

Functional Area: \_\_\_\_\_ Start Date: \_\_\_\_\_ Overall Auditors: \_\_\_\_\_

Module: Operational Management

Date: \_\_\_\_\_ Auditors: \_\_\_\_\_

Standard: The infection risk associated with endoscopy is minimised through optimal decontamination

Observation: 1

Question Set: Operational Management – Management

	Question	Guidance	Yes	No	N/A	Comment
1	Are up to date infection prevention and control policies and guidelines available and accessible by staff? (77, 78, 82)	Check staff can access guidelines and that all documents are dated within the last two years. Also check that the following are included: Hand hygiene, personal protective equipment, sharps handling and disposal, decontamination of equipment, management of blood/body fluid spillage, waste management.				
2	Is there evidence that audits have been undertaken and practice changed to improve infection prevention? (14, 82)	Ask to see most recent audit and action plan. This must include endoscope decontamination and hand hygiene audits.				
3	Are there sufficient numbers of staff to ensure timely and safe reprocessing of flexible endoscopes?	Check staff rotas, risk assessments and risk register				
4	Is decontamination a standing item of the endoscopy user group meetings?	Check minutes & action plans.				
5	Is there reference to infection prevention and control in staff job descriptions? (82)	Ask to see staff job descriptions.				
6	Is there evidence of a process for reporting untoward incidents in relation to infection prevention and control? (77, 78, 82)	Ask to see incident records.				

Question Set: Operational Management – Policies, Procedures and Guidelines

	Question	Guidance	Yes	No	N/A	Comment
1	Prior to undergoing an endoscopic procedure are patients assessed for their risk of CJD and/or vCJD?	Answer should follow guidance set out in Annex J of DH TSE guidance.				
2	Is there a procedure for patients with Transmissible Spongiform Encephalopathy's such as sporadic Creutzfeldt–Jakob Disease (sCJD) and variant Creutzfeldt–Jakob Disease (vCJD)? (105, 106)	Local SOPs and Risk Assessments. Answer can include referring to the latest DH guidance (e.g. Annex F of DH TSE guidance).				
3	Is there a procedure for processing and recording loan endoscopes? (105, 106)	Check policies, records and traceability systems.				
4	Are systems in place to ensure infection prevention input is sought prior to purchase of equipment? (77, 78, 82)	Check policy/local procedure for purchasing new equipment. Check for evidence that infection prevention team has been consulted prior to purchase of any new equipment.				
5	If endoscopes are transported to another facility for decontamination are they moved in a rigid sealed container to prevent cross contamination? (105)	Check SOP/ask staff member to describe procedure and ask to see container.				

Module: Decontamination

Date: \_\_\_\_\_ Auditors: \_\_\_\_\_

Standard: The risk infection associated with endoscopy is minimised through optimal decontamination

Observation: 1

Question Set: Decontamination – Pre-Cleaning

	Question	Guidance	Yes	No	N/A	Comment
1	Are all channels flushed and external surfaces wiped with a detergent solution immediately after use? (105, 106)	Check SOP and observe practice.				
2	Is the endoscope protected from damage and environmental contamination when transferred to the decontamination area? (105, 106)	Check SOP and observe procedure.				
3	Are used internal channels kept moist during transportation to the decontamination facility? (105)	Check SOP and observe practice.				

Question Set Comments/Recommendations for Decontamination - Pre-Cleaning

Observation: 1

Question Set: Decontamination – Manual Cleaning

	Question	Guidance	Yes	No	N/A	Comment
1	Does decontamination of used endoscopes take place as soon as possible after use? (105, 106)	Check SOP and observe practice.				
2	Are all endoscopes subject to manual cleaning before placement in the EWD? (105, 106)	Check SOP and observe practice.				
3	Are all valves and detachable distal tips removed before cleaning? (105, 106)	Check SOP and observe practice.				
4	Is a leak test undertaken before manual cleaning and the result documented? (105,106)	Check SOP and record of endoscope maintenance.				
5	Are all valves and other re-usable items subject to manual cleaning? (105, 106)	Check SOP and observe practice.				
6	Is there a record of what action is taken when the leak test fails? (105, 106)	Check SOP and observe practice.				

## EDP-Gen

## Care Setting Process Improvement Tool: Endoscopy - Decontamination

	Question	Guidance	Yes	No	N/A	Comment
7	Is the endoscope carefully examined for damage before cleaning? (105, 106)	Check SOP and observe practice.				
8	Is manual cleaning carried out in a dedicated sink? (105, 106)	Check SOP and observe practice.				
9	Is an underwater technique used whilst performing a manual clean? (105, 106)	Check SOP and observe practice.				
10	Is the concentration and temperature of the diluted detergent measured and used in accordance with the manufacturer's recommendations? (105, 106)	Check SOP and observe practice.				
11	Is the detergent solution discarded after each use? (105, 106)	Check SOP and observe practice.				
12	Are all external surfaces cleaned? (105, 106)	Check SOP and observe practice.				
13	Are all accessible ports and channels brushed at least three times each during cleaning? (105, 106)	Check SOP and observe practice. This includes endoscopes with raiser bridge/elevator wire channels.				
14	Are all channels brushed and or flushed with detergent solution? (105, 106)	Check SOP and observe practice.				
15	Are the correct diameter single use size/length brushes and other cleaning devices available for all the endoscopes in use in the department? (105, 106)	Check SOP/manufacturer's instructions and then check availability.				
16	Are all brushes and other cleaning devices designated single use discarded after one use? (105, 106)	Check SOP and observe practice.				
17	Are there instructions available illustrating all the channels and decontamination procedures of all the endoscopes in use in the department? (105, 106)	Check user manuals and observe practice.				
18	Are the control wheels cleaned? (105, 106)	Check SOP and observe practice.				

## EDP-Gen

## Care Setting Process Improvement Tool: Endoscopy - Decontamination

	Question	Guidance	Yes	No	N/A	Comment
19	Is there evidence that the checks after manual cleaning are recorded to show the device is visually clean and undamaged? (105, 106)	Checklist and SOP's.				
20	Is there evidence that valves are visually clean before processing in an EWD? (105, 106)	Checklist and SOP's.				
21	Are endoscopes transferred to a separate sink for rinsing in fresh water post manual cleaning? (105, 106)	Check SOP and observe practice.				
22	Are all internal channels and external surfaces rinsed? (105, 106)	Check SOP and observe practice.				
23	Are endoscopes processed in the EWD within 3hrs of use?	Check SOP and tracking audits				
24	If endoscopes cannot be processed in the EWD within 3hrs of use has a risk assessment been undertaken?	Check for risk assessment				
25	If a scope irrigation system is used to aid manual cleaning processes is there a routine sanitization system in place to prevent internal bio- film formation? Are they tested for water quality	Check SOP and observe practice				

Question Set Comments/Recommendations for Decontamination - Manual Cleaning

## Question Set: Decontamination – Endoscope Re-processing and Use of AER

	Question	Guidance	Yes	No	N/A	Comment
1	Are endoscopes protected from environmental contamination when being transferred to the EWD? (105)	Observe practice and check SOP's.				
2	Is there evidence that biopsy valves are discarded after use particularly if breached? (106)	Check SOP and observe practice.				
3	Are detachable parts placed in a wire basket during EWD processing? (105, 106)	Cloth bags are not acceptable.				
4	Are the endoscope valves always matched with their associated endoscope? (105, 106)	Observe practice to identify how they are matched to the endoscope. Check evidence to support this.				
5	Are used gloves removed and hands decontaminated before unloading the EWD? (90, 105)	Observe practice. Moment 3 - After body fluid exposure				
6	Are the external surfaces of processed endoscopes dried before next use or storage? (105, 106)	Observe practice.				
7	Does the drying process exclude the use of alcohols? (105, 106)	Observe practice and check SOP.				
8	Are processed endoscopes transported in purpose built trolleys and containers if moved around the hospital? (105)	Observe practice.				
9	Are all surfaces of the trolleys and trays decontaminated between uses?	Observe practice and check SOP.				

Question Set: Decontamination – Accessories

	Question	Guidance	Yes	No	N/A	Comment
1	Are all accessories (apart from water bottles) single use unless there is no suitable alternative? (105)	Check SOP and observe practice.				
2	If reusable accessories are used does a single use alternative exist?	Check SOP and observe practice.				
3	If reusable accessories are used when single use alternatives are available is there a risk assessment illustrating why single use is not used?	Check SOP and observe practice.				
4	Are all reusable accessories reprocessed within the Sterile Services Department? (105)	Check SOP and observe practice.				
5	Is sterile water used in the water bottle? (106)	Check SOP and observe practice.				
6	Are water bottles reprocessed in the Sterile Services Department? (106)	Check SOP and observe practice.				
7	If disposable water bottles are used are they discarded at the end of each session?	Check SOP and observe practice.				

Question Set Comments/Recommendations for Decontamination - Accessories

Question Set: Decontamination – Tracking and Traceability

	Question	Guidance	Yes	No	N/A	Comment
1	Is there a robust tracking and tracing system that records each stage of decontamination, the persons involved, storage and subsequent patient use? (105)	Check traceability system, question staff, observe practice.				
2	Does the system still function if endoscopes are used at multiple locations?	Check SOP and observe practice.				
3	Are endoscopes and reusable accessories kept and used together forming a unique set to allow accurate tracking of usage? (105, 106)	Check traceability system, question staff, observe practice.				
4	Are loan endoscopes also tracked and traced? (105, 106)	Check SOP and observe practice.				
5	Does the tracking system relate patients to individual endoscopes? (105, 106)	Check traceability system and sample of patient notes.				
6	Is it possible to track back all the patients that have been in contact with a particular endoscope and re-usable accessories? (105)	Check traceability system - how long can you trace back?				
7	If an electronic system is used, is the tracking system data backed up? (105)	Check traceability system.				

Question Set Comments/Recommendations for Decontamination - Tracking and Traceability



Question Set: Decontamination – Endoscope Storage

	Question	Guidance	Yes	No	N/A	Comment
1	Are stored endoscopes protected from environmental contamination? (105)	Check where endoscopes are stored.				
2	Are processed endoscopes used within 3 hours of processing? (105)	Observe practice, check machine records and drying cabinet records.				
3	If endoscopes are used after the validated storage time has a risk assessment been carried out? (105)	Check risk assessment.				
4	Is the drying cabinet (if used) operated according to the manufactures instructions? (105)	Observe practice, check SOP and manufacturer’s instructions.				
5	Is the endoscope stored with the valves removed? (105)	Observe practice and check SOP.				
6	Are processed endoscope valves stored with the associated endoscope? (105)	Observe practice.				
7	Are endoscopes with wired channels/raiser bridges excluded from drying cabinets unless a dedicated connector is available? (105)	Observe practice.				
8	Is there documentary evidence of storage cabinet maintenance (if used)? (105)	Reports/Maintenance file.				

Question Set Comments/Recommendations for Decontamination - Endoscope Storage

Question Set: Design and Layout of the Decontamination Room - Decontamination Room

	Question	Guidance	Yes	No	N/A	Comment
1	Does decontamination take place in a separate dedicated decontamination room? (105, 106)	Observe practice				
2	Are there clear and separate areas for clean and dirty procedures i.e. no cross over? (105)	Observe practice.				

## EDP-Gen

## Care Setting Process Improvement Tool: Endoscopy - Decontamination

	Question	Guidance	Yes	No	N/A	Comment
3	Is the environment visibly clean? (15, 20, 52, 53, 80, 84, 86)	Check walls, windows, ceilings, fans and light fittings are free from dust/debris/insects etc.				
4	Is the environment free from any visible damage? (20, 53, 77, 80, 84, 85, 95)	Check for flaking paint, damaged walls/ceilings/window frames and surfaces. Check for evidence of action taken to repair.				
5	Is there a clear one way flow from dirty to clean? (105)	Visually check.				
6	Are all surfaces resistant to chemicals and easily cleanable? (53)	Visually check for damage.				
7	Is there sufficient storage space for the storage of all equipment? (106, 108)	Check that all equipment is stored appropriately.				
8	Are chemicals stored in a contained manner to prevent spillage and allow ease of environmental cleaning?	Visually check.				
9	Are there suitable facilities for manual cleaning? (105)	I.e. Sinks of adequate size and depth to accommodate endoscopes?				
10	Is there a designated hand wash basin? (15, 53, 80, 82, 90)	Visually check.				
11	Is the hand wash basin plug free? (15)	Check the hand wash basin does not have a plug.				
12	Is the hand wash basin overflow free? (15)	Check the hand wash basin does NOT have an overflow.				
13	Is the waste offset so the water does not flow directly into it? (15)	Check the water from the tap does NOT flow directly into the plug hole.				
14	Are elbow/sensor taps available? (15)	Visually check.				
15	Are mixer taps or thermostatically controlled water available? (15)	Test water temperature.				
16	Is the hand wash basin appropriately located? (53, 80)	Check for obstructions e.g. equipment.				

	Question	Guidance	Yes	No	N/A	Comment
17	Is the hand wash basin in a good state of repair? (15)	Check there are no cracks or chips.				
18	Is the hand wash basin visibly clean? (52, 84)	Check plugholes and overflows for cleanliness & build up of limescale.				
19	Are hand wash basins free from extraneous items? (53)	e.g. mugs, medicine pots etc.				
20	Is the soap dispensed from a single use cartridge? (53, 80, 90, 92, 94)	Check cartridge, there should be enough soap for the next two uses.				
21	Is the soap dispenser visibly clean? (90)	Check the nozzle for build up of soap and debris.				
22	Are paper towels available from an enclosed dispenser? (53, 80, 90)	Paper towels should be soft tissue with enough in the dispenser for the next two washes.				
23	Is the paper towel dispenser visibly clean? (90)	Check underside of dispenser.				
24	Is there a promotional hand hygiene poster displayed? (90)	Check for poster. It should be laminated, clean and relevant to the room.				
25	Is alcohol hand rub available? (90)	Visually check.				
26	Are alcohol based hand rub dispensers visibly clean? (90)	Check there is no build up on the nozzle. The dispenser should be functioning with enough solution in the dispenser for the next two uses.				
27	Are sharps disposed of safely and at the point of use? (20, 81)	Observe practice or ask a member of staff to describe procedure. Also check that clean trays/bins are available and are compatible with the bins in use.				
28	Are there comprehensive written cleaning standards and procedures? (85, 86)	Check cleaning schedules; ensure responsibility for cleaning all areas is clearly identified.				
29	Is the floor visibly clean? (20, 52, 84, 85, 86)	Check the edges and corners are clean and free of dust and grit.				
30	Is the floor covering washable and impervious to moisture? (20, 53, 80, 84)	Is the floor covering appropriate for the room.				
31	Is the flooring in a good state of repair? (52, 53)	Check for rips and tears.				

Module: Design and Layout of the Decontamination Room

Date: \_\_\_\_\_ Auditors: \_\_\_\_\_ Room: \_\_\_\_\_

Function: Decontamination Room

Standard: The risk infection associated with endoscopy is minimised through optimal decontamination

Observation: 1

Design and Layout of the Decontamination Room – Decontamination Room

	Question	Guidance	Yes	No	N/A	Comment
32	Are all work surfaces smooth, impervious, with covered edges to facilitate easy cleaning? (20, 53, 80, 84)	Check all work surfaces.				
33	Are all work surfaces intact and in a good state of repair?	Visually check.				
34	Are all work surfaces free from clutter?	Visually check.				
35	Is there adequate lighting to allow good visibility? (108)	Visually check.				
36	Is there a hands-free domestic waste bin available for the disposal of paper towels? (53, 56, 80)	Visually check.				
37	Is the foot pedal of the domestic waste bin in good working order? (53, 80)	Check the foot pedal opens the lid.				
38	Is the domestic waste bin visibly clean, including lid and pedal? (23, 85, 86)	Check bins are clean externally and internally.				
39	Is the domestic waste bin in good condition? (23, 85, 86)	Check for rust i.e. underneath lid.				
40	Are blinds visibly clean? (52, 84, 85, 86)	Check curtains and blinds.				
41	Is personal protective equipment available? (20)	Check for gloves, aprons and eye protection.				

Question Set Comments/Recommendations for Design and Layout of the Decontamination Room - Decontamination Room

Module: Endoscopy Staff

Date: \_\_\_\_\_ Auditors: \_\_\_\_\_

Standard: The infection risk associated with endoscopy is minimised by staff being appropriately trained and the risks to staff are assessed and staff are appropriately protected.

Question Set: Endoscopy Staff - Staff Training

	Question	Guidance	Yes	No	N/A	Comment
1	Is there evidence that all staff undertaking decontamination have received decontamination competency based training? (105, 106)	Check personal file/PDP/training records/DOPS				
2	Do staff receive training at induction and at regular intervals? (105)	Check Induction package/Manufacturers certificate/training records.				
3	Do the topics covered include at the minimum: Design and construction of endoscopes. Use and maintenance of EWDs. Tracking and traceability systems. Record keeping. Use of personal protective equipment (PPE)/H&S. Principles of decontamination (106)	Course notes or programme/e-learning/PDP/Manufacturers Certificate				
4	Is there evidence that the designated user has undergone training on their roles and responsibilities relating to endoscope decontamination? (105)	Check training record				

## Question Set: Endoscopy Staff - Staff Safety

	Question	Guidance	Yes	No	N/A	Comment
1	Are spillage kits or alternative available for use on body fluid spillages? (20, 60, 84)	Kit: Check expiry date and that it contains a brush/scrapper. Alternative: Check expiry of hypochlorite.				
2	Is personal protective equipment available? (20)	Check for gloves, aprons and eye protection.				
3	Is personal protective equipment worn as indicated in the infection prevention and control policy? (20)	Observe practice.				
4	Is clinical waste safely contained? (23)	Observe practice.				
5	Are there eye wash facilities available throughout the department? (105)	Check for facilities.				
6	Are in use sharps containers safely positioned and out of reach of vulnerable people? (20, 81)	Check bins are not stored in an open access area and are positioned at a safe height.				
7	Are suction bottles/containers safely disposed of according to local policy on healthcare waste? (23)	Observe practice.				
8	Is there a policy on staff exclusion from work with regards to infection prevention? (47, 48, 77, 78, 82)	Check policy. Check staff are aware of the need to remain off work for 48 hours after resolution of illnesses such as diarrhoea/vomiting/Group A Streptococcal infection.				
9	Are staff aware of the procedure for managing an inoculation contamination injury? (20, 81)	Ask two members of staff to describe the procedure.				
10	Do occupational health policies require staff to be offered immunisation in line with current national guidance? (39, 45, 48, 77)	Randomly select two members of staff and ask whether their immunisation status has been assessed.				
11	If required do all staff handling chemicals have access to an occupational health department (106)	Staff records, SOPs, occupational health (OH) records, risk assessments.				