



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.
 - Exceptions to this requirement are outlined at the end of the audit form.
- The review will require evidence of the process reports, documents, manuals, and correct responsible personnel signatures are to be produced for acceptance.
- 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	
National guidance used for the audit (please ensure nation specific)	

Section 1 - Personnel responsibilities

1.1	Unit/department manager	
1.2	Endoscopy unit manager - team leader	
1.3	Estates manager responsible for building management and controls/maintenance	
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)	

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?		
3.1	(Evidence of structure, reports/minutes/agenda of		
	meetings etc)		
	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		
3.3	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.		
	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?		
3.4			
3.4	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?		
	Has the organisation, or unit, maintained	The estates or contractors may hold this	
	competency certificates or information for the	information and assurance may be required	
	CP(D)s carrying out the testing or service work on		
	the decontamination equipment?		
2.6	Are the certificates appropriate for the		
3.6	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		
	review the CP(D) assessment at routine frequencies?		

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

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?		
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Added comments on the operational management and policies and procedures by the AE(D) as a result 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 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 and endoscope cabinets, ventilation and water systems.		

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?		

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

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 persons in each section ie CP(D), AP(D), and user		Note: Provide comments on the suitability of those signing.
7.5	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
Deconta	amination 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				<u> </u>
Ensure t	that the reports are signed off and checked by the relevo	ant persons in each section le 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	If there is a scope cassette system in use? Note to assessors: If yes additional information may be required from the AE(D) on the equipment, layout, and process		
8.7	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 co	omments		

Chem	hemicals		
8.8	Are process chemicals used compatible with process and as recommended by EWD manufacturer? 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. Are there ventilated storage cabinets manufactured specifically to house decontamination chemicals? Is each chemical appropriately segregated? MONITORING!!!			
	ets — storage that the reports are signed off and checked by the relevant of t	ant persons in each section ie CP(D), AP(D), A	E(D) and User	
8.13	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 period for scope storage?			
8.14	Are the test reports for all cabinets signed by the appropriate personnel, such as User, AP(D) and AE(D)			
8.15	Has the unit any elongated storage/transport systems in use? Such as vacuum pack Are they validated at regular periods to guarantee the integrity of these devices over the prescribed storage periods? [state validated storage times]			

8.16	Is there a pre-cleaner endoscope irrigation system used in the unit to aid 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?		
8.17	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	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)			
9.4	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 high 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?		
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?		
9.11	What is the condition of room surfaces?		

Remote endoscope storage facilities or equipment

This section only to be filled in if the endoscopes are transported, stored, and used in a completely remote area to that of the decontamination unit.

Note - If there is no remote storage facility or unit, carry on to section 10 of this audit

	Criteria	Evidence	Comment (concern on flows, space, design)	Risk
9.12	Location – give a brief description of the location of the remote storage facility.			
	Is decontamination carried out on/off site? By internal/external provider?			
	Is the location suitable for purpose (storage of endoscopes)?			
	Are the controlled environment storage cabinets located correctly?			
9.13	Are the endoscopes stored in a controlled environment storage cabinet of a suitable design?			

9.14	How are the endoscopes transported to this location?	
	Management and controls? Process segregation (separate dirty/clean systems)? Cleaning regimes for all transport systems? Is the process audited?	
9.15	Is the transportation method used to acceptable and with monitored standards?	
	e.g., Are the scopes packed in moist bags/containers for transit?	
9.16	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.	
9.17	Has the remote unit any elongated storage cabinets in use?	
9.18	How is this storage facility or cabinet managed and controlled?	
9.19	Are there routine validation/testing protocols to support the storage period of these systems?	
	Who is responsible for this testing/reporting?	

9.20	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 period for scope storage?		
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.		

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) 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			

activity? [This log could be a paper or electronic record]		10.6	,		engineering	
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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	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	Does the 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
	What training records are available for	E.g. Staff log books,	
	decontamination staff (including staff who	Continuing professional development	
12.1	undertake any part of the decontamination or		
12.1	handling of endoscopes)		
	Are the original training records maintained within		
	the facility?		
	Is there evidence of a structured induction, training		
12.2	and re-validation program for staff involved in		
12.2	decontamination using a competency assessment		
	tool		
	Is there evidence that staff who undertake the daily		
12.3	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? Is there evidence that staff who undertake		
	breakdown and service activity of EWD(s) and		
12.5	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?	
	onal comments on the above questions and review	
Refere	nce	

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	Environment and ventilation		
13.4	Environment - Room layouts and general condition Including flows of endoscopes and staff		
13.5	Infection Prevention issues – safety (COSHH, PPE) – equipment levels		
13.6	Procedures and Training		
13.7	Testing		
13.8	Assessment of key personnel. Appointments, certification, on-going training		



Name[s] of auditor[s] /revie	ewer(s)				
Signature[s]					
Date of review					
Report submitted to					
Name of responsible persor	n for actions				
Review status					
Red	Red/amber	Amber	Amber/green	Green	7
Immediate actions required AE(D)	d as recommended by the				
AL(D)					
Signature of AE(D) present	on site				
Dated					

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



Guidance on exceptional circumstances preventing an AE(D) attending site

As a result of the 2020 COVID-19 pandemic, many services and functions have been disrupted across the UK. To strengthen governance arrangements and ensure ongoing patient safety, in December 2020 an agreement was made between IHEEM and JAG to clarify expectations when exceptional circumstances arise. The agreement was reached with advice from the Infection Prevention Society.

The following guidance notes relate to when a site audit cannot be carried out because of exceptional circumstances:

- It remains a requirement for the AE(D) to attend site to carry out the audit on an annual basis unless exceptional circumstances arise.
- A risk assessment must be carried out by the AE(D) before attending the site to check on the status of the hospital/unit in question and to consider their own wellbeing. The risk assessment should inform a decision whether or not to attend the site. The AE(D) must ensure that appropriate infection prevention protocols including appropriate PPE is available for use and that he or she is able to adhere to the protocols.
- Under exceptional circumstances e.g. national, or local measures restricting access, personal health issues, or a backlog due to national emergencies, an annual site visit may not be possible. In such cases the AE(D) must immediately inform the clients lead professional responsible for appointment, the office of the Director of Estates, or their equivalent and those professionally and organisationally accountable for provision of endoscopy services, that normal audit procedures will not take place. The following must then be considered, documented and an action plan created to identify when normal arrangements can resume.
 - Any changes to the standard procedures must be agreed by all parties prior to undertaking the audit and deemed as a temporary status while exceptional circumstances exist. Documented advice from the local infection prevention team is required. Agreement on any delays must be made by all parties and documented.
 - o If it is agreed that the audit is to be carried out remotely (e.g. via video conference), the highest assessment outcome possible is a green/amber score, as a full green score can only be awarded if the site is attended by the AE(D).
 - Remote audits can only be carried out when the AE(D) has conducted a previous audit, there were no reported red review status outcomes on the last audit and the AE(D) is familiar with the site.
 - An agreed person(s) can be delegated responsibility to carry out an audit and provide the AE(D) with technical information. An appropriately trained AP(D), competent in the decontamination of endoscopes and associated equipment, could perform the

- remote duties. The AP(D) must be appointed by the AE(D) and assessed for competence prior to the audit. The responsibility for the final assessment and approval of documentation remains with the AE(D).
- Alternatively audit duties can be sub-contracted to another registered AE(D). Those accountable for endoscopy services should be consulted and informed of this arrangement and appropriate contractual agreements may need to be considered.
- The AE(D) must be in direct contact with the unit at the time of the remote audit (preferably by video).
- o Following a remote audit, a site visit must be arranged as soon as possible. Reassessment should be made within four months after the original audit date if a site visit has not been undertaken. JAG cannot award accreditation without an in date IHEEM audit report.
- The responsibilities for any breach in patient safety considerations resulting from any deviations to the standard audit procedures will fully reside with the appointing organization and the AE(D).
- For mentoring purposes, the audit may be carried out under the direct supervision of an AE(D) by an AE(D) trainee who is registered on the IHEEM/EWP framework scheme provided this is agreed prior to attending site and they are accompanied by the AE(D) to oversee procedures. This is to allow trainees to gain experience in auditing in the presence of an AE(D) who takes the professional responsibility.
- Any queries should be addressed to the IHEEM office for clarification.