NHS

National Endoscopy Programme

Decontamination Standards for Flexible Endoscopes

Updated March 2008

Introduction

Providing an effective endoscope decontamination service within a safe environment is an essential requirement for every endoscopy unit in England. (DoH Health Act, 2006) The guidance and standards for decontamination practice are available in various forms, from a number of agencies. In response to requests from the service, the NHS National Endoscopy Programme established a working group to design a quality assurance tool that would encompass all the decontamination standards in a format which would be relevant to the end users. This tool should be used by endoscopy teams to self assess their decontamination environment and processes against national standards.

This document has been developed to support the safety item of the Global Rating Scale (GRS) and is used to assess local practice as part of the JAG Accreditation process. The document is based on the BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy 2008.

The document should be used as the basis for departmental policy and procedure documentation which will need to be produced as evidence during external assessments together with other forms of evidence outlined in the document.

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This document has been developed in consultation with the BSG, NHS and Industry.

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DECONTAMINATION STANDARDS FOR FLEXIBLE ENDOSCOPES

	Evidence	Yes	No	Action Plan
Operational Management				
Written procedures for decontamination of endoscopy equipment are available and reviewed every 2 years.				
Nominated decontamination lead at Trust board level.	Organisational structure Interview with Trust Lead			
Operational decontamination manager who has (i) clear line management; (ii) representation on Trust committee whose remit includes decontamination; and (iii) ability to act on any concerns regarding decontamination practice from endoscopy personnel	Trust decontamination policy			
Overall decontamination training lead attached to the endoscopy unit.	Interview with Unit Lead			
Involvement from the infection control department and a named microbiologist in managing and maintaining the service.	Interview with Infection Control			
Decontamination matters regularly discussed in Endoscopy User Group meetings.	Endoscopy User Group agenda / minutes			
A record of adverse incidents and evidence of appropriate action taken.	Adverse incident book and action plans			
Evidence of bi-annual audits of decontamination processes and action taken.	Audits and action plans			
Evidence of annual Trust audit on decontamination processes and action taken presented to Trust Board.	Audit and action plans			
There is evidence that detergents, disinfectants, endoscopes, Automated Endoscope Reprocessing machines (AER) and disinfectant generators are used in accordance with the manufacturers' guidelines.	Records of staff training			
There is evidence of document control for standard operating procedures.				
There are written procedures for out of hours emergency endoscopy to ensure that it only occurs if there is someone available who is trained in endoscope decontamination.	Out of hours protocol Training & Assessment record			

	Evidence	Yes	No	Action Plan
Environment, design and layout				
There is a: (i) designated and dedicated decontamination area (ii) separate dirty, clean and storage areas (iii) one-way flow for equipment.				
There is adequate ventilation and extraction in place to protect staff, patients and the public from exposure to hazardous substances.	Estates records			
There is a double sink for the washing and rinsing of endoscopic equipment within the decontamination area which is sufficient to meet required capacity and throughput.				
Sinks should be: (i) of adequate size to ensure manual cleaning is car ried out effectively and (ii) positioned to minimise the risk of occupational injury				
There is a dedicated hand washing basin that is used in the decontamination area.				
Safety				
Endoscopy decontamination areas should be designed to ensure an effective and efficient service that does not harm staff, patients or the public.				
There is evidence of COSHH risk assessments.	Risk assessments			
Units should have evidence of their risk assessment for the use of Personal Protective Equipment				
All staff involved in decontamination have access to and wear appropriate personal protective equipment including full face visors, single-use gloves and aprons.	Staff interviews			
During manual cleaning, forearms should be protected.				
Staff must wear protective equipment as instructed by the manufacturers' when mixing and loading chemicals into the AER.				

	Evidence	Yes	No	Action Plan
Respiratory protection is employed against chemical and microbial hazards in line with COSHH assessments.				
Health surveillance for staff should be considered, in consultation with occupational health departments for exposures to disinfectants that are not aldehydes or chlorine-releasing agents or other strong irritants. If agents similar to glutaraldehyde are used, then health surveillance should be carried out.	OH policy Staff interviews			
There is a policy and equipment available for spillages; chemicals, detergents, body fluids.	Spillage policy Site visit			
In the event of the inability to provide an automated decontamination system, the endoscopy activity must cease until the automated process is regained. Manual disinfection and rinsing are not acceptable.	Evidence of action taken Staff interviews			
A procedure must be in place for the safe and proper disposal of any residual chemicals, either residual container quantities or quantities beyond their expiration date, used in the endoscopy reprocessing area. The procedure should include disposal guidelines according to the nature of the detergent or disinfectant, and should specify who is responsible for such disposal.				
Staff Training				
There is evidence of a structured induction, training and re-validation programme for staff involved in decontamination using a competency assessment tool.	Competency Training package			
There is evidence of mandatory training records eg. manual handling. The Decontamination E-learning training package is used as part of a decontamination training package. www.decontamination.nhs.uk	Training records			
Training programmes are based on: Competence 21 of the national endoscopy competence framework and; Competencies 1 to 6 of the Decontamination Competence Framework. Competence is measured and documented using an assessment framework. www.skillsforhealth.org.uk	Training programmes/ assessment records			
Training programmes should include: • identification of individual endoscopes and all				

	Evidence	Yes	No	Action Plan
associated channels • design and function of endoscopes • theory on decontamination, microbiology, detergents, disinfectants and AERs • health & safety and infection control • knowledge and skills assessment on assembly and dismantling of scopes, pre-cleaning, manual cleaning, reprocessing accessories and ancillary equipment, disinfection and use of the AER, drying, transportation, storage, tracking/traceability, maintenance, testing and validation.				
There is evidence of COSHH training.	Training records			
There is evidence of staff training from the manufacturers of AERs and generators.	Training records			
Instructions for decontamination processes including Top Ten Tips from MHRA are visually displayed.				
Up-to-date manufacturers' (endoscope, AER and chemical) instructions and departmental policies are easily accessible.				
There is evidence that staff who undertake testing and validation of AERs are trained.	Training records			
Stages of endoscope decontamination				
Decontamination of endoscopes is undertaken at the beginning and end of each list, and between patients, by trained staff in a dedicated room.				
There is evidence that Trusts have undertaken a risk assessment as to the need for manual cleaning and automatic disinfection before endoscopes are used at the start of each day.	Risk assessment			
All endoscopes have a record of their decontamination status such that they are fit for use on patients.	Tracking system			
Preliminary cleaning				
Endoscope channels are flushed immediately following the procedure and the external surfaces socially cleaned, ideally by the endoscopist.				
An air/water flushing valve is used in endoscopes with combined air/water channels.				

	Evidence	Yes	No	Action Plan
Channels are checked for patency during this process.				
Endoscopes are transported to the decontamination area in a covered receptacle that is of an appropriate size so as to avoid contaminating the environment.				
Manual Cleaning				
Endoscope valves and detachable distal tips are removed from the endoscope prior to manual cleaning.				
Endoscopes are leak tested and inspected for damage prior to manual cleaning.				
Manual cleaning is carried out in a dedicated sink and is filled with water to an identified level to ensure correct detergent concentration and temperature in accordance to manufacturers instructions. Detergent and water solutions are discarded after each use.				
A low–foaming enzymatic detergent which is endoscope compatible is used at the appropriate dilution and temperature according to manufacturers' guidelines.	Data sheets			
All accessible channels and ports are brushed with a purpose-built single-use cleaning device at least 3 times each using a correct size device for that channel ensuring the cleaning device is visibly clean at the end of the process				
Channels are cleaned as recommended by the manufacturer.				
All auxiliary water channels, exposed elevator wire channels and balloon inflation channels in endoscope ultrasound probes are cleaned as per the manufacturers' guidelines, even if they have not been used.				
The external surfaces of the endoscope are cleaned according to manufacturers' instructions. Particular attention is given to the control wheels.				
There is evidence that visual checks are made to ensure endoscopes are visually clean and not damaged.	Log book/ tracking system			
Endoscopes are transferred to a sink, separate to that used for manual cleaning, for rinsing to remove residual detergent.				

	Evidence	Yes	No	Action Plan
Endoscopes are transferred to the AER in an appropriately sized receptacle so as to avoid contamination of the environment.				
Valves and detachable parts				
Biopsy caps are discarded after all procedures involving the passage of accessories through the endoscope.				
The surfaces and lumens of reusable valves and detachable parts are cleaned using a purpose-built single-use cleaning device and rinsed with clean water prior to processing in the AER. (The practice of ultrasonic cleaning of valves in batches should be abandoned.)				
Visual checks are made to ensure valves are visually clean and not damaged.				
Reusable valves should be decontaminated in accordance with manufacturers' instructions and processed with their corresponding endoscope.				
Valves including flushing valves and removable parts are kept with the endoscope to form a unique set of equipment.				
Disinfectants				
It is not considered acceptable to use Glutaraldehyde for endoscope disinfection in the United Kingdom.				
The chemical used is CE marked and is compatible with all endoscopes, their accessories and the AER and used at the correct temperature, concentration and contact time as recommended by the manufacturer throughout the decontamination process.	Data sheets			
Single use disinfectants are preferable. If this is not practicable then there is a means to ensure that the automatic cycle will not start when the disinfectant concentration has fallen to, or below, the minimum recommended by the manufacturer or established by independent testing with test strips/kits to assess the efficacy of the solution and ensure optimal activity of the product.	Site visit AER manual			

	Evidence	Yes	No	Action Plan
There is a log of disinfectant batch numbers and expiry dates.	Log book			
Loan endoscopes are compatible with the disinfectants used in the unit.				
Automated Endoscope Reprocessing machines (AER)				
AERs are used for all endoscope decontamination following manual cleaning. Manual disinfection is not acceptable.				
Use only validated processes following guidance from Department of Health HTM-01 (2008) Decontamination of reusable medical devices; BS EN ISO 15883-1 (2006) Washer disinfectors – Part 1: General requirements, terms and definitions and tests; MHRA Device Bulletin DB2002(05) Decontamination of endoscopes; and Microbiology Advisory Committee Manual on Decontamination. www.dh.gov.uk www.mhra.gov.uk				
All endoscopes within the department can be processed in an AER.				
AERs should be compliant to HTM-01 /ISO 15883 standards and have: (i) individual channel irrigation and monitoring (ii) verification of channel connection (iii) lockable lids (iv) ability to physically separate scopes if reprocessing simultaneously (v) a hard copy or electronic method of verification that the cycle is complete (vi) appropriate fume extraction. (vii) ability to indicate when detergent/disinfectant containers require replacement (viii) ability to irrigate all channels including auxiliary and raise wire channels (ix) ability to undergo self disinfect cycle	AE(D) Certificate*			
All endoscopes are reprocessed using an AER with the appropriate connections to ensure irrigation of all channels. Staff must ensure that all channels including auxiliary and raiser wire channels are connected to the AER prior to starting the cycle.	Visual displays			
All AERs and associated water treatment systems should undergo a self disinfect cycle at the beginning of each day. This should be with a chemical different from that used for endoscope disinfection. Heat may be used. There is a	Log book			

	Evidence	Yes	No	Action Plan
means to indicate to staff that this cycle has taken place and evidence that records are retained.				
There are procedures in place for automatic reprocessing of endoscopes that have been used in patients at risk of vCJD.				
These include: (i) single use disinfectant (ii) avoiding simultaneous endoscope reprocessing in dual chamber AERs (iii) extra rinse cycle after endoscope removal (iv) solid waste including AER outlet strainers or tissue to be disposed of by incineration				
Department of Health: Annex F (2004) www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=24000&Rendition=Web Department of Health: Annex J (2006) http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/tseguidance_annexj.pdf				
Detergents used within the AER are used in accordance to their validated efficacy, compatibility and toxicity data as part of the overall process.	Data sheets AER instructions			
Connectors are inspected prior to removal of the endoscope on completion of the cycle to confirm all channels have been irrigated.				
Verification that the cycle was successful and complete is obtained from the print out or via electronic means prior to removal from the AER.	Tracking records			
Bacteria free water is used for the final rinse of the decontamination cycle.				
External surfaces of the endoscope are dried and the scope then either stored immediately in a suitable cabinet or transported individually in a covered receptacle to prevent recontamination or damage.				
When transporting endoscopes to and from areas outside the endoscopy unit, endoscopes are transferred in a receptacle with a hard lid that completely encloses the endoscope.				

	Evidence	Yes	No	Action Plan
Storage				
Endoscopes are stored so that residual fluid does not remain in the channels.				
They should be protected from the risk of environmental contamination.				
Endoscopes are stored, with their detachable parts having been dismantled, in a manner that ensures security of the items and keeps components together as a unique set.				
Endoscopes should be reprocessed if more than 3 hours has elapsed from the last decontamination process unless a risk assessment states otherwise.	Tracking records Risk assessment			
If drying cabinets are used, operational procedures (eg. verification of filtered airflow, out of hours use) should be in place.	Log book			
Drying cabinets are used in accordance with manufacturers' guidance.				
Patient Traceability				
Tracking of the decontamination cycle, personnel and patient association of each endoscope is undertaken using manual or electronic methods.	Tracking system and data collected			
Each endoscope has a unique identification code and there is a system in place to track loan scopes.	Records of loan scopes			
Each step of the decontamination cycle is recorded including the name of the person undertaking each step and is directly associated to individual patient use.	Tracking records			
A record of the decontamination process is recorded in the patient's notes. If a printout from the AER is used, this must be used in conjunction with a log book.				
The tracking system is evaluated to assess its effectiveness twice a year.	Audits and action plans			
There is a means of tracking the use of reusable endoscopy accessories to individual patient use.				

	Evidence	Yes	No	Action Plan
Valves and removable parts are kept with the endoscope to form a unique set of equipment.	Tracking system			
Accessories				
Single use cleaning devices should be used for manual cleaning.				
Single use biopsy forceps should be used for all procedures.				
All other accessories should be single use unless no suitable alternative is obtainable.	Staff interviews			
Reusable accessories that can be autoclaved are inspected, manually cleaned, packed appropriately and sent to the SSD for sterilisation. Checks are in place to ensure that the item is fit for use on return to the unit.				
All accessories, whether marketed as reusable or single-use, should be disposed of by incineration after use in patients at risk of vCJD.				
There is evidence that a risk assessment involving the Infection Control department has taken place for reusable items that cannot be autoclaved.	Risk assessments			
Water bottles are manually cleaned and sent to the SSD for sterilisation as per the manufacturers' instructions.				
Water bottles are changed after each endoscopy session.				
Sterile water is used in the water bottle.				
Maintenance				
There is documented evidence of planned and unplanned maintenance for endoscopes, AERs, disinfectant generators, water treatment systems and storage cabinets according to manufacturers' instructions.	Service history			
All AERs are under a service contract	Service contracts			
A schedule of maintenance and disinfection of any water purification system should be specified. Records of periodic sanitization should be kept.	Maintenance programme			

	Evidence	Yes	No	Action Plan
Testing and Validation				
There is evidence that AERs have been validated on installation in accordance with the recommendations described in HTM-01.	AER records			
AERs are revalidated following the introduction of a new disinfectant.				
A designated trained person is responsible for undertaking/ organising daily, weekly, quarterly and yearly testing in accordance with HTM-01 www.grs.nhs.uk (Knowledge Management System)	Training records			
A designated person is responsible for auditing test data obtained and implementing remedial action if required. An action plan for remedial action should be available.	Test data Action plan Testing records Action plans			
Testing is carried out in conjunction with the Estates department and a record of results is retained in the unit.	Log book			
There is evidence of weekly testing of the final rinse water for bacterial counts, and of annual testing for atypical mycobacteria. Where water tests have fallen below accepted standards there should be evidence that an action plan has been implemented.	Record of test results/ action plans			
An action plan, compiled in conjunction with the infection control department, is available which describes the action to be taken in the event of failed water tests.	Action plan for failed tests			
Procurement				
There is evidence that the Trust's Authorised Engineer (Decontamination) (AE(D)) is involved in the acquisition of Automatic Endoscope Reprocessors (AER) and other relevant decontamination equipment; together with the endoscopy users, Infection Control and Health & Safety departments, the decontamination manager and decontamination lead.	Asset register Interview Decontamination Lead			
There is a planned programme for replacement endoscopy and decontamination equipment.				

* AE(D) – Authorised Engineer (Decontamination)

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