JAG
Joint Advisory Group
on GI Endoscopy

IHEEM

Annual Review of Flexible Endoscope Decontamination Facilities

IHEEM Decontamination Technical Platform [DTP]

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

This decontamination review summary report is designed to assess the suitability of the decontamination facilities in readiness for the further assessments on clinical competency by the JAG organisation and will determine if they are fit for purpose and meet the requirements of the NHS, of the United Kingdom and the Private Healthcare Sector.

SCORE MASTER SHEET

ONLY VALID FOR JAG ACCREDITATION IN PDF FORMAT

Site – Hospital		**Auditors**	
Department		**Date**	
Department personnel		**AE(D) Authorising Engineer (Decontamination) and contact details**	
National guidance used for the audit (please ensure nation specific)			

Section 1 - Personnel responsibilities

Unit/Department Manager	
Endoscopy Manager	
Lead Nurse	
Designated person responsible for decontamination	
Infection prevention (include contact details of personnel involved)	
EWD / Cabinet test engineers – [contractors or in-house] (include contact details of personnel involved)	
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
Decontamination Lead	
Endoscopy Manager/ Lead Nurse	
Designated person responsible for Decontamination facility and staff	
EWD / Cabinet test engineers – [Contractors or in-house]	
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.**

Question	**Evidence**	**Comments**
a) What is the structure for reporting decontamination issues to the organisations Board/CEO?		
b) How does the Decontamination Lead report to the organisations Board/CEO?		

c) 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)		
d) 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?		
e) Is there an appointed AP(D) to manage the engineering aspects of the decontamination equipment and service?		
d) Has the organisation or unit maintain 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.

Question	Evidence and details	Comments
a) What local written operating procedures are there available to cover the endoscope decontamination pathway? Is there evidence of regular review/updates		
b) 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 and provide risk assessments and identified risks.		
c) What is the policy and process for the out of hours/off site endoscope decontamination process		
d) Are there any endoscopes, [such as Choledocoscopes] being sterilized for use? e) Details of the sterilization units being used on site or off site? f) Details of the process being used g) Has the sterilization unit attained MDD accreditation?		

Section 5 - Business planning for the decontamination facility

Question		Evidence and details
a) 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.	
b) 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

Question	Evidence	Comments
a) What records are kept for each EWD and cabinet/storage systems/automated flushing devices		
b) Do the EWDs and cabinets have a maintenance contract in place		
c) 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 - Type	Age and Serial Number		Comments

Details of the decontamination equipment for reference and records

Storage / Drying Cabinets Details - Manufacturer	Model - Type	Date of manufacture Serial Number	Details	Comments

Section 7 – Validation and test reports

EWD(s)	Periodic Test Reports(including Microbiological tests) reviewed by/date	Comments
Daily(including self disinfection)		
Weekly *including final rinse water samples*		
Quarterly *Evidence from HTM tables*		

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*		*Comments on signatures*

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

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Note.

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

Risk levels – 1- high 2 – medium 3- low C- comment

Section 8 - Equipment review

	Review	Evidence	Comment	Risk
Decontamination sinks				
1	Are adequate cleaning sinks available (Twin sink units)? Is one used for the rinse water? Is the detergent sink rinsed between use?			
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*				
2	Are all the installed EWDs periodically tested to the recommendations of HTM 01.06 [WHTM 01-06],including all tests as required			
3	Are the annual test reports for all EWDs signed by the AE{D}			
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?			
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?			

	Review	Evidence	Comment	Risk
6	If there is a Scope cassette system in use. *Note to assessors: If yes additional information may required from AE(D) on the equipment, layout and process*			
7	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	Are process chemicals used compatible with process and as recommended by EWD manufacturer? Are they operating within their optimum parameters? • (Ref Chemical suppliers information) Are the chemicals stored correctly in accordance with Data Safety Sheets?			
9	Give details of the detergents in use, and a) **EWD [s]** -If the detergents are not those recommended by the EWD manufacturer: • have they been type tested for that specific model? • were the EWD's appropriately revalidated when the chemicals were changed over and Manufacturers approval obtained? b) **Sinks** Are detergents suitable for purpose, CE marked, COSHH assessments available.			

10	Disinfectants in use in EWD If the disinfectants are not those recommended by the EWD manufacturer: • Have they been type tested for that specific model? • Were the EWD(s) appropriately revalidated when the chemicals were changed over and manufacturers approval obtained? • Are they suitable for purpose, CE marked, COSHH assessments available.			
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*				
Review		**Evidence**	**Comment**	**Risk**
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?			
13	Are the annual test reports for all cabinets signed by the AE{D}			

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]			
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?			
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?			
17	Has the unit any elongated storage/transport systems in use? *Such as vacuum pack*			
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

Note

Questions 19 to 43 are to be assessed as a collective comment and assessment

Section 9 - Environment - layouts				
	Observation	Evidence	Comment –concern on flows –space -design	Risk
19	There is the correct flow from dirty to clean within one facility?			
20	Is a Single or split room operation in use? Are there systems in place: • To minimize cross contamination? • Prevent inadvertent release of scopes which have not been seen decontaminated appropriately? • Ensure correct flow of instruments and operators Adequate space for working			
21	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 wash room 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)			

22	If the EWD(s) have its own ventilation e.g. carbon filters. Is this included within the maintenance schedule?			
23	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 paracetic acid measured at low, medium and high levels from floor • ***NB paracetic acid is heavier*** than air			
24	What maintenance and validation is available for the ventilation system. Note: this should be in accordance with HTM 03-01 for critical systems			
25	Is there a treatment system in place for final rinse water?			
26	Water treatment units and housing system well designed and maintained? Are there documented membrane/ filter change regimes in place?			
27	What is the condition of any exposed engineering services -comments			
28	What is the condition of room surfaces			

Section 10 - Maintenance contracts/Service

	Review	Evidence	Comment	Risk
29	What is the maintenance regime for the EWD's as installed			
30	How is the maintenance carried out on the EWD(s) in-house manufacturer or by an independent contractor?			
31	What type of contracts are in place for all decontamination equipment including, drying and storage equipment, ventilation and plant including water purification systems? Review			
32	Permit to work 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			
33	Who operates the permit to work system? (Give details] a) Estates department b) User c) AP(D)			
34	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 10 - Tracking/Traceability

	Observation	Evidence	Comments	Risk
35	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.			
36	How does the tracking and traceability system function and record if endoscopes are used at multiple end/user locations?			
37	Are endoscopes and reusable accessories stored and used together forming a unique set to allow accurate tracking and tracing (recommended)?			
38	How are loan endoscopes and accessories also tracked and traced?			
39	Does the traceability system relate patients to individual endoscopes and accessories?			
40	Is it possible to trace all the patients that have been in contact with a particular endoscope or reusable accessories?			

Section 11 - Training and education on decontamination equipment

	Question	Evidence	Comments
41	What training records are available for decontamination staff (including staff who undertake any part of the decontamination or handling of endoscopes)	Staff log books Continuing professional development	
42	Is there evidence of a structured induction, training and re-validation program for staff involved in decontamination using a competency assessment tool		
43	There is evidence that staff who undertake the daily and weekly testing of EWD(s) are trained and educated to meet national requirements.		
44	There is 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.		

	Question	Evidence	Comments
45	There is evidence of COSHH training for all decontamination staff.		
46	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 11 - Summary of review

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

Comments and any relevant observations from the audit review process.

a) EWD[s]	Comments including actions required or recommended
b) Storage cabinets	Comments including actions required or recommended
c) Environment and ventilation	Comments including actions required or recommended
d) Environment - Room layouts and general condition Including flows of endoscopes and staff	Comments including actions required or recommended
e) Infection Prevention issues – safety (COSHH, PPE) –equipment levels	Comments including actions required or recommended

Procedures and Training	Comments including actions required or recommended
Testing	Comments including actions required or recommended

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)
Comments and actions

Signature of AE(D)…… Dated……...