PART 4: RECOMMENDED PRACTICES FOR ENDOSCOPY UNITS

Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices

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Part 4
Recommended Practices for Endoscopy Units

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1 Facility design

1.1 Introduction

The reprocessing of endoscopes should take place in a designated and controlled area. This improves the efficiency of the decontamination process, minimises contamination and provides a safe working environment.

1.2 Scope

The objective of this procedure is to outline the principles of a safe working environment for decontamination of endoscopes.

1.3 Contents

Section One: Unit design

Section Two: Lighting and electricity

Section Three: Ventilation

Section Four: Temperature

Section Five: Walls, floors and ceilings

Section Six: Sinks

Section Seven: Workstations, furniture, shelving and equipment

Section Eight: Storage facilities

Section Nine: Restricted entry

1.4 Procedure

Section One: Unit design

- Endoscope decontamination should be performed in a designated endoscope reprocessing unit.
- The unit should be physically separated from all other work areas including patient treatment areas.
- The unit should be designed to allow segregation of 'dirty' and 'clean' activities.
- The design should facilitate a uni-directional work flow from the 'dirty' area (receipt of contaminated endoscopes) to the 'clean' area (inspection, drying and storage of decontaminated endoscopes).
- Changing, shower and toilet facilities and lockers should be provided in proximity to the decontamination area.

Section Two: Lighting and electricity

- There should be sufficient electricity supply points, computer terminal points and work stations in the endoscope decontamination unit.
- There should be adequate task lighting to allow the visual inspection of endoscopes, accessories etc.

Section Three: Ventilation

- There should be adequate ventilation and extraction in place to protect staff and third parties from exposure to hazardous substances.
- The configuration of the room and the ventilation system will depend on the choice of automated endoscope reprocessor (AER).
- The preferred configuration is for separate rooms for 'dirty' and 'clean' activities with a pass-through AER installed within the wall between the 'dirty' and 'clean' rooms.

Section Four: Temperature

- Temperature should be controlled within a range of 18°C - 22°C.

Facility design

Section Five: Walls, floors and ceilings

- The finishes on walls and other surfaces should be smooth, water resistant and able to withstand frequent cleaning.
- The junctions between walls, floors and ceilings should be coved and flush.
- The floors should be covered in a washable non-slip sheet material which should be adequately sealed.

Section Six: Sinks

- There should be two separate sinks within the unit; one for washing and one for rinsing the washed endoscopes and accessories.
- The sinks should be of sufficient size to permit immersion of the endoscopes.
- There should be adequate put down spaces alongside and between the sinks.
- There should be a dedicated wash hand basin for hand hygiene within the unit.

Section Seven: Workstations, furniture, shelving and equipment

- The area should be free from opening windows.
- The work surfaces should be smooth and have impact resistant surfaces which are impermeable, water resistant and able to withstand frequent cleaning.
- The furniture and fittings should be made from non-shedding materials.
- The shelving and equipment used for holding raw materials and finished products should be designed to allow adequate protection and accommodation for the goods to prevent contamination or deterioration.

Facility design

Section Eight: Storage facilities

- Adequate space should be provided for drying and storing of decontaminated endoscopes. This space should be independent of the area used to hold 'dirty' scopes awaiting decontamination. The decontaminated endoscopes should be stored hanging vertically in a designated dry and well ventilated cupboard.
- There should be a locked, flameproof cupboard for storage of hazardous chemicals.
- Storage facilities for bulk items should be provided external to the decontamination area.
- Required personal protective equipment should be easily accessible in the work area.

Section Nine: Restricted entry

- The area should be managed by dedicated, trained staff.
- Entry to the decontamination area should be restricted to authorised personnel only.

2 Procurement

2.1 Introduction

Procurement includes all activities from requisition, through payment, to disposal and should be the responsibility of all staff involved in the process. All staff engaged in procurement-related actions are required to familiarise themselves with all relevant regulations. Any procurement undertaken must meet the terms of the Health Service Executive procurement policy.

2.2 Scope

The objective of this procedure is to provide guidelines on the procurement of decontamination equipment, endoscopes and ancillary materials.

2.3 Contents

Section One: Specialist group

Section Two: Procurement policy

Section Three: Decontamination assessment

Section Four: CE marking

Section Five: Value for money

Section Six: Prior to use

Section Seven: Asset register/inventory

Section Eight: Maintenance

2.4 Procedure

Section One: Specialist group

- The organisation should have a specialist group in place to consider the procurement of endoscopes and their accessories.
- Key representatives on the specialist group should include:
  - i. Decontamination Coordinator
  - ii. Endoscopy Clinical Staff
  - iii. Endoscope Decontamination Unit Staff
- And where appropriate should also include:
  - i. Infection Prevention and Control Personnel
  - ii. Quality and Risk Management
  - iii. Bio-medical Engineering/Clinical Engineering/Medical Physics
  - iv. Materials Management
  - v. Finance Holder/Budget Holder/Business Manager
  - vi. Other relevant experts (Qualified Person (Decontamination), Microbiologist)
  - vii. Health and Social Care Professional Representative

Section Two: Procurement policy

- The organisation should have a documented procurement policy.
- Goods and services should be purchased from suppliers in line with HSE procurement policy.
- There should be a detailed specification for each endoscope which should include the type, model number and design features relevant to the decontamination of each endoscope.
- The endoscope specifications should be available in the endoscope decontamination unit.
- The procurement of endoscopes and accessories should be based on agreed specifications and should comply with documented procurement policy.
- Whenever possible, only single-use biopsy forceps should be purchased.

Procurement

Section Three: Decontamination assessment

- A decontamination assessment should be undertaken prior to purchase of reusable endoscopes to:

  i. Ensure that the organisation has the facilities to decontaminate the endoscopes in accordance with the manufacturers' instructions.

  ii. Verify that the endoscopes and their accessories are compatible with the process chemicals used for decontamination.

- Where the decontamination instructions for new equipment are not consistent with existing departmental decontamination procedures, a new procedure should be produced and endoscopy staff trained as necessary.

- Where practicable, single-use components and accessories should be used. Where re-usable accessories are used they should be capable of being sterilised by steam.

- Where parts are single-use or have restricted use, this information should be provided prior to purchasing.

Section Four: CE Marking

- The endoscope and accessories should be CE marked as this will constitute the manufacturer's assurance that the device will be safe and will perform as intended.

Section Five: Value for Money

- Value for money issues should be considered when purchasing endoscopes and accessories.

Section Six: Prior to use

- The endoscope should undergo a full decontamination process prior to use.

Procurement

Section Seven: Asset Register/Inventory

- Sufficient endoscopes should be available to allow adequate time for reprocessing in the endoscope decontamination unit without requiring 'shortcuts' to be taken in the decontamination process or adversely affecting clinical throughput.
- The organisation should maintain an asset register or inventory of all endoscopes. This should include details of the type, model number and design features relevant to the decontamination (e.g. number and type of channels) of each endoscope.
- Records should be kept of endoscopes sent for service and repair and of endoscopes received on loan (whether from the manufacturer or another organisation) and on service exchange.

Section Eight: Maintenance

- There should be documented evidence of planned and unplanned maintenance for endoscopes.
- Preventive maintenance should be planned and performed in accordance with the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

3 Decontamination equipment

3.1 Introduction

The decontamination unit should be equipped in accordance with the guidance on decontamination equipment in the HSE Code of Practice for Decontamination of RIMD, 2007. All decontamination equipment should be procured, validated, periodically tested, monitored and maintained to current standards.

3.2 Scope

The objective of this procedure is to outline recommended practices in relation to the equipment required in the endoscopy unit and the validation and maintenance of this equipment.

3.3 Contents

Section One: Equipment and consumables

Section Two: Specialist group

Section Three: Procurement policy

Section Four: General principles

Section Five: Testing

Section Six: Validation

Section Seven: Monitoring and control

Section Eight: Maintenance

3.4 Procedure

Section One: Equipment and consumables

- Disposable cleaning brush (similar to tooth brush).
- Disposable syringe (or adaptor mounted on water tap) for flushing inaccessible channels e.g. air/water.
- Cotton buds.
- Valve cleaning brushes.
- Channel cleaning brushes – single-use.
- Automatic Endoscope Reprocessor (AER).
- Endoscope connectors for use in AER.
- Ultrasonic cleaner.
- Purified rinse water.
- Process chemicals (Detergents and Disinfectants).

Section Two: Specialist group

- The organisation has a specialist group in place to consider the procurement of AERs.
- Key representatives on the specialist group should include:
  - i. Decontamination Coordinator
  - ii. Bio-medical Engineering/Clinical Engineering/Medical Physics
  - iii. Endoscope Decontamination Unit Staff
- And where appropriate should also include:
  - i. Infection Prevention and Control Personnel
  - ii. Quality and Risk Management
  - iii. Materials Management
  - iv. Endoscopy Clinical Staff
  - v. Finance Holder/Budget Holder/Business Manager
  - vi. Other relevant experts (Qualified Person (Decontamination), Microbiologist)
  - vii. Health and Social Care Professional Representative.

Decontamination equipment

Section Three: Procurement policy

- The organisation should have a documented procurement policy.
- There should be a detailed specification for each automated endoscope reprocessor (AER) which includes the type, model number and design features relevant to the decontamination of the types of endoscope used.
- The AER specifications should be available in the endoscope decontamination unit.
- The procurement of AERs and accessories should be based on agreed specifications and should comply with documented procurement policy.
- Goods and services should be purchased from suppliers in line with HSE procurement policy.
- All ancillary materials and components should be fit for their intended use.
- All process chemicals should be fit for their intended use.

Section Four: General principles

- There should be sufficient AERs to meet the needs of the endoscope decontamination unit.
- AERs are of two principle types; endoscope washer-disinfectors (EWD) and liquid chemical disinfectors (LCD).
- The use of an endoscope washer-disinfector (EWD) is strongly recommended as the best practice method.
- EWDs provide process stages designed to clean and disinfect flexible endoscopes. Requirements for EWDs are specified in ISO/FDIS 15833-4.
- LCDs provide process stages to disinfect flexible endoscopes that have previously been cleaned manually. Prior to the disinfection stage the LCD may provide a rinse stage to ensure that residues from manual cleaning have been removed and to wet the surfaces to be disinfected.
- Both EWDs and LCDs may provide:

  i. A leak test facility to verify the integrity of the endoscope before the admission of water, cleaning solutions or disinfectant solutions.

  ii. A purging stage after the post-disinfection rinse to ensure that the channels are cleared of water.

  iii. A drying stage to dry the channels and the outer surfaces of the endoscopes.

Decontamination equipment

- Whichever type of automated endoscope reprocessor (AER) is used, manual cleaning should be done first in accordance with the endoscope manufacturers' instructions. The lumens of the endoscope channels may be too narrow to permit a sufficient flow of water or detergent solution to ensure the removal of all soiling if the channels are not cleaned of debris by brushing.

Figure 3-1 Automated Endoscope Reprocessor (AER)

Decontamination equipment

Section Five: Testing

- The automated endoscope reprocessor (AER) should be subjected to a planned programme of testing both before delivery and on-site.
- Data from the tests and checks carried out during manufacture of the AER should be supplied with the AER.
- The data supplied with the AER should include microbiological validation of the process and should define the disinfectant concentration, contact time and the minimum and maximum temperatures. These data may be provided either by the AER manufacturer or the disinfectant manufacturer.
- The on-site test procedures should include installation qualification, operational qualification and performance qualification.
- The AER process should provide adequate assurance of the required microbial lethality (see ISO/DIS 15883-4).
- The AER should include a self-disinfection (machine disinfection) cycle. This disinfection process should provide thermal disinfection of the machine, or chemical disinfection, with a disinfectant different from that used to disinfect the endoscopes.
- AER processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- AER processes should be controlled and monitored to demonstrate attainment of the required disinfectant concentration at the required temperature for the required time.
- The AER should be revalidated following the introduction of a new disinfectant.
- Periodic testing should be undertaken in accordance with European Standards, manufacturers' instructions and local policy including efficacy tests during operational conditions.
- The operational manager for the endoscope decontamination unit should be responsible for ensuring that the automated endoscope reprocessor (AER) is tested in accordance with ISO/FDIS 15883-4.
- A trained person should have designated responsibility for undertaking testing of the AER in accordance with ISO/FDIS 15883-4.
- A qualified person (decontamination) should have designated responsibility for auditing the test data obtained and advising on remedial action required. An action plan for any necessary remedial action should be available.
- A record of all test results should be retained within the endoscope decontamination unit.

- For endoscope washer-disinfectors (EWDs) the validation should include confirmation of the cleaning efficacy of the process. The test method should include the use of one or more test soils specified in EN ISO 15883-5.
- EWDs should be tested quarterly for cleaning efficacy.
- Protein residue tests should be carried out weekly on cleaned endoscopes.
- There should be evidence of weekly testing of the final rinse water for bacterial counts and of annual testing for atypical mycobacteria. Where water test results are outside accepted standards there should be evidence that a remedial action plan has been implemented.
- An action plan, compiled in conjunction with the infection control team, should be available which describes the action to be taken in the event of failed water tests.

Section Six: Validation

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the endoscope washer-disinfector (EWD) is functioning correctly and that it will produce cleaned and disinfected loads consistently.
- The effectiveness of the disinfection process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if correct conditions are created throughout the EWD chamber and the load during every cycle.
- Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is considered as a process which comprises:

    1. Commissioning (installation qualification and operational qualification).
    2. Performance qualification.
    3. Periodic testing.
    4. Annual and revalidation tests.

Decontamination equipment

1. Commissioning

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier*, that it is safe to operate (installation qualification) and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions (operational qualification).

It consists of:

Installation qualification tests

- Verification of calibration of washer-disinfector instruments, automatic control test, water quality tests, water supply temperature and water supply pressure.

Operational qualification tests

- Weekly safety checks, automatic control test, verification of calibration of washer-disinfector instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical vapour discharge test, chemical additive dosing tests, load carriers, washer-disinfector self-disinfection test, final rinse decontamination test, channel patency test, disinfectant concentration test cleaning efficacy test, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric tests for thermal disinfection, microbiological test of disinfection efficacy, load dryness test, test for air quality and sound pressure.
- These tests should be carried out when a new endoscope washer-disinfector (EWD) is purchased or when a used EWD has been relocated to another premises. Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of EWDs. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the EWD is functioning correctly.
- Even though the manufacturer should have tested a EWD before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is **working correctly.**

Decontamination equipment

2. Performance qualification

Performance qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean/disinfect. Performance qualification is indicated for initial use of a new/ relocated endoscope washer-disinfector (EWD) or when the load profile changes. It should be carried out by a Test Person (or other suitably qualified person). These tests consist of:

- Thermometric tests for a full load of items not previously represented by the reference load, load dryness test, cleaning efficacy test, microbiological tests for efficacy of chemical disinfection for a full load of items not represented adequately by the reference load, and process residues.

3. Periodic testing

- After validation and when the EWD has been passed for use, it is subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals.
- The daily, weekly and quarterly tests supply evidence that the EWD is still operating within the limits established during commissioning.
- Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.

  i. ***Daily***: Remove and clean strainers and filters.

  ii. ***Weekly***: Automatic control test, weekly safety checks, daily tests, water hardness, water conductivity, cleaning efficacy test (residual soil detection) and final rinse water supply.

  iii. ***Quarterly tests***: Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection, cleaning efficacy test and channel patency test.

  iv. ***Annual tests***: Weekly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical vapour discharge, chemical additive dosing, load carriers, washer-disinfector self-disinfection test, final rinse decontamination test, channel patency test, disinfectant concentration test, chamber wall temperature test, load carrier temperature test, cleaning efficacy, over-temperature cut-out, thermometric tests for disinfection stage, microbiological test of disinfection efficacy, load dryness test, test for air quality and sound pressure.

Decontamination equipment

Section Seven: Monitoring and Control

- Cycle variables should be monitored to ensure that the specified parameters are obtained for each cycle. The critical cycle variables are temperature, time, detergent concentration and water pressure or flow rate.
- Validation, routine monitoring and control should be carried out in accordance with European Standards, manufacturers' instructions and local policy including efficacy tests during operational conditions.

Section Eight: Maintenance

- There should be documented evidence of planned and unplanned maintenance for automated endoscope reprocessors (AERs), disinfectant generators, water treatment systems and storage cabinets according to manufacturers' instructions.
- Preventative maintenance should be planned in accordance with the manufacturers' instructions.
- Planned preventative maintenance should be undertaken in accordance with manufacturers' instructions and local policy including:
  i. Inspecting and cleaning all filters.
  ii. Dismantling and cleaning spray arms and nozzles.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The automated endoscope reprocessor (AER) should not be used to process endoscopes and accessories until all scheduled maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- An automated endoscope reprocessor (AER) maintenance and repair log book should be maintained for each AER.
- All AERs should be under a service contract.
- A schedule of maintenance and disinfection of any water purification system should be specified. Records of periodic sanitization should be kept.

4 Personal protective equipment

4.1 Introduction

Personal protective equipment (PPE) must be worn by personnel when decontaminating endoscopes to reduce the risk of exposure to potentially infectious material. Managers must ensure that PPE is made available and all personnel are responsible for ensuring the correct use and disposal of same.

PPE involves use of protective barriers such as gloves, gowns, aprons, masks or protective eyewear. PPE also provides protection against other hazards in the healthcare facility such as chemicals and physical injury. Standard precautions and safe work practices are required to minimise the risk of infection to both patients and healthcare workers. They include, but are not limited to, good hygiene practices, particularly hand-washing, the use of PPE and the appropriate handling and disposal of waste. The provision of PPE is based on a risk assessment in accordance with Part V of the Safety, Health and Welfare at Work Act (General Application) Regulations, 1993.

4.2 Scope

The objective of this procedure is the outline the PPE that must be worn by staff to reduce risk of exposure to potentially infectious material.

4.3 Contents

Section One: Attire

Section Two: Head/hair cover

Section Three: Protective eyewear and face-shields

Section Four: Masks

Section Five: Plastic aprons and gowns

Section Six: Gloves

Section Seven: Footwear

4.4 Procedure

Section One: Attire

- All personnel working in the decontamination area should wear freshly laundered low linting attire.
- Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered attire should be changed daily or whenever it becomes visibly soiled or wet.
- Staff who are involved in the maintenance of decontamination equipment should be required to wear the same type of clothing.
- On leaving the decontamination area, staff should change into their normal day wear.
- After use, the attire should be discarded appropriately in a designated post use container/bag.
- Work attire should never be worn outside the decontamination unit.

Figure 4-1: Personal Protective Equipment (Decontamination Area)

Section Two: Head/hair cover

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.
- After use, headgear should be discarded in the appropriate healthcare waste stream.
- Stud earrings may be worn and should be totally confined within the head cover.
- **Note:** Make-up or jewellery should not be worn in the decontamination unit.

Personal Protective Equipment

Section Three: Protective eyewear and face-shields

- Healthcare workers (HCWs) should wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear or face shields should be single-use.
- Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- Face shields should cover the eyes, nose, mouth and chin.

Section Four: Masks

- HCWs should wear fluid repellent masks and/or face-shields to reduce the risk of pathogenic organisms being transferred to the nose or mouth.
- Fluid repellent masks and/or face-shields should be fitted and worn according to the manufacturers' instructions.
- Fluid repellent masks and/or face-shields should not be touched by the hand while being worn.
- Fluid repellent masks and/or face-shields should cover both mouth and nose while being worn.
- Fluid repellent masks and/or face-shields should be removed immediately if they become moist or visibly soiled and should be discarded in the appropriate healthcare waste stream.
- **Fluid repellent masks and/or face-shields should not be worn loosely around the neck.**

Figure 4-2: Face shield

Personal Protective Equipment

Section Five: Plastic aprons and attire

- Healthcare Workers (HCWs) should wear impermeable attire with long cuffed sleeves and tuck-inside-gloves during procedures that are likely to generate splashes of blood or body fluids or during activities that may contaminate clothing, uniforms and/or personnel with microorganisms or infectious material.
- Fluid repellent attire and aprons should be changed whenever they become visibly soiled or wet.
- After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

Section Six: Gloves

- Gloves should be used for handling contaminated RIMD and waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- Avoid letting the gloves snap, as this may cause contaminates to splash into eyes or mouth or onto skin or other personnel in the area.
- **It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.**
- HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves should be discarded in the appropriate healthcare waste stream.

Personal Protective Equipment

Section Seven: Footwear

- Healthcare Workers (HCWs) should wear non-slip enclosed footwear that can protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally).
- Footwear should be regularly cleaned and disinfected.
- Footwear should be appropriate to the area in which HCWs are designated.

5 Transport of contaminated endoscopes and accessories

5.1 Introduction

All endoscopes and their accessories are considered to be soiled and contaminated after each use and can be a potential source of infection. Contaminated endoscopes and accessories should be handled, collected and transported in a manner that avoids dissemination of contamination. Transport of soiled endoscopes and accessories to the decontamination area should be accomplished **as soon as possible after use**. If delay is unavoidable, the user must make sure that the items safely contained and secured to await collection.

5.2 Scope

The objective of this procedure is to provide guidelines in relation to the transportation of contaminated endoscopes and accessories.

5.3 Contents

Section One: Containers and trolleys

Section Two: Staff

5.4 Procedure

Section One: Containers and trolleys

- Contaminated endoscopes and accessories should be placed in re-usable, solid walled, leak proof containers/trolleys and transported to the decontamination area as soon as possible after use.
- Transport containers should protect both the product during transit and the handler from inadvertent contamination.

Transport of contaminated endoscopes and accessories

Section Two: Staff

- Personnel should be trained to handle, collect and transport contaminated endoscopes and accessories and should wear PPE in accordance with local safety policies and procedures.
- Policies and procedures for transportation of contaminated endoscopes (return of used items for reprocessing) and accessories should be developed, reviewed periodically, and readily available within the practice setting.

Figure 5-1 Transport of contaminated endoscopes and accessories

6 Cleaning and disinfection

6.1 Introduction

Endoscopes and their accessories are classified as medical devices under the Medical Devices Directive (MDD). Flexible endoscopes and their accessories present particular problems in terms of cleaning, disinfection and sterilisation. Failure to adequately decontaminate flexible endoscopes between use may increase the risk of transmission of infection between patients and/or compromise the quality of clinical samples.

6.2 Scope

The objective of this procedure is to provide guidelines in relation to cleaning and disinfection of contaminated endoscopes and accessories. Cleaning is the initial and most crucial step in breaking the chain of disease transmission.

6.3 Contents

Section One: Pre-cleaning

Section Two: Manual cleaning

Section Three: Rinsing

Section Four: Disinfection

6.4 Procedure

Section One: Pre-cleaning

1. Wipe the insertion tube

- Immediately on removal of the endoscope from the patient, with the endoscope still attached to the light source, grasp the control head and using a disposable cloth dampened in freshly prepared enzymatic detergent solution, wipe the insertion tube from the control head to the distal tip.
- Discard the cloth appropriately after use.

Figure 6-1: Wiping the insertion tube

Cleaning and disinfection

2. Aspirate enzymatic detergent through the suction/biopsy channels

- Place the distal tip in the enzymatic detergent solution.
- Aspirate the enzymatic detergent through the entire suction/biopsy channel system until the expelled solution is visibly clean.
- Alternate the suctioning of enzymatic detergent solution and air several times - finish by suctioning air.

Figure 6-2: Aspirating the enzymatic detergent through the suction/biopsy channel

3. Purge air/water channels

- Depress and release air/water button several times to flush water channel.
- Occlude air button to force air through air channel.

Figure 6-3: Purging air/water channels

Cleaning and disinfection

4. Detach removable components

- Remove the endoscope from the light source.
- Attach protective video cap (if using video endoscope).

Figure 6-4: Removing the endoscope from the light source

- Remove all valves/buttons/caps and soak in enzymatic detergent solution.

  Note: Where valves/buttons/caps are interchangeable it is preferable to have extra valves/buttons/caps to allow more time to ensure that adequate cleaning is performed prior to disinfection/sterilisation.

Figure 6-5: Removing valves/buttons and caps

Cleaning and disinfection

- Transport to the cleaning area in a re-usable, solid walled, leak proof container/trolley that prevents dispersal of contamination to the environment.

Figure 6-6: Transporting to the cleaning area

5. Leak testing

Note: Endoscope washer-disinfectors (EWDs) complying with ISO FDIS 15883-4 should include leak testing as part of the automatic cycle.

- The endoscope should be leak tested according to the manufacturers' instructions.
- All endoscopes should be leak tested prior to immersion and between each patient use.
- The leak test will detect damage to the interior or exterior of the endoscope.
- Perforated channels of endoscopes are an infection control risk and damage may also occur to parts of the endoscope not designed for fluid exposure.

Figure 6-7: Leak testing

a. Attach the leak tester and pressurise the endoscope

- Some manufacturers specify removing detachable parts prior to leak testing - others do not.

b. Immerse the endoscope in water and observe for a continuous stream of bubbles

- If the leak tester has a pressure gauge, observe for pressure loss prior to immersion (this indicates a significant leak).
- Completely immerse the entire endoscope.
- Flex the distal portion of the endoscope in all directions.
- Observe for a continuous stream of bubbles which indicates a leak.
- Observe the head of the endoscope, the insertion tube, distal bending section and the umbilical cable for bubbles coming from the interior of the endoscope.
- Repeat the leak test before and after automated reprocessing in an automated endoscope reprocessor (AER).
- The instructions provided by the endoscope manufacturer and AER manufacturer should be followed.

c. Processing endoscopes that fail the leak test

- If a leak is detected, or the endoscope appears damaged, the endoscope manufacturer or supplier should be contacted to ascertain whether reprocessing can be undertaken without additional damage to the endoscope.
- If the endoscope fails the leak test, staff should not attempt to clear a blocked endoscope by blowing air under pressure through the lumen.

Cleaning and disinfection

Section Two: Manual Cleaning

Cleaning is either:

i. Carried out manually before disinfection in a liquid chemical disinfector (LCD).

or:

ii. Carried out manually and then further cleaned and disinfected in an endoscope washer-disinfector (EWD).

The manual cleaning process is common to both processes. Appropriate PPE must be worn by staff

1. Make up detergent solution

- Make up fresh enzymatic detergent solution to the manufacturers' instructions for reprocessing each endoscope (fresh solution prevents cross contamination).

2. Immerse endoscope

- Completely immerse the endoscope.
- Whenever practical, leave the endoscope immersed in the detergent solution while performing all subsequent cleaning steps to prevent the production of aerosols of contaminated fluid.

Figure 6-8: Immersing the endoscope

Cleaning and disinfection

3. Disassemble removable parts and clean

- Remove all buttons/valves/caps and other removable parts (if you have not already done so).
- Correctly dispose of parts designated as single use.
- Brush and clean non-disposable parts with a small soft brush paying particular attention to internal surfaces and lumens.
- The preferred method of reprocessing re-usable accessories (buttons and valves) is in a central decontamination unit, in accordance with manufacturers instructions .
- The endoscope should be completely disassembled so that all surfaces may be reached for a thorough cleaning.

4. Brush and wipe exterior

- Wash all debris from outer surfaces by brushing and wiping the endoscope.
- Use a soft brush to gently clean the distal tip.
- Brush control handles and the biopsy port.
- Brush around valves seats and clean thoroughly.
- Check that all visible debris has been removed.

Cleaning tools

- Use of non-abrasive and lint-free cleaning tools will prevent damage to the endoscope.
- Soft brushes are useful to clean grooved control handles and to brush the distal tip.
- Valve seats and biopsy ports should be brushed using brushes supplied by the manufacturer which are designed for this purpose.
- Cotton buds should be used to clean the suction valve port but should not be used in the air/water port as threads can become caught and cause blocked channels.
- Cleaning brushes for valve ports should be available from manufacturer.

5. Brush all channels

- Brush all accessible endoscope channels including the body, insertion tube and the umbilical cable or universal cord of the endoscope.
- After each brush passage, rinse the brush tip in the detergent solution, removing any visible debris before retracting the brush and reinserting it.
- Continue brushing each channel a minimum of three times or until there is no debris visible on the brush.
- Finish brushing process with use of valve port brush to remove any debris which has been translocated to this area from brushing the channels.
- Drain water from the sink.
- Curl endoscope for transfer to a separate sink.
- Discard the brush appropriately after use.

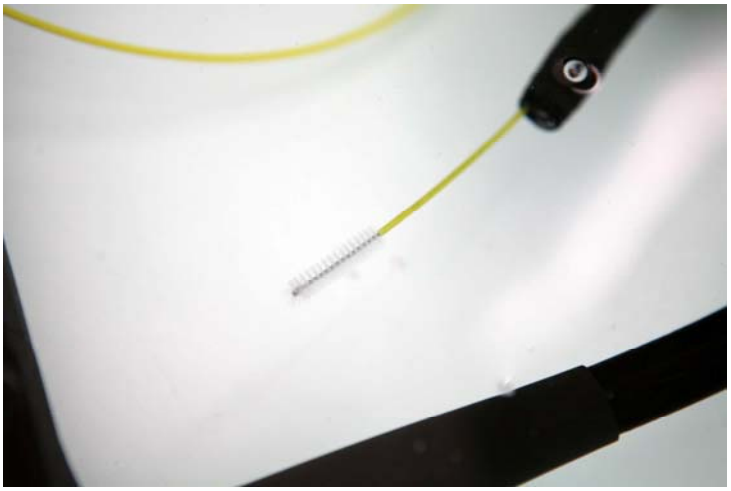

Figure 6-9: Brushing channels

Cleaning and disinfection

Brushes

- Single-use brushes are preferred.
- When re-usable brushes are used, after each use they should be cleaned, inspected and steam sterilised before re-use.
- If on inspection, the re-usable brush is worn, frayed or bent or the shaft is kinked or the brush is otherwise damage it should be discarded.
- Cleaning brushes for all brushable channels should be supplied by the manufacturer.
- A brush size compatible with each channel should be used.
- Rinsing the brush tip when it has emerged from the endoscope maximises cleaning of the channels by ensuring that as much debris as possible is removed before retraction or reinsertion of the brush.

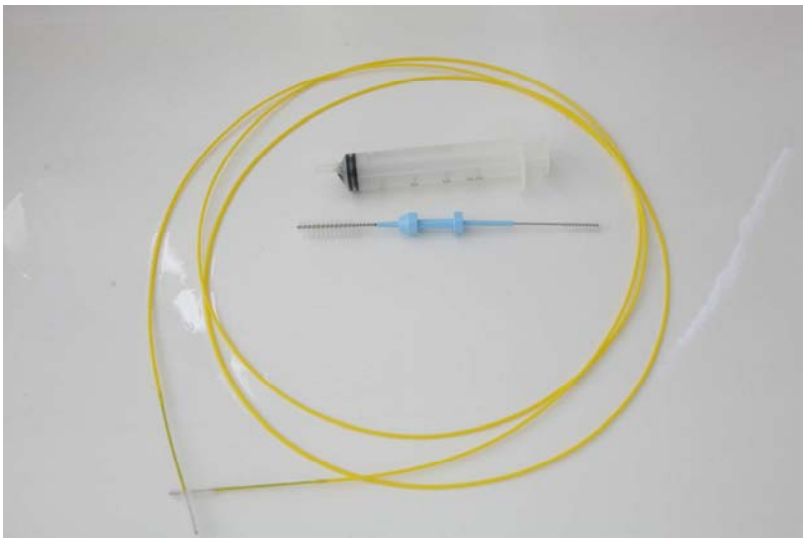

Figure 6-10: Brushes

Cleaning and disinfection

Section Three: Rinsing

1. *Water rinse*

- Transfer the endoscope to a sink, (separate to that used for manual cleaning), for rinsing to remove residual detergent.
- Flush all channels thoroughly with water.
- Rinse outer surfaces of the endoscope with water.
- Rinse all removable parts with clean water.
- Clean running water should be used to remove all traces of detergent prior to disinfection.
- The use of clean water for each endoscope will limit the potential for cross infection.
- The amount of water required to thoroughly rinse the endoscope after cleaning will vary according to the design and length of the endoscope.

2. *Purge internal channels with air*

- Purge water from all the channels with air to remove rinsing water.
- Removing water from all channels and the exterior of the endoscope prevents dilution of the biocide used for disinfection.
- This process can be completed using a syringe or compressed air.
- The endoscope should be transferred to the automated endoscope reprocessor (AER) in an appropriately sized receptacle so as to avoid contamination of the environment.

Cleaning and disinfection

Section Four: Disinfection

- The Health Service Executive regards the use of an automated endoscope reprocessor (AER) to process flexible endoscopes as mandatory. Unless specifically required by the endoscope manufacturer it is not acceptable to carry out chemical disinfection manually.
- The chemicals used throughout the decontamination process should be used at the correct concentration, volume, temperature and contact time as recommended by the manufacturer.
- The chemical used in the disinfection stage should be CE marked.
- The chemical used in the disinfection stage should be accepted as compatible with the endoscope by the endoscope manufacturer.
- The chemical used in the disinfection stage should be accepted as compatible with the AER by the AER manufacturer.
- The disinfectant should be in contact with all surfaces requiring disinfection at the required concentration for the required time.
- The temperature throughout the disinfection stage should be monitored, or controlled and monitored, to ensure that it remains within specified limits.
- Single-use disinfectants are preferred.
- There should be a log of disinfectant batch numbers and expiry dates.
- The water supplied to the AER for the rinsing after the chemical disinfection stage should be purified water and should be free from microbial contamination.

7 Automated endoscope reprocessing

7.1 Introduction

Automated reprocessing of endoscopes should take place in an Automated Endoscope Reprocessor (AER). These may be of two types; an endoscope washer-disinfector (EWD) or a liquid chemical disinfector (LCD)

An EWD provides an automated process with leak test, cleaning, rinsing disinfection and final rinsing stages.

An LCD process provides a high level chemical disinfection stage and a post-disinfection rinse stage to remove chemical disinfectant residuals. It does not provide an automated cleaning process although there may be an initial rinse to remove residues from the manual washing process and to ensure that all contact surfaces of the endoscope are wetted.

An EWD conforming to EN ISO FDIS 15883-4:2007 is preferred.

Manual washing is normally required whether or not the AER includes a cleaning stage. The narrow internal diameters of the channels of an endoscope require the mechanical action of brushing to ensure that they are cleaned. Manual cleaning in accordance with the endoscope manufacturers instructions followed by a validated automated cleaning process is the preferred method.

7.2 Scope

The objective of this procedure is to provide guidance in relation to automated cleaning and disinfection of contaminated endoscopes.

7.3 Contents

Section One: General principles

7.4 Procedure

Section One: General principles

- Determine the exact number of channels on the endoscope to be used.
- Determine the number of irrigation ports available for use in the automated endoscope reprocessor (AER).
- Ensure that the automated process on the AER will irrigate, clean where relevant, and disinfect all channels (including auxiliary and elevator wire channels) on the endoscope.
- Ensure that the AER and all services are operational. **Note:** The AER should not start if any anomalies are present.
- Transfer the endoscope(s) (that have been manually cleaned) to the AER.
- The channels of the endoscope should be attached to the appropriate connection in the AER to ensure the free passage of fluids through the channels during processing.
- Check that the attachment tubing is not kinked.

Figure 7-1: Attaching the endoscope channels

- Check that the endoscope blanks/caps are intact and secure.
- Select appropriate cycle.
- Enter endoscope code and user code.
- Initiate AER automatic cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the endoscopes processed should be inspected.

Figure 7-2: Selecting the cycle

Automated endoscope reprocessing

- Information should be recorded for each automated endoscope reprocessor (AER) cycle. Documentation is required for every AER cycle and should contain the following:

  i. AER identification number.

  ii. Cycle number.

  iii. Type of AER.

  iv. Type of cycle used.

  v. Date and time of start of cycle.

  vi. Load content.

  vii. Critical parameters for the specific AER cycle.

  viii. Operator's name.

  ix. Results of AER process.

  x. Signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters

  xi. Any notes or observation for the process cycle

- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- Cycles which were aborted should be documented with the action taken in a log book.
- All automated endoscope reprocessors (AERs) should undergo a self-disinfect cycle at the beginning of ach day. This should preferably be by thermal disinfection or with a chemical disinfectant different from that used for endoscope disinfection.
- There should be a means to indicate that the self disinfection cycle has taken place and been completed satisfactorily and evidence that records are retained.

Figure 7-3: AER record

8 Post cleaning inspection and function testing

8.1 Introduction

All cleaned and disinfected endoscopes should be inspected for cleanliness. All cleaned and disinfected endoscopes should be tested or inspected for functionality. Inspection, maintenance and testing of endoscopes should be carried out by trained persons in accordance with the manufacturers' instructions.

8.2 Scope

The objective of this procedure is to provide guidelines in relation to the post cleaning inspection and function testing of RIMD.

8.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Documentation post automated cleaning

Section Four: Monitoring and control

8.4 Procedure

Section One: Equipment

- Work bench.
- Magnifying glass and oblique of stereo-microscope.
- Light source.

Post cleaning inspection and function testing

Section Two: Procedure

When the automated cleaning process is complete, the following should be carried out:

- Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted.
- If there is no record of cleaning the endoscope is rejected and returned for re-cleaning.
- Make a visual inspection of the endoscope in order to ensure that there is no obvious damage, staining or residue.
- Make a visual inspection of the endoscope for dryness.
- Where an endoscope may not be properly cleaned the load is rejected and returned for re-cleaning.
- Any damaged, incomplete or malfunctioning endoscopes should be reported immediately to the supervisor.
- Each endoscope should be checked that there is free movement of all parts.

Section Three: Documentation post automated cleaning

- All documentation for automated cleaning should contain the following information:

  i. Automated endoscope reprocessor (AER) identification number.

  ii. Cycle number.

  iii. Type of AER.

  iv. Type of cycle used.

  v. Date and time of start of cycle.

  vi. Load content.

  vii. Critical parameters for the specific washer disinfector cycle.

  viii. Operators name.

  ix. Results of washer-disinfector process.

  x. Signature of an authorised qualified person confirming whether or not the process cycle was within recommended parameters.

  xi. Any notes or observation for the process cycle.

Post cleaning inspection and function testing

- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.

Section Four: Monitoring and control

The user should be aware of the factors that may alter the efficacy of the method:

- Staff training/competence.
- Age of the endoscope.

9 Drying

9.1 Introduction

Drying minimises rusting, staining and reduces the risk of recontamination during inspection and assembly of endoscopes. Residual moisture can damage endoscopes.

9.2 Scope

The objective of this procedure is to provide guidelines in relation to the drying of endoscopes.

9.3 Contents

Section One: General principles

9.4 Procedure

Section Two: General Principles

- In many automated endoscope reprocessors (AERs) the operating cycle provides an option after the final rinse stage for either a purge stage to remove excess rinse water from the endoscope when the endoscope is intended for immediate use or a more prolonged drying stage when it is intended to store the endoscope before use.
- When the purge cycle has been used, on removal from the AER, the outside of the endoscope should be wiped with a disposable dry lint free cloth.

10 Transport of decontaminated endoscopes and accessories

10.1 Introduction

Decontaminated endoscopes and accessories should be transported in a manner that will not compromise their status. Loss of sterility is event related and depends on the extent and nature of handling and environmental conditions during transportation and storage.

10.2 Scope

The objective of this procedure is to provide guidelines in relation to the transportation of reprocessed endoscopes and accessories.

10.3 Contents

Section One: General principles

10.4 Procedure

Section One: General principles

- Reprocessed endoscopes and accessories should be transported in clean dry containers and trolleys in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage.
- The re-usable transport container should be clean and disinfected, dry, solid walled and leak proof.
- There should be an adequate number of transport containers and trolleys in the endoscope reprocessing unit.

11 Storage

11.1 Introduction

All items should be stored in such a way that their level of processing is maintained (e.g. sterile, high-level disinfected). Endoscopes and accessories should be stored in a clean, dry environment and protected from sharp objects that may damage them.

11.2 Scope

The objective of this procedure is to provide guidelines in relation to the storage of endoscopes and accessories.

11.3 Contents

Section One: Storage facilities

Section Two: Detachable components and parts

Section Three Cleanliness and functionality

11.4 Procedure

Section One: Storage facilities

- Separate storage facilities should be provided for sterile and non sterile goods.
- Endoscopes should be stored hanging vertically in a designated dry and well-ventilated storage cupboard.
- Storage cupboards should be cleaned weekly with warm water and detergent and dried well and cleaning should be recorded.
- Storage cupboards should be well ventilated.
- Endoscopes should be stored so that residual fluid does not remain in the channels.
- Endoscopes should be protected from the risk of environmental contamination.
- Storage facilities for decontaminated endoscopes should be secure and only accessible to personnel who have a legitimate need.

Storage

Section Two: Detachable components and parts

- All detachable components should remain detached during storage and should not be replaced until the endoscope is next used.
- All detachable parts should be stored in a manner that ensures security of the items and keeps components together as a unique set.

Section Three: Cleanliness and functionality

- Endoscopes should be reprocessed if more than three hours has elapsed from the last decontamination process unless stored in a dedicated storage cabinet that has been validated for more prolonged storage.
- Prior to reuse, all decontaminated endoscopes should be inspected for cleanliness.
- Prior to reuse, all decontaminated endoscopes should be tested or inspected for functionality.
- All endoscopes that fail inspection for cleanliness or functionality should be segregated.

Note: Prior to storage at the end of the day the rubber seals of the suction and air/water valve should be lubricated sparingly with silicone oil in accordance with manufacturers' instructions.

Figure 11-1: Storage

12 Valves, detachable parts and accessories

12.1 Introduction

Endoscope accessories should be cleaned, disinfected, or sterilised, and maintained in accordance with the manufacturers' instructions.

12.2 Scope

The objective of this procedure is to provide guidelines in relation to valves, detachable parts and accessories

12.3 Contents

Section One: Valves and detachable parts

Section Two: Accessories

12.4 Procedure

Section One: Valves and detachable parts

- Biopsy caps should be discarded after all procedures involving the passage of accessories through the endoscope.
- Unless otherwise specified by the manufacturer, the surfaces and lumens of re-usable valves and detachable parts should be cleaned using a purpose-built single-use cleaning device and rinse with clean water prior to reprocessing.
- Visual checks should be 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 should be kept with the endoscope to form a unique set of equipment.

Note: Prior to storage at the end of the day the rubber seals of the suction and air/water valve should be lubricated sparingly with silicone oil in accordance with manufacturers' instructions.

Valves, detachable parts and accessories

Section Two: Accessories

- Endoscopic accessories are devices used in conjunction with an endoscope to perform diagnostic and therapeutic procedures. These may be passed via the biopsy channel/working channel of an endoscope during a procedure. Examples include biopsy forceps, water bottles, snares, buttons etc.
- Single use accessories should always be used in preference to re-usable accessories (unless no suitable alternative is available).
- Where re-usable accessories have to be used they should be sterilised. This should be carried out in a central decontamination unit and should be done in accordance with the manufacturer's instructions.
- Checks should be in place to ensure that the item is fit for use on return to the endoscopy unit.
- There should be evidence that a risk assessment involving the infection prevention and control team has taken place for re-usable items that cannot be sterilised.
- Single use devices should be used for manual cleaning.
- Single use biopsy forceps should be used for all procedures.
- Water bottles should be sent to the central decontamination unit to be cleaned and sterilised in accordance with the manufacturers' instructions.
- Sterile water should be used in the water bottle.
- Accessories and removable parts (other than single use items) should be kept together with a single endoscope forming a unique set.

Figure 12-1: Accessories

13 Traceability

13.1 Introduction

In order to provide full traceability it is essential to be able to identify which endoscopes and accessories were used on which patients and to trace the process records through the decontamination life cycle. Systems should be in place to allow the methods, operational cycles and personnel involved in the processing a particular endoscope/endoscope set to be tracked through the decontamination process and to the patient on whom devices have been used.

13.2 Scope

The objective of this procedure is to provide guidelines for the effective tracking of endoscopes and accessories through the decontamination life-cycle.

13.3 Contents

Section One: Unique identifier

Section Two: Records

Section Three Recording system

13.4 Procedure

Section One: Unique identifier

- All endoscopes should have a unique identifier/serial number before use and there should be a system in place to track loan scopes.

Traceability

Section Two: Records

- Records should be maintained for all the endoscopes/endoscopes set, identifying:
  - i. The cleaning, disinfection and sterilisation method used.
  - ii. The name of the person undertaking each step of the decontamination cycle.
  - iii. Details of the actual endoscope/endoscope set being processed.
  - iv. These details should be directly associated to individual patient use.
- Records relating to decontamination processes should be maintained for the life-time of the equipment plus eleven years.

Section Three: Recording system

- Tracking should be undertaken using and IT based or manual (paper based) recording system.
- An IT based system is preferred.

Figure 13-1: Manual traceability system