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 manager	
1.3	Lead nurse	
1.4	Designated person responsible for decontamination	
1.5	Infection prevention (include contact details of personnel involved)	
1.6	EWD / Cabinet test engineers (contractors or in-house. Include contact details of personnel involved)	
1.7	Estates engineer/AP(D) (include contact details of personnel involved)	

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	Decontamination lead	
2.2	Endoscopy manager/ lead nurse	
2.3	Designated person responsible for Decontamination facility and staff	
2.4	EWD / Cabinet test engineers (contractors or in-house)	
2.5	Estates Engineer/Authorised Person (Decontamination) AP(D) – contact details	

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?		
3.2	How does the decontamination lead report to the organisation's board/CEO?		
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)?		
3.4	Is the endoscope decontamination unit accredited to the medical device directive, ISO 13485 or ISO 9001 or has it plans to work towards any of these in the future?		
3.5	Is there an appointed AP(D) to manage the engineering aspects of the decontamination equipment and service?		
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?	*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 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 hours/off site endoscope decontamination process		
4.4	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 MDD accreditation?		

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.		
5.2	What are the replacement programmes in place for equipment >5 years old? 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	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), AE(D) and user)		*Note: Provide comments on the suitability of those signing.*

Evidence of testing reports to the NHS guidance, HTM 01.06, [WHTM 01.06 Compliant Endoscope Decontamination Unit] BS EN 15883 parts 1,2 and 4, 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?			
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	Are the annual test reports for all EWDs signed by the AE(D)?			
8.4	Can all channels including ancillary channels in complex endoscopes be connected and irrigated in the EWD? Are there any types/make of endoscopes that cannot be processed through the EWDs as installed?			
8.5	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?			
8.6	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 in place in the event of microbiological failure (specifically where pseudomonas and Environmental Mycobacteria involved)?			
Chemicals				
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: o have they been type tested for that specific model? o were the EWDs appropriately revalidated when the chemicals were changed over, and manufacturer's approval obtained? **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: o Have they been type tested for that specific model? o Were the EWD(s) appropriately revalidated when the chemicals were changed over, and manufacturer's approval obtained? o Are they suitable for purpose, CE marked, COSHH assessments available?			

8.11	What systems are in place to manage chemical spillages within the decontamination area or rooms? Are there emergency extraction systems in place?			
Cabinets – storage 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				
8.12	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?			
8.13	Are the annual test reports for all cabinets signed by the AE(D)			
8.14	Are any types of portable storage devices in use validated at regular periods to guarantee the integrity of these devices over the prescribed storage periods? [state validated storage times]			
8.15	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?			
8.16	Are endoscopes with ancillary channels e.g. raiser bridge, balloon channel excluded from the installed cabinets unless a dedicated connector and pump is available?			
8.17	Has the unit any elongated storage/transport systems in use? *Such as vacuum pack*			
8.18	Are there routine validation/testing protocols to support the storage period of these systems?			

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? (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	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. ○ *NB peracetic acid is heavier* than air			
9.6	What maintenance and validation is available for the ventilation system? This should be in accordance with HTM 03-01 for critical systems			
9.7	Is there a treatment system in place for final rinse water?			
9.8	Are water treatment units and housing system well designed and maintained? Are there documented membrane/ filter change regimes in place?			
9.9	What is the condition of any exposed engineering services?			
9.10	What is the condition of room surfaces?			

Section 10 - Maintenance contracts/Service

	Criteria	Evidence	Comment	Risk
10.1	What is the maintenance regime for the EWD(s) as installed?			
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?			
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? Other–give details			
10.5	Who operates the permit to work system? (Give details) a) Estates department b) User c) AP(D)			
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)?			

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?			

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)	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 national requirements?		
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?		
12.5	Is there evidence of COSHH training for all decontamination staff?		
12.6	Who is the recognised training lead for the department?	Job description, personal development plan, unit policies	

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
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 of auditor /reviewer(s)	
Signature	
Date of review	
Report submitted to	
Name of responsible person for actions	

Review status

Red	Red/amber	Amber	Amber/green	Green

Immediate actions required as recommended by the AE(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.
    - 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).
    - 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 organisation 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.