium; 3 – low

	Criteria	Evidence	Comment	Risk
Decontamination sinks				
8.1	Are adequate cleaning sinks available (Twin sink units)? Is one used for the rinse water? Is the detergent sink rinsed between use? Is the concentration and temperature of the diluted detergent measured and used in accordance with the manufacturer's recommendations? To include a recent certificated calibration procedure for the thermometer and dosage pump.			
EWD(s) *Ensure that the reports are signed off and checked by the relevant persons in each section Ie CP(D), AP(D), AE(D) and User*				
8.2	Are all the installed EWDs periodically tested to the recommendations of HTM 01.06 [WHTM 01-06], including all tests as required?			
8.3	Can all channels including ancillary channels in complex endoscopes be connected using manufacturers supplied connectors and irrigated in the EWD? Are there any types/make of endoscopes that cannot be processed through the EWDs as installed?			
8.4	If two endoscopes are processed together in the same EWD chamber, is there a mechanism or process to ensure that they do not touch or have contact with each other?			

8.5	If there is a scope vault system in the department, is it being used correctly in accordance with manufacturers guidance (used to reprocess sensitive design systems such as TOE scopes).			
8.6	Are weekly water test results available for review and a water escalation policy dedicated for endoscopy rinse water in place in the event of microbiological failure (specifically where pseudomonas and Environmental Mycobacteria involved)?			
Any comments				

Chemicals				
8.8	Are process chemicals used compatible with process and as recommended by EWD manufacturer? If not, who is accepting liability? Are they operating within their optimum parameters? (Ref Chemical supplier's information) Are the chemicals stored correctly in accordance with Data Safety Sheets?			
8.9	Give details of the detergents in use, and **EWD(s)** - if the detergents are not those recommended by the EWD manufacturer: ○ Were the EWDs appropriately revalidated when the chemicals were changed over, and Decontamination Lead/User/AE(D) approval obtained? ○ Has the chemical supplier presented the type testing or declaration of conformance for that specific model/chemical supply? Has a formal risk analysis been completed prior to conversion? ○ **Sinks -** are detergents suitable for purpose, CE marked, COSHH assessments available?			

8.10	Disinfectants in use in EWD - if the disinfectants are not those recommended by the EWD manufacturer: ○ Were the EWDs appropriately revalidated when the chemicals were changed over, and Decontamination Lead/User/AE(D) approval obtained? ○ Have they been type tested for that specific model? ○ Has the chemical supplier presented the type testing or declaration of conformance for that specific model/chemical supply? Has a formal risk analysis been completed prior to conversion? ○ Are they suitable for purpose, CE marked, COSHH assessments available?			
8.11	List of chemicals used: Clinic – Bed-side clean Pre-clean irrigators – sanitisation Sink - detergent EWD – detergent EWD – disinfectant (single or multiple parts – please specify each)			

8.12	What systems are in place to manage chemical spillages within the decontamination area or rooms? Are there emergency extraction systems in place? Are the spill kits positioned appropriately for emergency access? Is there an evacuation strategy in place to guide on spillages/leaks. The evacuation strategy must include guidance for safe re-entry to the decontamination area.				
8.13	Are dedicated chemical storage cabinets in place, are they appropriately ventilated and manufactured specifically to house decontamination chemicals? Is each chemical segregated/separated to prevent solutions reacting together? Are cabinets serviced at routine intervals?				
8.13	Are systems installed to continuously monitor the working environment for exposure to hazardous chemicals throughout the decontamination unit, including both the dirty and clean rooms? In addition, are repeater panels provided to display the environmental conditions outside the room?				
Cabinets – storage Ensure that the reports are signed off and checked by the relevant persons in each section i.e. CP(D), AP(D), AE(D) and User					

8.15	Does the unit use any elongated storage or transport systems, such as vacuum-pack systems? Are these systems validated at defined intervals to ensure their integrity over the specified storage period? Please state the validated period currently in place. What drying methods (if applicable) are used as part of this process, and is this procedure documented within an approved SOP?			
8.16	What methods are in place to validate drying efficacy in accordance with HTM 01/06 or BS EN 16442? Are surrogates used reflective of endoscopes processed on site and in compliance with type tested data?			
8.17	Is there a pre-cleaner endoscope irrigation system used in the unit to support manual cleaning processes? If so is there a routine sanitization system in place in accordance with manufacturer's instructions to prevent internal bio-film formation? Are they tested for water quality? e.g. TVC? Are internal/flush tubing purged periodically or disposed of at periodic intervals? Where innovative systems are used to clean scopes outside of formal IFU, are they supported by appropriate risk assessments and validation that has been reviewed by the AE(D)?			

8.17	What types of brushes are used for manual cleaning, and are they confirmed as compatible with the endoscope manufacturers' Instructions for Use (IFU)? Are the brushes managed appropriately prior to use, including verification that they are within their stated expiration date? Do the training systems in place adequately cover the correct manual cleaning methods and the appropriate use of these brushes?			
8.18	Are endoscopes with ancillary channels e.g. raiser bridge, balloon channel excluded from the installed cabinets unless a dedicated connector and pump is available?			

Note on the machines or environment: if any issues are seen or need to be reported on, such as inadequate monitoring equipment, tracking systems or EWD installation, add them to the comments within the summary report at the end of the audit pages.

Section 9 - Environment - layouts

Sections 9 - 11 are to be assessed as a collective comment and assessment.

	Criteria	Evidence	Comment (concern on flows, space, design)	Risk
9.1	There is the correct flow from dirty to clean within one facility.			
9.2	Is a single or split room operation in use? Are there systems in place to: ○ Minimise cross contamination ○ Prevent inadvertent release of scopes which have not been seen decontaminated appropriately ○ Ensure correct flow of instruments and operators ○ Ensure adequate space for working?			
9.3	Please state the approximate number of endoscopes processed through the unit over the course of one year. How many clinical lists per week does the decontamination unit support? How many endoscopes—specifying types and designs—are handled within the facility?			

9.4	Is the ventilation flow suitable for the process i.e., negative pressure in dirty room or flow from clean to dirty in a one room setting with at least 10Pa differential between the clean room and surrounding areas and 5 Pa differential between the washroom and surrounding areas if a two room decontamination unit? (Check latest version of HTM 03.01 guidance) Is the system adequate for the process chemicals used within the decontamination area? Are COSHH risk assessments available where the Chemicals are stored? (Ref COSHH information)			
9.5	What systems are in place to independently verify that chemical exposure levels remain within safe working limits? Where such systems exist, which specific chemical constituents are included in the independent verification process? How often is such testing completed and is the supplier accredited to complete such testing?			
9.5	If the EWD(s) have its own ventilation e.g. carbon filters, is this included within the maintenance schedule?			

9.5	Is there low-level gas extraction in the ventilation system for the removal of peracetic acid? What systems are in place to mitigate risks where LLE is not present?			
9.6	How is the environment monitored to ensure the safety and comfort of staff and what is the escalation process for unsafe working conditions? Monitoring to include ○ Temperature ○ Atmospheric peracetic acid measured at low, medium, and elevated levels from the floor. ○ Periodic environmental monitoring ○ *NB peracetic acid is heavier* than air			
9.7	What maintenance and validation is available for the ventilation system? This should be in accordance with HTM 03-01. Such units should be classified as essential/critical systems. Split and cassette air conditioning units serving decontamination area, must be serviced/cleaned/maintained. Are systems in place to inspect and clean every three months and the drainage system checked. (Ref HTM 03/01 part B) .			

9.8	Is there a treatment system in place for final rinse water? Is there any pretreatment with biocide on site before the purification plant? Is this compatible with any installed mechanical purification plant?			
	What type of compressors supply air to the equipment within the unit? Is the system configured as a duplex arrangement, and does it provide adequate resilience to maintain continuous operation in the event of component failure? Is the quality of the supplied air verified at defined intervals in accordance with applicable IFU or pharmacopeia standards?			
9.9	Are water treatment units and housing system well designed and maintained? Are there documented membrane/ filter change regimes in place?			
9.10	What is the condition of any exposed engineering services? To include all utilities within the decontamination unit?			
9.11	What is the condition of room surfaces? Flooring/Walls/Ceilings etc.			
	Are all rooms within the unit visibly clean? Are cleaning regimes documented and how often are they completed? Is cleaning segregated using dedicated dirty of clean equipment? Are tops of cabinets/EWD's and other items free of dust etc.?			

Remote endoscope decontamination facilities and storage

This section only to be filled in if the endoscopes are decontaminated in an off-site facility or are transported, stored, and used in a completely remote area to that of the on-site decontaminationunit.

Note - If this section of the audit is not applicable move on to section 11

	Criteria	Evidence	Comment (concern on flows, space, design)	Risk
9.12	Is decontamination carried out off site? Is the off-site facility accredited to the medical device regulations, ISO 13485 or ISO 9001? Is the off-site facility subject to a JAG – IHEEM Decontamination Audit? Are the transportation methods used acceptable and with monitored standards? Are timings of transport/transfer in alignment with HTM 01/06 and BSG and processed within the EWD at a time not to exceed 3 hours? e.g., Are the scopes packed in moist bags/containers for transit?			

9.13	Location – give a brief description of the location of the remote storage facility. Are the endoscopes stored in a controlled environment storage cabinet of a suitable design? *Is the storage location suitable for purpose (storage ofendoscopes)?* *Are the controlled environment storage cabinetslocated correctly?*			

9.14	How are the endoscopes transported to this location? Is this recorded on the traceability system? *Management and controls?* *Process segregation (separate dirty/clean systems)?* *Cleaning regimes for all transport systems?* *Is the process audited?*			
9.15	Frequency of the transportation times to the storage area e.g. as soon as practically possible after decontamination, time not to exceed 3 hours post conclusion of the EWD cycle.			
9.16	Has the remote unit any elongated storage systems in use? (Greater than 30 days storage)			

9.17	How is this storage facility or cabinet managed and controlled?			
9.18	Are there routine validation/testing protocols to support the storage period of these systems? *Who is responsible for this testing/reporting?*			

9.19	Are all the installed cabinets periodically tested to the recommendations of HTM 01.06 [WHTM 01-06], to include performance requalification for the maximum time for scope storage?			
9.20	What methods are in place to validate drying efficacy in accordance with HTM 01/06 or BS EN 16442? Are surrogates used reflective of endoscopes processed on site and in compliance with type tested data?			
9.21	Are the annual test reports for all cabinets in use signed by the AE(D)			
9.22	Outline any items of concerns from this audit in the management, transportation, and storage of the endoscopes in question.			

9.23	Outline any recommendations that would improve remote storage location and methods utilized.			
9.24	Are moist bags used where there are delays transferring back to the Decontamination centre? How is this usage managed to prevent biofilm formation?			

Section 10 - Maintenance contracts and Service Requirements

	Criteria	Evidence	Comment	Risk
10.1	What is the maintenance regime for the EWD(s) as installed? Is the maintenance activity covered by an SOP and is this adhered to?			
10.2	How is the maintenance carried out on the EWD(s) in-house manufacturer or by an independent contractor?			
10.3	What type of contracts are in place for all decontamination equipment including, drying and storage equipment, ventilation and plant including water purification systems? Length of contract? Is it fully comprehensive? Is performance monitored under a KPI agreement?			
10.4	Is there a system in place of operating a permit to work system on the equipment? a) EWD(s) b) Storage cabinets c) Water supply systems d) Ventilation system? e) Compressed air plant? f) Is there a policy to control and manage contractors working within the premises?			
10.5	Who operates the permit to work system? (Give details) a) Estates department b) User c) AP(D) d) other			

10.6	Are technical reports given after the work is carried out specifying what was carried out? Are those reports signed by the AP(D) and/or user (give details)? Is a log record available to record each engineering activity? [This log could be a paper or electronic record]			

Section 11 - Tracking/Traceability

	Criteria	Evidence	Comments	Risk
11.1	What is the tracking and tracing system used in the unit that records each stage of the decontamination process, the persons involved, storage and subsequent patient use? What is the backup system e.g. in the event of the failure of an electronic system?			
11.2	Are recordings on the traceability system accurate with timings of process? To include: Bedside and Manual Cleaning Automated Cleaning Storage Transport			
11.2	How does the tracking and traceability system function and record if endoscopes are used at multiple end/user locations?			
11.3	Are endoscopes and reusable accessories stored and used together forming a unique set to allow accurate tracking and tracing (recommended)?			
11.4	How are loan endoscopes and accessories tracked and traced?			
11.5	Are records available to track automated cycle details? This should include information from the EWD, CESC and other emerging technologies used in the decontamination process. Is this data networked via a secure server?			
11.5	Do all traceability system relate patients to individual endoscopes and accessories?			
11.6	Is it possible to trace all the patients that have been in contact with a particular endoscope or reusable accessories? Is an audit report available to demonstrate this?			

Section 12 - Training and education on decontamination equipment

	Criteria	Evidence	Comments
12.1	What training records are available for decontamination staff (including staff who undertake any part of the decontamination or handling of endoscopes) Are the original training records maintained within the facility?	E.g. Staff log books, Continuing professional development	
12.2	Is there evidence of a structured induction, training and re-validation program for staff involved in decontamination using a competency assessment tool		
12.3	Is there evidence that staff who undertake the daily and weekly testing of EWD(s) are trained and educated to meet requirements of guidance (e.g. HTM)? Is the training provider accredited for purpose and/or has training been completed by equipment manufacturer or designated agent?		
12.4	Is there evidence that staff who undertake the quarterly and annual testing and validation of EWD(s) and drying/storage cabinets have undertaken nationally recognised training and attended validated courses? Are the certificates appropriate for equipment under test? ***Was the training course attended relevant to the current guidance and standards e.g. HTM 01-06; BS EN ISO 15833 etc.?*** Do they undertake such work on a routine basis?		
12.5	Is there evidence that staff who undertake breakdown and service activity of EWD(s) and drying/storage cabinets have undertaken training within formal mechanical and electrical disciplines?		

12.6	Is there evidence of COSHH training for all decontamination staff? Are there routine refreshers? Is training delivered by the chemical supplier?		

Additional comments on the above questions and review	
Reference	

Section 13 - Summary of review

The assessor should conclude if the unit or a process is to be coloured **red, amber or green**

		Comments including actions required or recommended	Rating Applicable
13.1	EWD[s]		
13.2	Storage cabinets		
13.3	Ancillary Services		
13.4	Environment and ventilation		
13.5	Environment - Room layouts and general condition Including flows of endoscopes and staff		
13.6	Infection Prevention issues – safety (COSHH, PPE) – equipment levels		
13.7	Procedures and Training		
13.8	Testing		
13.9	Assessment of key personnel. Appointments, certification, on-going training		

Name[s] of auditor[s] /reviewer(s)	
Signature[s]	
Date of review	
Report submitted to	
Name of person responsible for actions	
Date of next JAG Assessment	

Immediate actions required as recommended by the AE(D)	

Section 14 – Recommended Action Plan

Action plan to be developed in response to assessment

Action Plan of Recommendations	Responsible Lead to Adress Actions	Was the Action outstanding from previous assessment?

Signature of AE(D) present on site	
Dated	

Name/Signature of JAG Assessor verifying the report	
Dated	

The audit form must be signed by the AE(D) appointed for the site or department and presented in pdf format

Appendix – Photographs of Visit	