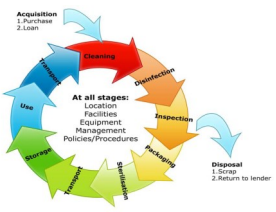
Health Service Executive Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities



Framework for Improving Quality in our Health Service

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Description:	The Standards and Recommended Practices are a guide to support the practices for safe Operational Management of Endoscope Decontamination Facilities based on current legal requirements and professional best practice
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Contact Details:	Caroline Conneely Decontamination Advisor National Quality Improvement Team Health Service Executive Dr Steeven's Hospital, Dublin, Eircode: DO8 W2A8 Ireland Email: caroline.conneely1@hse.ie

*(**Note:** This document, provides guidance to healthcare facilities on the application of legislative and regulatory requirements associated with the decontamination of reusable invasive medical devices. The document is based upon best available international evidence at the time of guidance development. This document will not be update until 2024 unless there are significant legislative or regulatory changes that may impact on practice, facilities, equipment or testing regimes in the interim period).*

Terminology and Acronyms used within the Guidance Document

AED	Authorising Engineer for Decontamination
ACPD	Advisory Committee on Dangerous Pathogens
AHU	Air Handling Unit
BSG	British Society of Gastroenterology
CE	CE Mark that conforms to European Standards
CDU	Central Decontamination Unit
CESC	Controlled Environment Storage Cabinet
CJD	Creutzfeldt Jakob Disease
CP(D)	Competent Person for Decontamination
DGSA	Dangerous Goods Safety Advisor
EDUs	Endoscope Decontamination Units
EN	European Standard
EWD	Endoscope Washer Disinfector
GI	Gastrointestinal
GS1	Global Standards
HSE	Health Service Executive
HBS	Health Business Services
HBV	Hepatitis B Virus
HCAI	Healthcare Associated Infections
HCW	Healthcare Workers
HIQA	Health Information Quality Authority
HPSC	Health Protection Surveillance Centre
IMS	Independent Monitoring Systems
IPC	Infection Prevention and Control Practitioners
JAG	Joint Advisory Group

Terminology and Acronyms used within the Guidance Document

MDR	Medical Devices Regulation 2017/745
PCHCAI	Prevention and Control of Healthcare Associated Infections
PPE	Personal Protective Equipment
RO	Reverse Osmosis
RIMDs	Reusable Invasive Medical Devices
SDS	Safety Data Sheet
UDI	Unique Device Identification
sCJD	Sporadic CJD
vCJD	Variant Creutzfeldt-Jacob Disease

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Part 1 Introduction

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Part 1
Introduction to Operational Management of Endoscope Decontamination Facilities

1. Introduction

Standards and Recommended Practices for Endoscope Decontamination Units were reviewed in 2016. Based on extensive consultation with service providers, HSE Health Business Services (HBS) Estates and experts in the field of Endoscope Decontamination it was agreed that there was a need to provide more in-depth guidance on the design of Endoscope Decontamination Units (EDUs), testing of equipment and operational management of the service. Additionally, the publication of EN 16442 (2015) "Controlled Environment Storage Cabinet (CESC) for processed thermolabile Endoscopes" has led to changes in the expected validation regimes for such cabinets. Thus, the HSE Standards and Recommended Practices for Endoscope Decontamination Units will now be presented in three parts.

Part-1 HSE Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Facilities.

Part-2 HSE Standards and Recommended Practices for Commissioning, Validation and Testing in Endoscope Decontamination Facilities.

Part-3 HSE Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities.

Purpose of the Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities

This document has been developed to support best practice in the day to day operational management of Endoscope decontamination services, facilities and equipment and is written to reflect the need to continuously improve outcomes in terms of patient safety, clinical effectiveness and patient experience.

The primary aim of this document is to provide guidance to decontamination facilities who process all types of flexible Endoscopes and reflects the need to ensure the safety of the service provider, the user and the patient. The content of this document is based on:

- Extensive literature search;
- consideration of the opinion of experts knowledgeable in the subject;
- consideration of the available current best practice, both in Ireland and Internationally, that may impact on decontamination of Endoscopes;
- feedback from service providers which has been considered and where appropriate, incorporated into this revised version of the standards and recommended practices.

1.1 Who Should Use This Document?

This document aims to provide support and guidance to Healthcare Planners, Endoscope Decontamination Unit (EDU) Managers, Central Decontamination Unit (CDU) Managers, CEOs, General Managers, Infection Prevention and Control Practitioners (IPC), Microbiologists, Theatre Managers, Health and Safety Managers, Risk Managers, Procurement Officers, Clinical Engineers, Design Teams, suppliers of specialised equipment, Competent Persons for Decontamination (CP(D) and Authorising Engineers for Decontamination AE(D). The reliability of the decontamination process critically impacts on the safe effective management and control of cross contamination risks associated with the use of Endoscopes.

The operational management of the decontamination life cycle requires input from relevant experts in the field.

Personnel Who may be Involved in the Operational Management of EDUs:

- Decontamination Lead, Decontamination Manager, Decontamination Technician;
- the Users of the service/Theaters/Day Surgery/Endoscopy;
- Authorising Engineers for Decontamination (AE(D));
- Competent Persons for Decontamination (CP(D);
- Infection Prevention and Control and Microbiologist;
- Procurement;
- suppliers of the required specialist equipment;
- IT Specialties, Health and Safety Managers;
- experts involved in the management of Endoscope decontamination service provision, Estates and Facility Managers.

1.2 Aim of the Standards and Recommended Practices for Operational Management of EDU Facilities, Equipment and Services

The overall aim the Standards and Recommended Practices for Operational Management of EDUs, is to achieve a reprocessed flexible Endoscope that meets with the "general requirements" identified in Annex I Chapter II of the Medical Devices Regulations 2017/745 and the decontamination requirements identified by the Joint Advisory Group (JAG) on GI Endoscopy, and the Health Information Quality Authority (HIQA) Standards for Prevention and Control of Healthcare Associated Infection (PCHCAI,2017).

The Medical Devices Regulation (2017/745)

The Medical Device Regulation applies to manufacturers, including those who perform in-house manufacturing and those placing medical devices on the market. In doing so, it specifies the general requirements to be met by any medical device.

These general requirements should be regarded as the minimum acceptable Standard whether or not the decontamination unit qualifies as a 'manufacturer' within the terms of the Regulations.

Decontamination Requirements Associated with the Regulation

Devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation (Annex I, Chapter II paragraph 11.2).

The device and manufacturing processes must be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Annex I, Chapter II paragraph 11.1).

Devices delivered in a sterile state must be manufactured and sterilised by an appropriate, validated method (Annex I, Chapter II paragraph 11.5).

Devices intended to be sterilised must be manufactured in appropriately controlled environmental conditions (Annex I, Chapter II paragraph 11.6).

Instructions for Use—Requirements Associated with the Regulation

The instructions for use shall contain details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection including any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; (Annex I, Chapter III paragraph 23.4).

(***Note:*** *The general requirements in paragraphs 11.5 and 11.6 refer to sterile devices. However, the requirements apply equally in respect of devices intended to be disinfected.*

New research identifies that Endoscopes are being used more invasively and therefore may require sterilisation after high level disinfection depending on their intended use)

(***Note:*** *Products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) 2017/745 are deemed medical devices under the Regulation)*

1.3 HIQA Standards for Safer Better Healthcare

The Health Information Quality Authority identify 8 themes for quality and safety which are intended to work together. Collectively, these themes describe how a service provides high quality, reliable safe care. The four themes on the upper half of Figure 1 relate to dimensions of quality and safety, the four themes on the lower half of Figure 1 relate to capacity and capability.

Endoscope decontamination practice is aligned to all 8 themes in some way; however Effective Care and Support (Theme 2) and Safe Care and Support (Theme 3) are the key dimensions of quality and safety needed to support the delivery of safe decontamination services in Endoscope Decontamination Units. HIQA Standards for Prevention and Control of Healthcare Associated Infections (2017) aim to promote evidence-based practice and encourage a multidisciplinary team-based approach within acute services to prevent and control Healthcare Associated Infections (HCAI).

Figure 1: Themes for Quality and Safety

1.4 Definitions

Themes = HIQA identify 8 themes for Quality and Safety which are intended to work together. Collectively, these themes describe how a service provides high quality, reliable safe care.

Standards = term used by the Health Information Quality Authority and the Health Service Executive to describe the high-level outcomes required to contribute to the quality and safety of decontamination services.

Features = term used by the Health Information Quality Authority to describe elements of a standard that when taken together, will enable progress toward achieving the standard.

Recommended Practices = best practice in relation to the decontamination process. The recommended practices are intended to define correct decontamination practice and to promote service user and staff safety and serve as the basis for policy and procedure development.

Table 1: What do HIQA PCHCAI Standards Mean for the Endoscope Decontamination Unit

Theme 1: Patient Centred Care and Support	
Standard 1.1	Service providers effectively communicate with their patients about prevention, control and management of Healthcare Associated Infection, (HCAI).
Theme 2: Effective Care and Support	
Standard 2.4	A monitoring programme is in place to measure and report on effectiveness of infection prevention and control practices.
Standard 2.6	Healthcare is provided in a clean and safe physical environment that minimises the risk of transmitting a HCAI.
Standard 2.7	Equipment is cleaned and maintained to minimise the risk of transmitting a HCAI.
Standard 2.8	Reusable Invasive Medical Devices are decontaminated and maintained to minimise the risk of transmitting a HCAI.
Theme 3: Safe Care and Support	
Standard 3.2	Service providers integrate risk management practices into daily work routine to improve the prevention and control of HCAI.
Standard 3.3	Service providers effectively identify, manage, report and investigate any HCAI incidents.
Standard 3.4	Service providers support initiatives to promote and encourage quality improvements in infection prevention and control practices.
Standard 3.5	Service providers adhere to hand hygiene practices to minimise the risk of acquiring or transmitting infection.
Standard 3.8	An occupational health service is in place to decrease the risk of infection to staff.
Theme 5: Leadership Governance and Management	
Standard 5.3	Service providers have formalised governance arrangements in place for the prevention and control of HCAI.
Standard 5.4	Service providers have effective management arrangements in place for the prevention and control of HCAI.
Standard 5.5	Service providers ensure that externally contracted services adhere to safe and effective Infection Prevention and Control practices.

Theme 6: Workforce Planning	
Standard 6.1	Service providers plan, organise and manage their workforce to meet the service's infection prevention and control needs.
Standard 6.2	Service providers ensure their workforce have the competencies and training required to provide safe and effective infection prevention and control practices.

Theme 7: Use of Resources	
Standard 7.2	Service providers ensure medical devices and equipment that are purchased, loaned, borrowed, serviced or repaired are safe to use.

Theme 8: Use of Information	
Standard 8.2	Service providers have effective arrangements in place for information governance for infection prevention and control related data.

1.5 What Does this Mean to the Service User?

The service is always looking for ways to make healthcare safer.

The service is not just reacting when things go wrong it is actively looking for ways to make the way it provides care safer.

The service learns from international and national evidence about the best ways of keeping the service user safe.

The service uses information relevant to the provision of safe services to inform continuous improvement of the safety of the service.

Note:

HIQA Standard 2.6, 2.7 and Standard 2.8 under Theme 2 Effective Care and Support, Theme 3 Safe Care and Support, Standard 5.5 and Theme 6 Workforce Planning are most applicable to Operational Management of Endoscope Decontamination Facilities.

2. About this Document

Flexible Endoscopes are complex Reusable Invasive Medical Devices (RIMDs) that require unique consideration with respect to validating the decontamination process.

Internationally it is recognised that Endoscopes are the most common medical device to be associated with cross contamination and infection transmission (CDC,2008; Of Stead *et al*., 2010; Greenwald, 2011). With the emergence of multi-drug resistant organisms, the increasing risk of infection transmitted via endoscopic procedures have been highlighted in the literature.

Endoscope procedure related HCAIs have been linked to decontamination equipment, practice and process failures (Schelenz & French, 2000; Sirinivasan et al., 2003, Shimono et al., 2008, NHS Northumbria, 2014, FDA Safety Notice, 2015). Environment, equipment and practice are therefore considered significant risk factors for transmission of infectious agents, placing a greater emphasis on the need for organisations to have effective mechanism in place to control these risks.

The HIQA National Standards for the Prevention and Control of Healthcare Associated Infection (2017) clearly identifies the need for "Hospitals to have necessary resources in place to meet their Infection Prevention and Control needs and priorities". Standards, policies, procedures, protocols and guidelines in relation to decontamination must be in place. Resource to support the prevention of HCAI include ,but are not limited to, appropriate training for Endoscope decontamination personnel, management of health and safety risks ,integration of risk management practices into daily work routine to improve the prevention and control of HCAI and the implementation of a monitoring programme to measure and report on effectiveness of Infection Prevention and Control practices (HIQA, 2017).

The HSE Standards and Recommended Practices for the Operational Management of Endoscope Decontamination Facilities provides guidance to EDU Managers, Theatre Managers, Facilities Managers, Authorising Engineers for Decontamination (AEDs), Infection Prevention and Control Managers, Health and Safety Managers, Procurement Managers, Healthcare Planners, Quality Risk and Safety Managers and Senior Management Teams, on decontamination practices and regimes required to support safe reliable care.

How Should We Read This Document? This document is provided in two parts:

- **Part 1** provides you with critical features associated with Operational Management of Endoscope Decontamination Facilities;

- **Part 2** provides guidance on the practices associated with reliable Endoscope decontamination ensuring the service meets the requirements of HIQA Standards for the Prevention and Control of Healthcare Associated Infection PCHCAI, (2017). All elements within Part 2 correspond with HIQA PCHCAI Standards Themes 2,3,5,6,7 and 8.

(***Note:*** *Authorising Engineers, who are involved in supporting or advising on the Operational Management of EDUs in Ireland,* ***must*** *use this document as a template to ensure compliance to HIQA PCHCAI requirements (2017))*

3. Endoscope Decontamination Considerations

3.1 Life Cycle for Reusable Invasive Medical Devices

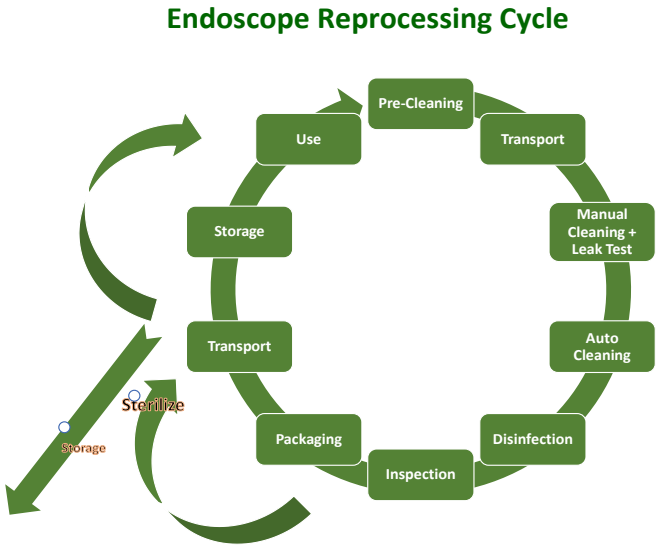
The effectiveness of decontamination is determined by all elements of the RIMD life cycle. All aspects of the life cycle need to be controlled and managed if decontamination is to be fully effective.

The design of the decontamination facility and the management and control of decontamination equipment and services, for example, supply of microbial free water and supply of appropriate air handling services are critical if decontamination is to be fully effective and safe for staff and users.

Training for all staff involved in the decontamination of flexible Endoscopes is essential.

Workflow to and from the point of use to the EDU and from the EDU, needs to be considered to minimise the risk of cross-contamination. The decontamination life cycle highlights the extent to which decontamination effects the whole organisation and not just areas processing Endoscope. Figure 2 highlights each stage of the decontamination process through which Endoscopes must pass prior to every use. Effective decontamination requires the attainment of acceptable standards at all stages of the life cycle. Failure at any stage may result in inadequate decontamination .

Figure 2: Endoscope Reprocessing Cycle

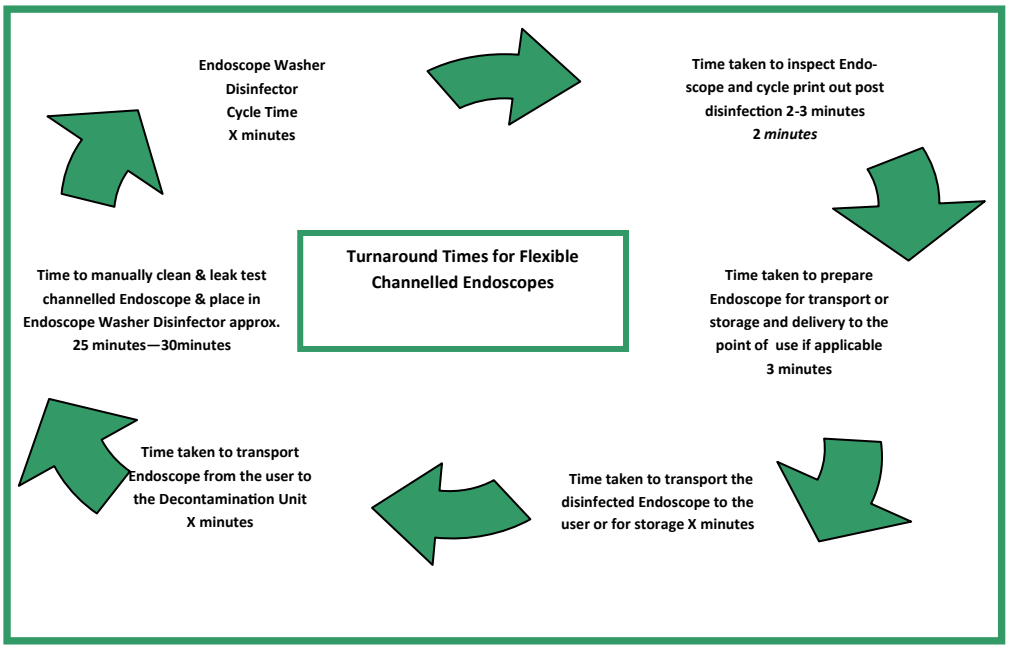


3.2 Endoscope Decontamination Considerations

Development of new services and redesign of existing services must ensure that adequate numbers of Endoscopes are provided to the service to facilitate a minimum turnaround time of up to 90 minutes (depending on EDU adjacencies to end user locations etc.,) to support safe decontamination of Endoscopes.

It is estimated that a minimum time frame of 25 minutes is required to manually decontaminate and leak test a flexible multi-channeled Endoscope safely, prior to automated disinfection. This time includes, key processes such as donning Personal Protective Equipment (PPE), preparation of solutions for cleaning, scope tracking, scope examination, connection of the Endoscope to the EWD etc.

Figure 3: Example Template to Evaluate Endoscope Turnaround Times



EWD cycle time depends on the make or model of the EWD; however average cycle time is approximately 40 minutes. It is estimated that the time taken to remove the Endoscope from the EWD, visually inspect cycle parameters, perform scope tracking procedures and prepare the scope for transport (back to the user or storage) requires a further 5 minutes. Time taken to transport the Endoscope to the user location for immediate reuse or storage is specific to each site.

EDUs should consider providing a service level agreement to users of their service to manage expectations regarding turnaround times required to safely decontaminate each Endoscope type.

(***Note:*** *Non–channelled Endoscopes may take up to 15 minutes to manually decontaminate and leak test with a further 5 minutes to remove from the EWD and prepare for transport, as described above)*

3.3 Decontamination Process

Decontamination is the combination of processes (including cleaning, disinfection and sterilisation) used to render Reusable Invasive Medical Devices (RIMD) safe for handling by staff and for use on service users. Effective decontamination of RIMD is an essential component in the prevention of healthcare associated infection.

Failure to adequately decontaminate an Endoscope will increase the risk of transmission of cross-infection between patients. Effective decontamination of Endoscopes is necessary to maintain the functionality of Endoscopes, maintain integrity of biopsy specimens and protect the patient from the adverse consequences of non-sterile contaminants.

3.4 Manufacturer Instructions

Endoscopes must be accompanied by their manufacturers' instructions for decontamination and reprocessing (see EN ISO 17664). Instructions must be strictly followed to ensure appropriate decontamination takes place and include:

- Details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc.;
- the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;
- any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;
- information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation. Information shall be provided to identify when the device should no longer be reused, e.g., signs of material degradation or the maximum number of allowable reuses;
- devices that are reusable shall bear a Unique Device Identification (UDI) carrier on the device itself. The UDI shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device;
- the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, — identification of any consumable components and how to replace them (MDR, 2017/745).

3.5 Guide to Classification of Infection Risk

Cleaning is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.

High-level disinfection — refers to complete inactivation of all infectious microorganisms (vegative bacteria, mycobacteria, enveloped and non-enveloped viruses) in or on a device, but not necessarily bacterial spores. High level disinfection requires the use of specific disinfectants, specialist equipment and trained staff (e.g., Endoscope Decontamination Practitioners).

Sterilisation— refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. Sterility is an absolute condition - an item is either sterile or not sterile.

3.6 Spaulding Classification Guidance

Spaulding Classification is a system devised by Professor Earle Spaulding (proposed in 1939 and refined in 1968) to determine the infection risk associated with the intended use of a medical device and the level of decontamination required to make the reusable device safe for reuse on a patient.

Spaulding classification defines three broad risk categories and the required decontamination level for each category (it should be noted that some devices may only withstand Low Temperature Sterilisation processes– always follow manufacture guidance).

The Spaulding classification suggests that devices that enter sterile body tissues are in the critical risk category. It states that these devices require sterilisation. Therefore, Endoscopes that are used as part of a surgically invasively procedure (e.g. a choledocoscope) would fall into this risk category.

Table 2 (page 13) , provides guidance on the classification of infection risk associated with the decontamination of Endoscopes. As with all generalisations, this table cannot represent all possible variations associated with clinical use. Local clinical advice should be sought, as necessary. Where a service is provided for a range of clinical specialties, risk assessments should reflect the hazards posed to patients at highest risk.

Table 2: Guide to Classification of Infection Risk Associated with the Intended Use of the Endoscope

(**Note:** *Table 2 provides guidance only and as with all generalisations, it cannot represent all possible variations associated with clinical use. Local clinical advice should be sought, as necessary. Where a service is provided for a range of clinical specialties, risk assessments should reflect the hazards posed to patients at highest risk*)

Risk	Application	Recommendation	Examples *	Outcome
Critical	Items that enter sterile tissues/sterile body areas or the vascular system.	Requires sterilisation.	Choledochoscopes, semi-rigid pleurascopes, rigid Endoscopes such as laparoscopes, arthroscopes, and flexible ureteroscopes that are used percutaniously through incision.	**Endoscopes that enter sterile body tissues:** Manual cleaning followed by automated cleaning and disinfection; followed by sterilisation.
Semi-critical	Items in contact with mucous membranes or non-intact skin.	Sterilisation preferred but at a minimum, requires high level disinfection.	Flexible Endoscopes entering the body through natural orifices such as gastroscopes, bronchoscopes, duodenoscopes, flexible ureteroscopes passed through the bladder and nasendoscopes.	**Endoscopes that enter sterile body cavities via contaminated body cavities :** Manual cleaning followed by automated cleaning and disinfection in an EWD. **Endoscopes that enter contaminated body cavities :** Manual cleaning followed by automated cleaning and disinfection in an EWD. **Endoscopes without lumens:** Manual cleaning followed by automated cleaning and disinfection in an EWD is Best Practice as this is a validated repeatable process.
Non-critical	Items in contact with intact skin but not mucous membranes or not in contact with the patient.	Can be processed by cleaning (and low level disinfection where necessary).	Endoscope consoles and keyboards.	**Endoscope System (not the Endoscope itself)** Manual cleaning (and low level disinfection where necessary).

(***Note:*** *Examples are for illustrative purposes only/the manufacturer's recommendations for reprocessing must be followed)*

3.7 Decontamination Guidance for CJD (including both vCJD and sCJD)

The UK Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup document "Guidance to Minimise transmission risk of CJD and vCJD in healthcare settings"- Annex F and Annex E (2017), provides specific advice for the management of instruments used in all types of Endoscopic procedures.

This advice differs depending on the type of CJD that a patient has been diagnosed with, or for which symptoms are being Investigated and for those who are asymptomatic but for whom an increased risk of developing the disease has been identified. It is important to note that the risks from sporadic CJD (sCJD) and variant CJD (vCJD) are different, as the distribution of infectivity in tissues and body fluids differs.

The use of the term "sporadic" CJD in the context of this HSE document includes, sporadic CJD, sporadic fatal insomnia, Variably Protease-Sensitive Prionopathy (VPSPr), iatrogenic CJD(other than iatrogenically acquired variant CJD), genetic CJD, fatal familial insomnia(FFI) and Gerstmann-Straussler-Scheinker disease (GSS).

This HSE Document applies to all flexible Endoscopes other than flexible neuroendoscopes and rigid Endoscopes which are covered in the HSE Standards and Recommended Practices for Central Decontamination Units.

Appendix IV of this HSE document provides a summary of precautions advised for the use of flexible Endoscopes in patients with CJD(including both sCJD and vCJD) presumed infected or at increased risk. This guidance applies where an invasive procedure has been carried out. Table F2b, Annex F of the ACDP guidance provides detailed advice as to which common flexible Endoscopic procedures are classified as invasive or non-invasive.

This table (F2b, Annex F -ACDP Guidance) should be consulted when determining the invasive nature of any particular procedure in consultation with the consultant carrying out the endoscopic procedure. Examples of where the invasive nature of a procedure may alter include, breaching the integrity of fixed lymphoid tissue when taking a biopsy or causing tissue vaporisation by diathermy.

The Infection Prevention and Control Team, EDU and Theatre Manager must be informed if a patient is suspected to fall into any of the risk groups defined in the ACDP Guidance "Minimising the transmission risk of CJD and vCJD in healthcare settings"(2017) and is to undergo a procedure that is likely to involve contact with high or medium infectivity tissues (see Appendix IV in this document).

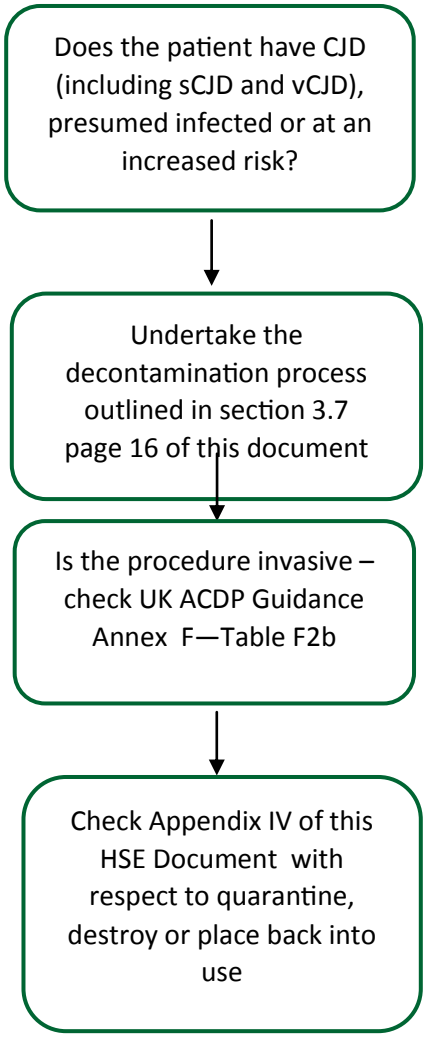
Any subsequent quarantining of devices must be discussed with the Infection Prevention and Control Team and EDU Manager prior to the procedure.

When an Endoscopy is likely to involve an invasive procedure (Table F2b, Annex F of the ACDP guidance) it is important to determine whether a patient has definite or probable sCJD or vCJD, or is presumed infected (that is, known to have received blood or blood components from a donor who later developed symptomatic vCJD). This will determine whether the Endoscope will require quarantining, destroying or can be placed back into service, Appendix IV of this HSE document should be used to support the decision making process in consultation with the ACDP guidance.

After the performance of an invasive procedure, flexible Endoscopes used on patients infected or presumed infected with CJD should be retained for use on that same patient after conventional decontamination (as defined in this HSE Document) or destroyed by incineration. The number of patients in these groups is very low. Advice should be sought before an irreversible action, such as disposal of reusable Endoscopes, is taken.

(**Note** *:Endoscope accessories used in such procedures should be single use wherever possible)*

Figure 4: CJD Process Map



Decontamination procedure required for Endoscopes used on patients with CJD (including sCJD and vCJD), presumed infected or at an increased risk), prior to quarantine or re-use:

- The bedside clean should take place immediately after the procedure has been carried out, and the Endoscopes should be manually cleaned according to the manufacturers' recommendations, and passed through an EWD as soon as possible after use;
- after manual cleaning in the EDU the Endoscope should be decontaminated alone using an automated Endoscope Washer Disinfector (EWD). No other Endoscopes should be present in the EWD during this cycle;
- after removing the Endoscope from the EWD, a normal cycle should be run with an empty chamber/bowl;
- provided that the EWD is decontaminated as indicated above, there is no known risk of transmission of CJD via this route;
- dispose of any endoscopic accessories (including normally reusable devices such as heater probes) and cleaning aids (such as channel cleaning brushes) as healthcare waste. Advice from the Microbiologist should be sought, since some reusable items may need to be discarded as they cannot be cleaned to the required standard;
- the valve on the Endoscope biopsy/instruments channel port should be disposed of as healthcare waste.

(**Note:** *Single use biopsy forceps should be used in all patients. Endoscope accessories should be single use wherever possible. It is essential to have systems in place that enable Endoscopes, together with other detachable components and any re-used accessories, to be traced to the patients on whom they have been used)*

Quarantine Procedure

The Endoscope should be placed in an impervious rigid plastic container with a close-fitting lid. The lid should be sealed with heavy duty tape and labelled with the patient's identification details (i.e. name, date of birth and hospital number). The label should also state the procedure in which the Endoscope was used and the name of the responsible person (e.g. the Team or Unit Manager).

The sealed box can be stored indefinitely in a suitable designated place until the outcome of any further investigations is known (see reuse after quarantine below), or the Endoscope is required for another procedure on the same patient.

Reuse of Endoscopes after Quarantine :

An Endoscope may be removed from quarantine for reuse under the following circumstances:

1. For use on the same patient (the patient the Endoscope was used on prior to quarantine) in the case of definite, probable and asymptomatic (presumed infected or at increased risk) patients;
2. for use on any patients and returned to general use where investigations show that the diagnosis for the patient use that led to the quarantine is not related to Transmissible Spongiform Encephalopathies (TSE). Under no circumstances should quarantined Endoscopes be reprocessed for use on other patients unless the diagnosis of a TSE has been positively excluded.

Under such circumstances a risk assessment should be performed in collaboration with the Infection Prevention and Control Team and AE(D) before the Endoscope is used. It should be noted that there is a small risk of biofilm development within the Endoscope channels during prolonged periods of quarantine.

The Endoscope must then be put through a manual clean and automated EWD process in accordance with manufacturers instructions.

After the decontamination process is completed and before reuse :

- Perform a residual protein test;
- perform a microbiological sampling test on all Endoscope channels;
- swab outer surfaces and in between wheels and send for culture;
- ensure the risk review team, have evaluated and documented the safety risks of placing the Endoscope back into use.

See HSE Standards and Recommended Practice for Commissioning, Testing and Validation in EDUs (2019) for residual protein testing and sampling methodologies.

Documents to Access

Advisory Committee on Dangerous Pathogens (ACDP) Guidance to " Minimise transmission risk of CJD and vCJD in healthcare settings"

Annex F Endoscopes

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/470292/ACDP_TSE_Annex_F_Oct_2015.pdf

Advisory Committee on Dangerous Pathogens (ACDP) Guidance to " Minimise transmission risk of CJD and vCJD in healthcare settings"

Annex E Quarantining

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/547149/Annex_E_August_2016.pdf

3.8 Guidance for the Management of Endoscopes Used Out of Hours for Unplanned Emergency Procedures

Reusable flexible Endoscopes provide potential routes for transmission of pathogenic agents between patients in healthcare facilities. Timely and effective decontamination processes between patient use, is a vital component in the prevention of device related Healthcare Associated Infections.

Staff involved in the decontamination of flexible Endoscopes must be adequately trained and meet the competencies needed to safely reprocess flexible Endoscopes.

Training should include an awareness of the channel configuration of all Endoscopes, manual cleaning procedures, use of EWDs and channel irrigation adaptors (British Society Gastroenterology (BSG) 2017).

Staff should be annually assessed on their competency to perform all steps of the decontamination process for each type and model of Endoscope to be used on the patient. Units should ensure that competent staff are available to reprocess all Endoscopes used for out of hours unplanned emergency procedures.

(**Note:** *If an unplanned emergency Endoscopic procedure, for example a gastric bleed, is performed out of hours, an individual with knowledge of the Endoscope decontamination process must be available to prepare and clean the equipment (BSG ,2017*))

Local Risk Assessment

Best practice identifies that Endoscopes must be reprocessed immediately after the patient procedure has been carried out to minimise the risk of infection transmission to patients. The period of time that an Endoscope can be safely reprocessed, outside of the requirement for immediate reprocessing, has not been determined by evidence based research.

It is best practice for hospitals to have trained staff available to reprocess flexible Endoscopes used for emergency out of hours unplanned procedures, or have arrangements in place so that the used flexible Endoscope is transferred to a unit, within the hospital, where trained staff are available to reprocess flexible Endoscopes for these emergency unscheduled procedures.

It is not acceptable to leave an Endoscope, which has been used out of hours for an unplanned emergency procedure, without undergoing full reprocessing the following morning (see practical considerations page 21).

Always follow any special manufacturer instructions in the event of delayed reprocessing. The flowchart in Appendix V illustrates a process that should be followed to ensure the risk of infection transmission is minimised and best practice is carried out. In the case of emergency out of hours use of Endoscopes, a full risk assessment of the process and agreed documented operational procedures must be put in place.

A review group for each healthcare facility should be set up to include; the Infection Prevention and Control Specialists, Consultant Microbiologist, Risk Manager and Endoscopy Lead. A baseline assessment of the frequency of unplanned out of hour's emergency use of Endoscopes is recommended to inform practice and resource requirements.

The review group need to risk assess the effectiveness of the decontamination of Endoscopes that have been used out of hours for unplanned emergency procedures. Regardless of whether Endoscopes are used out of hours or within normal working hours the standards of decontamination must be the same to ensure patient safety.

Testing the cleanliness and/or microbial status of reprocessed Endoscopes, which have been used for out of hours unplanned emergency procedures, should be performed, to provide assurance that delayed reprocessing has not facilitated poor cleaning efficacy or the formation of biofilms on the inner channels of the Endoscope.

ATP measurement systems, when validated, may be used as a general indicator of cleanliness. ATP can be used as measure of the presence of living cells including microbial and complex somatic cells. These can be present in residual complex organic soils arising from clinical use of the Endoscope and/or microbial biofilms, however, ATP testing cannot be seen as a replacement for residual protein or microbial testing.

Testing for the microbial status of the Endoscope should be performed after a full reprocessing cycle which includes manual pre-clean, leak testing, manual clean and automated cleaning and disinfection. Testing should involve microbial testing of the flexible Endoscope outer surfaces and inner channels. The review group should risk assess the need to quarantine these Endoscopes until satisfactory results have been reported (see Standards and Recommended Practices for commissioning Validation and Testing in EDU Facilities for Sampling Methodology).

Practical Considerations

Research identifies that preventing the Endoscope channels from drying out, prior to full manual pre cleaning, is a critical risk factor for cleaning efficacy, therefore, flexible Endoscopes should be kept moist after use and before manual cleaning and disinfection. The term 'moist' is considered to be high levels of relative humidity of the air in the pack. If Endoscopes are allowed to dry during this period, soil will be difficult to remove. Endoscopes should be transferred from the point of use to the designated decontamination area as soon as possible.

- An Endoscope can be kept 'moist' during transportation by, for example, placing a non-linting sterile absorbent pad ,moistened with several **millilitres** of purified water (usually sterile water is readily available in theatre settings) with the endoscope in a sealable plastic bag. Once the bag is sealed it should then be placed into a rigid container, which supports the body of the Endoscope. Using a purpose built trolley, transport the container with the Endoscope to the decontamination facility to be fully decontaminated in accordance with the Process Flow Chart Appendix V.
- The creation of 'moist' conditions inside a pack should neither increase the weight of the pack significantly nor produce "free" liquid in the pack that could move about.
- Prior to adopting or changing the method, a trial may need to be conducted to assess the effectiveness of the method and determine possible adverse effects.
- Follow manufacturer's instructions (including any special instructions regarding delayed reprocessing of a particular Endoscope) for pre-cleaning, leak testing, manual cleaning, automated cleaning and disinfection and storage of each type and model of Endoscope.

- It is acknowledged that some organisations use an intense wash and disinfect cycle for Endoscopes which have been used out of hours and decontaminated the following morning. However, the efficacy of this process compared to a normal wash and disinfect cycle has not been established in published literature. If an intense cycle is to be utilised the cycle must undergo a full validation periodically and annually, in addition to the validation of the normal cycle. In all instances, it is recognised that the value of the manual cleaning process cannot be underestimated in terms of cleaning efficacy assurance. It is therefore essential that the full manual cleaning process takes place directly prior to reprocessing the Endoscope in the Endoscope Washer Disinfector.

Review and Resource Planning

It is recommended that a quarterly review of the unplanned emergency use of Endoscopes is performed to establish if there is a need for additional resources to support safe decontamination of Endoscopes in compliance with HSE Standards and Recommended Practices for the Operational Management of Endoscope Decontamination Facilities (2019).

An audit of the effectiveness of the local procedures, implemented to support cleaning and disinfection efficacy of Endoscopes used in unplanned emergency situations, should also be performed .

A Group Hospital approach to the management of unplanned “out of hours” emergency use of Endoscopes, ensuring effective decontamination of Endoscopes by dedicated decontamination personnel, should be considered.

4. Roles and Responsibilities for Operational Management of the Decontamination Facility

The approach chosen for this document is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual's role in connection with decontamination but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with decontamination and in some cases the same individual may take on more than one role. Whatever model of operational management is chosen, it is essential that the roles and responsibilities of the individuals involved are clearly defined and documented.

4.1 **Executive Management** of a healthcare organisation performing Endoscopy is defined as the owner, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises, including decontamination.

4.2 **Decontamination Lead JAG (2017)** recommends that there is a decontamination lead appointed by the hospital Senior Management with overall responsibility for Endoscopy decontamination practice. The expectation by JAG is that this individual is part of the management team, or equivalent role e.g. person with responsibility for governance, clinical quality etc. This individual is named as having overall responsibility for Endoscopy decontamination, so there is a direct line of communication from the point of service, through the organisation structure to board level. This person does not need to have decontamination knowledge, but must link with decontamination manager so that identified risks, challenges, capital planning or any other aspects relating to safe practice are controlled, managed and resources put in place to ensure actions are implemented.

4.3 **The Authorising Engineer for Decontamination AE(D)** is defined as a person designated by Management to provide independent auditing and technical advice on decontamination procedures, facilities, equipment and testing regimes associated with EDU services and to review and witness documentation on validation.

The Authorising Engineer for Decontamination AE(D)should be fully independent of the healthcare facilities' structure for maintenance, testing and management of the decontamination equipment and registered with the Institute of Healthcare Engineering and Estate Management Board (IHEEM). The AE(D) must have a reporting route to the Decontamination Lead and provide professional impartial advice on all matters concerned with decontamination including facility design and procurement of equipment.

The AE(D) will provide technical advice to the Competent/Test Person for Decontamination CP(D)s, Users and other key personnel involved in the control of decontamination processes in all healthcare facilities and will support independent audit of facilities, practices and equipment owned by the decontamination service.

4.4 **The User** is responsible for the day-to-day management of the EDU and EDU equipment and is responsible for ensuring that the EDU equipment is operated safely and efficiently. Endoscopy managers should have documented training records to demonstrate that they are competent at assessing the risks involved in inadequate decontamination of medical devices. Endoscopy managers training should also include an awareness of the roles and responsibilities of key personnel in the operation and testing of decontamination equipment.

The User/EDU Manager must be qualified to perform all daily and weekly tests, oversee testing and maintenance carried out by competent third parties, ensure dedicated Endoscope decontamination personnel receive appropriate health and safety training and assess the competencies of decontamination personnel to perform their duties .

The User/ EDU Manager must certify that the decontamination equipment is fit for use; hold all documentation relating to the decontamination equipment, including the names of other key personnel; to ensure that decontamination equipment is subject to periodic testing and maintenance; appoint operators where required and ensure that they are adequately trained; maintain production records; have documented training records demonstrating that dedicated decontamination personnel are competent to undertake assigned responsibilities; establish procedures for product release in line with the department quality management system; ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice and develop a plan to achieve compliance with HIQA, JAG and HSE Standards.

Regular training on auditing and quality assurance to support and improve the reliability of service delivery is essential. The User/EDU Manager must have access to professional advice from a suitably qualified Microbiologist, Infection Control Nurse Specialist, an Authorising Engineer (Decontamination) (AE(D)) and EWD manufacturer. The User/Manager must sit on the relevant Procurement/Decontamination Committees. A good strong team approach should be fostered with input from all relevant professions/disciplines including clinical staff.

4.5 Dedicated Trained Endoscope Decontamination Personnel are responsible for the reprocessing of flexible Endoscopes under their care. Their specialist skills reduce the risk of errors and cross-contamination; they should have a specialist knowledge of health and safety issues relating to reprocessing flexible Endoscopes; knowledge of contamination risks associated with reprocessing of Endoscopes; knowledge of the structure and operation of the Endoscopes under their care and specialist knowledge of the operation and care of the EDU equipment in their unit to enable nursing staff to attend to clinical duties.

4.6 Competent Person for Decontamination CP(D)

The Competent Person for Decontamination CP(D) is defined as a person who holds appropriate qualifications to perform validation, revalidation and periodic testing on specific EDU equipment. The CP(D) may also be known as the Test Person. The CP(D) or Test Person is designated by Management to carry out maintenance, validation and periodic testing of EDU Equipment. The CP(D) should report directly to an appropriate member of the estates department or should be subcontracted by them to perform this work and report to the responsible person for decontamination e.g., in cases where the responsible person may be a biomedical engineer or the Endoscopy Decontamination Unit Manager.

The principal responsibilities of a CP(D) are to carry out maintenance tasks; to carry out repair work; to conduct validation tests and periodic tests as given in HSE Standards and Recommended Practices for Commissioning, Validation and Testing in EDU Units in compliance with EN standards and EU regulation and to conduct any additional tests at the request of the User.

4.7 Management of Outsourced Contracts

Many of the services that support the operational functioning and validation of the EDU environment and equipment are outsourced. To ensure safe effective decontamination of Endoscopes the hospital must ensure that effective systems are in place to monitor and control services supplied by such contractors. This should always include a review of contractor and competent person competence. In addition, a procurement group must be in place and include representation from the Decontamination Lead, Authorising Engineer for Decontamination AE(D) and Infection Prevention and Control Team where appropriate. It is also important that there is clear oversight of and accountability for externally contracted services that the hospital uses.

Best Practice Contract Management Features include:

- Effective governance arrangements are in place to ensure that externally contracted services adhere to safe and effective Infection Prevention and Control practices, through setting up, managing and monitoring contracts of agreement.
- The contracts of agreement include the scope of service provided, audit requirements and governance arrangements for the quality and safety of services delivered. It includes complying with Infection Prevention and Control best practice and relevant legislation.
- The Decontamination Lead and/or where appropriate the Infection Prevention and Control Team are involved in the procurement decision for externally contracted services related to microbiological testing, validation, maintenance and periodic testing of EDU equipment, facilities, environment, water systems and AHUs (HIQA, 2017).

A microbiology laboratory service should be in place to support the service to prevent and control healthcare-associated infections. Features of such a service include the following:

- A microbiological service that is in line with best practice, evidence-based guidelines, national recommendations and legislation;
- the microbiological service provides at minimum a 5 days-a-week access to:
  - an accredited microbiology laboratory with appropriately trained and qualified staff;
  - expert advice by a consultant Authorising Engineer for Decontamination, Clinical Microbiologist or Environmental Microbiologist;
- microbiology results include information with interpretive comments to aid appropriate decision-making;
- a system for the rapid reporting of alert organisms to the User and the Infection Prevention and Control Team, which is accompanied by expert microbiological advice;
- the microbiology laboratory has the ability or has formal arrangements in place for the identification of alert organisms or micro-organisms that are epidemiologically associated with a known or potential out-break;

- safe and effective systems are in place for microbiological sample collection and transportation within the hospital and between laboratory sites in accordance with UN3373 regulations and advice given in the Guidelines for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013.

5.0 Training of Decontamination Personnel

5.1 HIQA Requirements Theme 6 Workforce Planning

It is acknowledged that decontamination personnel face daily challenges in the reprocessing of complex Endoscopes. The quality of the Endoscope decontamination is dependent on the competency of the personnel who perform the decontamination process.

Decontamination personnel have a responsibility to carry out part or multiple parts of the decontamination process, adequate education and training is critical to ensuring staff have the knowledge and understanding of the nature of their work and their responsibilities and most importantly the implications for non adherence to their training (HIQA ,2012).

A "Guide to HIQA's Thematic Review of Decontamination" (2018) was circulated to all CEO's and GM's in June 2018. The document requires that there is a continuing programme of training and education for personnel involved in medical device decontamination. The hospital must ensure that key personnel have been appropriately trained to the necessary standard of competence and are supported with on going education and training reflecting national and international evidence and best practice in relation to decontamination and reprocessing of reusable medical devices.

When a service sets its objectives for the delivery of sustainable high quality, safe care and support, it must determine the workforce requirements to deliver on these objectives. The individual members of a workforce must be skilled and competent and the workforce as a whole must be planned, configured and managed to achieve these objectives (HIQA, 2018).

As a minimum all new staff working in Endoscope Decontamination practice must complete HSEland Endoscope Reprocessing training on induction to the unit.

HIQA have also looked for the number of staff who carry out Endoscope decontamination who have received a FETAC Level 6 Minor Award in Decontamination during their inspections. A specific programme has been developed in collaboration with the Technology University Dublin Tallaght and the HSE to meet National and International best practice in the Decontamination of Endoscopes. Contact the Department of Life Long Learning the Technology University Dublin Tallaght.

It is essential that personnel at all levels involved in decontamination of Endoscopes should have a sound knowledge of decontamination, including knowledge of the basic elements of infection prevention and control, microbiology and process chemicals to meet health and safety obligations of the organisation and the individual and ensure reliable Endoscope decontamination to minimise the risk of infection transmission .

5.2 Type of Training

Occupation Health and Chemical Safety

Personnel who work in the decontamination environment must be trained on the Occupational Health and Safety risks associated with their work including, use of PPE ,potential for and management of percutaneous injury, chemical spillage, management and use and storage of chemicals, management of occupational exposure to chemicals including prevention of inhalation and splash of chemicals to the skin and mucous membranes.

Decontamination of Endoscopes

Personnel should be trained in the decontamination of all Endoscopes they will encounter. They should be trained and have demonstrated competence for each type and model of Endoscope that they will process. This training must include selection of the correct brush size to use for each Endoscope channel, correct connectors to be used for the specific EWD and CESC and training on the user interface between the EWD, CESC and other storage methods they will use, as well as any other techniques required in decontamination practice.

Use of EWD and CESCs

Detailed training on a particular model of EWD and CESC or other storage systems is essential and requires that adequate and separate training should be provided by the manufacturer, either on site or by courses at their premises. The training should be repeated at minimum every two years.

Daily and Weekly Testing of EWD and CESCs

The user must be trained to perform the necessary tasks to ensure daily and weekly testing of EWDs and CESCs are in compliance with HSE Standards and Recommended Practices for Commissioning Validation and Testing in Endoscopes Decontamination Facilities.

Professional Development Portfolio

All mandatory in-house training, specialist training for Endoscope Decontamination Practice and Equipment and competency assessment should be recorded in a Personal Development Portfolio and reviewed at least annually as part of an annual personal development planning (PDP) review.

(**Note:** *External parties (such as Endoscope manufacturers and Endoscope washer disinfector manufacturers) who provide user education should provide evidence of their own training and competency to provide training in their area of responsibility. This training should be signed off by the device manufacturer*)

(**Note:** *An example of competency training requirements for Endoscope training personnel is provided in Appendix VIII*)

5.3 Benefits to the Employment of Trained Decontamination Personnel

There are several advantages to the employment of trained specialist staff for the decontamination of flexible Endoscopes:

- Their specialist skills reduce the risk of errors and cross-contamination.
- they have a specialist knowledge of health and safety issues relating to reprocessing flexible Endoscopes;
- they have a specialist knowledge of the operation and care of the EWDs in their unit;
- they can receive training in decontamination, auditing and quality assurance, improving the standard of practice in the Endoscopy department;
- qualified nursing staff can attend to clinical duties.

5.4 What Should Training Include?

Training should include but not be limited to:

- Occupational Health and Safety;
- chemical Safety;
- user interface with EDWs, CECSs, other prolonged Endoscope storage equipment;
- all makes and models of Endoscopes to be processed including channel size, brush size.

5.5 Training on Specific Connectors, Connection Sets and Channel Separators:

- The user can identify and connect correct connection sets required for the EWD and CESC;
- the user can identify the correct configuration for connecting each Endoscope type/model to the EWD or the CESC to be used;
- connectors loading conveyors and trolleys, load carriers and load baskets are used effectively and safely when in use and are confirmed to be compatible with the Endoscopes to be processed;
- the user can identify the appropriate connections for irrigation/flushing of all channels of all Endoscope types/models in use;
- knowledge of connection points on the EWD and CESC and recognition of when O rings etc., need to be replaced.

Channel Separators:

- The user can identify all parts move smoothly;
- the user can perform attachment of fixed parts, and identify if parts that need to be attached are indeed attached;
- identify completeness of the channel separator, and if parts are missing;
- identify the condition of O-rings and interface with the Endoscope; is there damage or scratches to bending parts.

Connectors:

- The connection between the EWD and the Endoscope shall not impair the operation of the machine as a result of leaks, flow restrictions or other limitations;
- the user can inspect the connector and establish the condition of the O-rings and interface with the Endoscope, the EWD and the CESC;
- the user can identify damage to the connector and the tubes attached to the Endoscope, EWD and the CESC;
- the user ensures the connector tubes are not damaged or blocked by bending or twisting;
- the user can recognise when O rings etc., need to be replaced;
- the user can lubricate O rings if this is a requirement by the manufacturer of the separator, connection set, EWD or CESC.

6. Track and Trace

A comprehensive traceability system delivers a complete electronic record of all reprocessing stages for the decontamination of reusable invasive medical devices (RIMD) including Endoscopes and their associated accessories used for patient treatment.

Track and Trace systems provide evidence that Endoscopes and their associated accessories used in clinical procedures have been decontaminated prior to and after use. A Track and Trace system enables timely identification of reprocessed Endoscopes and their accessories to facilitate recall/withdrawal of potential faulty or contaminated Endoscopes or accessories from use. In addition, the system must facilitate timely identification of service users exposed to specific Endoscopes and accessories , which may require specific service user consultation follow-up, in the event of a reprocessing failure or exposure to potential infection risk. The HSE has implemented a National Endoscope Track and Trace software system, "Scope Track" for the recording of the decontamination process and storage of flexible Endoscopes and their accessories within the EDU.

The objective of the National Scope Track system is to ensure that there is effective audit trail in place which can track the Endoscopes and their accessories through the decontamination process and link them to the patient on whom they have been used and to ensure:

- Identification, mitigation and management of risk across EDU services;
- management information is available across the service;
- standard decontamination function across the Health Service;
- use of Unique Device Identification (UDI) and Standardised Coding (GS1) in compliance with the Medical Device Regulation 2017/745 which states that "Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device; business continuity and tracking of loaned and borrowed Endoscopes.

(***Note:*** *Computer terminal points to facilitate the instillation of the tracking system must be considered for all equipment including Endoscope storage systems*)

2

Part 2

Standards and Recommended Practices for Endoscope Decontamination

1. Occupational Health

HIQA Theme 2: Effective Care and Support	
Standard 2.6	Healthcare is provided in a clean and safe physical environment that minimises the risk of transmitting a HCAI.

Theme 3: Safe Care and Support	
Standard 3.2	Service providers integrate risk management practices into daily work routine to improve the prevention and control of HCAI.
Standard 3.5	Service providers adhere to hand hygiene practices to minimise the risk of acquiring or transmitting infection.
Standard 3.8	An occupational health service is in place to decrease the risk of infection to staff.

Features of a service meeting this HIQA Standard include:

Standard 2.1: An infection prevention and control programme is in place to ensure a well-organised and integrated approach to the prevention and control of healthcare-associated infections.

Training is provided to all personnel who may need to use Personal Protective Equipment (PPE) which includes:

- Appropriate indications for specific PPE component;
- proper donning, doffing, adjustment, and use of PPE; and
- disposal of PPE. Training is provided at induction and periodically updated (HIQA, 2017).

1.1 Standard Precautions and Safe Work Practices

Overview

The standard precautions and safe work practices are required to minimise the risk of infection to both service users 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. 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.

Chapter 3 of Part 2 and Schedule 2 of the Welfare at Work Act (General Application) Regulations 2007,sets out requirements relating to the provision and use of PPE , assessment of PPE, conditions of use and compatibility of PPE, personal use of PPE, maintenance and replacement of PPE and information, training and instruction.

PPE should be worn by personnel when decontaminating Endoscopes to reduce the risk of exposure to potentially infectious material. Managers should ensure that PPE is made available and all personnel including engineering contractors and personnel responsible for decontamination activities apply the correct use and disposal of same.

1.2 Endoscope Washroom Attire

Dress Code

- All personnel working in the Endoscope reprocessing (decontamination) unit should wear freshly laundered low linting attire. (Low linting attire 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 as other personnel working in the department;
- on leaving the decontamination unit, staff should change into their normal day wear;
- after use, the attire should be discarded appropriately in a designated post use container/bag;
- hands should be decontaminated before leaving the changing area;
- work attire should never be worn outside the decontamination unit.

Head/Hair Cover

The first item 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)*

1.3 Personnel Protective Equipment

Protection for Eyes/Nose and Mouth

Healthcare Workers (HCW) should wear single use PPE to reduce the risk of body fluid exposure from splashing and spraying of blood or body fluids, protection for eyes/nose and mouth should include the following:

- A face shield that covers the eyes, nose, mouth and chin or a fluid repellent mask and separate goggles or fluid repellent mask with integrated eye shield;
- masks and face shields should be single-use, fitted and worn according to the manufacturers' instructions, removed immediately if moist or visibly soiled and discarded in the appropriate healthcare waste stream;
- masks and face shields with integrated eye protection should be optically clear, antifog, distortion free, close fitting and shielded at the side.

*(**Note:** Fluid repellent masks, goggles and face shields should not be touched by hands while being worn or worn loosely around the neck. All PPE should be discarded in the appropriate healthcare waste stream)*

Protection for Skin and Clothing

Healthcare workers should wear plastic aprons or impermeable gowns 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.

(**Note:** *A risk assessment should be undertaken to determine whether a plastic apron or gown should be worn)*

Gloves

Healthcare workers should decontaminate their hands before and after removing gloves hand washing or using alcohol gel. (Alcohol gel should not be used on visibly soiled hands). Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.

- Gloves should be used for handling contaminated Endoscopes, waste and when performing environmental cleaning activities, selected and worn according to the task and replaced if 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.
- After use, gloves should be discarded in the appropriate healthcare waste stream. It is important to remove used gloves and decontaminate hands before touching a clean surface such as worktops, or pens.

Footwear

Healthcare workers 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 capable of being regularly cleaned and disinfected. Footwear should be dedicated to the area in which healthcare worker is designated.

Figure 1: Personal Protective Equipment "Decontamination" Area (receipt of Contaminated Scopes)

1.4 Endoscope Clean Room Attire

Dress Code

HCWs working in the 'clean' area (inspection drying and storage of decontaminated scopes) should wear a freshly laundered scrub suit. Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected. Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet. Appropriate clothing should be used by staff who are involved in the maintenance of reprocessing equipment. When working within the Endoscope reprocessing unit suitable cover attire should be worn.

Head/Hair Cover

The first item of clothing 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.

Figure 2: Personal Protective Equipment 'Clean' Area (Inspection, Drying and Storage of Decontaminated Scopes).

1.5 Management of Chemicals

Handling and Storage

The methods to be used for handling and storage of process chemicals should be defined in written policies, procedures protocols and guidelines. Chemicals that should not be stored together should be clearly identified. Chemicals should not be stored above shoulder height.

Chemicals should be stored in locked cabinet with the type defined according to the Safety Data Sheet (SDS). Suppliers of chemical agents must provide SDS for all chemical agents (including cleaning agents and disinfectants).

Copies of all SDS should be available to all employees in a designated area at all times, so that appropriate action can be taken in case of exposure to a hazardous substance.

Chemical Risk Assessment

The Chemical Agent Regulations 2001 and 2015 point out the specific requirements necessary to complete a Chemical Agents risk assessment of the chemical agents used in the work place. Advice should be sought from your Dangerous Goods Safety Advisor (DGSA).

The Chemical Agent Regulations Specify Requirements to:

- Determine the hazards (See Label, Safety Data Sheet, industry guidance);
- assess the risk (what is the exposure?) to employees and others;
- put prevention and control measures in place following the risk assessment;
- make arrangements to deal with accidents, incidents and emergencies;
- make arrangements for information, training and consulting their employees;
- provide appropriate health surveillance;
- keep exposure records.

If information is incorporated into policies, procedures, protocols and guidelines, the original wording should be used and the SDS referred to. Personnel should read and follow the precautions and instructions given on the SDS and on the label prior to handling and use (advice may be sought from the DGSA for your hospital or hospital group).

Chemical Training

All personnel who handle chemicals e.g., rinse aid, disinfectants; etc., should be trained in following:

- Safe handling of chemicals (check the advice on the chemical SDS sheet and with the DGSA for your hospital to clarify if decontamination personnel in contact with chemical disinfectants used to decontaminate Endoscopes require fit testing of face masks for use when the chemical on the EWD is being replenished or in the event of a chemical spill);
- method of managing chemical spillages;
- first aid required in the event of personal exposure;
- correct disposal of material used.

Chemical Spillage Kit

Safe storage provision is needed for containers of chemicals used in the EWD. These chemicals are irritants, toxic and frequently corrosive. Provision should be made in, or adjacent to, the storage area for an emergency eye-wash station, a source of running water to dilute any spillage and a spills kit. In each area where chemicals are used, a spillage kit should be available to allow safe and easy removal of spills.

A first aid eye wash station should be available nearby or on hand.

Where chemicals may contact eyes/skin, consideration should be given to the availability of chemical neutralisation within the department (e.g. the hypertonic, polyvalent, amphoteric compound Diphoterine can be used to neutralise and inactivate up to 600 chemicals, including spills on environmental surfaces and inadvertent chemical contact with skin, eyes or mucous membranes).

For EWDs employing volatile process chemicals (request advice from the DGSA), the exhaust ventilation should maintain the environmental concentration below any limit specified for occupational exposure and the discharge should be to a safe place. It must be ensured that emissions from the EWDs do not cause personal exposure to exceed the legal limits. Advice should be sought from the EWD manufacturer, the supplier of the chemical and/or the Health & Safety Officer or Dangerous Goods Safety Advisor. Emissions from the EWD during normal operation and maintenance including when opening the EWD at the end of the cycle or when changing chemical reservoirs should not expose personnel to concentrations in excess of legal limits.

A spills kit suitable for Endoscopy units should contain at least:

- Absorbent granules/powder – to absorb liquid spills;
- absorbent stock - to contain liquid spills;
- chemical inactivator - to neutralise a chemical spill;
- plastic apron, gauntlets and respirator/mask –Personal Protective Equipment (PPE);
- orange bag –for containing clinical waste;
- dust-pan and brush –to sweep up granules and Fuller's earth, if used.

The spills kit should be kept outside the decontamination room, but be easy to access in the event of a spill. This allows the operator to leave the area of immediate danger and don appropriate PPE prior to returning to address the spill of both detergents and disinfectants used should provide material safety data sheets for the products supplied. These should include details of biocompatibility studies. A hazard from EWD chemicals will occur when stock containers of concentrate are changed. Strict precautions and PPE in line with local risk assessments are required: chemical resistant gloves/gauntlets, respirator/mask (grade to suit chemical being handled), apron and good ventilation.

1.6 Management of Occupational Risk of Exposure to HCAIs and Injury*

The Health and Safety Authority Guide to the European Union Regulations (2014) "Prevention of Sharps Injury in the Health Sector" recognises that personnel working in decontamination practice are at risk of sharps and percutaneous injury.

- Staff must be facilitated to comply with standard precautions in all healthcare settings, for all patients, whether infection is known to be present or not. Staff are aware of the correct indications for application of personal protective equipment, including requirements for exposure prone procedures.
- Staff must be informed of the benefits and drawbacks of vaccination and failure to vaccinate. It is recommended that as a minimum that all staff who are at risk through contact with blood and/or body fluids should be immunised against Hepatitis B Virus (HBV), unless immunity has been previously established or vaccination contraindicated.
- A system for the identification of potential risk factors associated with staff acquiring a HCAI must include but are not limited to:
  - skin conditions such as dermatitis or other skin conditions that causes a break in skin integrity;
  - allergies to products such as latex and hand hygiene products;
  - exposure prone procedures; in high risk settings such as decontamination;
  - current infection and vaccination refusal or non-responder.
- Sharps must be disposed of at the point of use, prior to the transport of devices to the EDU.
- Provision of training relating to the risk of sharps injury to decontamination staff who are exposed to these risks.
- Staff must report any accident or incident involving an exposure to the risk of injuries and/or infections from sharps.
- Assessment and management** of staff as soon as possible following any injury sustained during the course of work.
- Regular monitoring of occupational related injury and HCAI rates to identify high risk healthcare settings.

*Injury includes needle stick or other sharps injury from instruments, human bite, splash from blood and body fluids may be associated with manual cleaning practices (especially exposure to broken skin or mucous membranes).

**Management includes first aid, risk assessment, testing, treatment (including post-exposure prophylaxis for HBV and HIV, where applicable), counselling and follow-up, records and documentation

2. Decontamination of Endoscopes

Theme 2: Effective Care and Support	
Standard 2.6	Healthcare is provided in a clean and safe physical environment that minimises the risk of transmitting a HCAI.
Standard 2.7	Equipment is cleaned and maintained to minimise the risk of transmitting a HCAI.
Standard 2.8	Reusable Invasive Medical Devices are decontaminated and maintained to minimise the risk of transmitting a HCAI.

The effectiveness of decontamination is determined by all elements of the Endoscope reprocessing life cycle (Figure 2 page 9). All aspects of the life cycle need to be controlled and managed if decontamination is to be fully effective. .

Features of a service meeting this HIQA Standard include:

2.8.1 All reusable invasive medical devices are safely and effectively decontaminated, maintained and managed in accordance with legislation, manufacturers' instructions, the National Decontamination Safety Programme, national decontamination standards and best practice recommendations.

2.8.5 Staff with responsibility for decontaminating reusable invasive medical devices have the necessary training and competencies to do so.

2.8.6 Staffing arrangements are in place to support out-of-hours decontamination.

2.8.7 Use of an equipment management system that supports and enables maintenance of an up-to-date track-and-trace record for reusable invasive medical devices, and reporting in the case of a healthcare-associated infection incident.

2.8.8 The service regularly reviews all the relevant stages of the decontamination life cycle of reusable invasive medical devices to ensure compliance with best practice. This includes reviews during any healthcare-associated infection incident or outbreak involving reusable invasive medical devices. Action is taken to address any areas identified for improvement.

2.1 Decontamination of Endoscopes—Choice of Decontamination Process

Endoscopes should be reprocessed and managed to a level appropriate for their intended use. The appropriate level depends on the body sites where the Endoscopes will be used and the risk associated with a particular procedure as categorised under the Spaulding Classification (Table 2 page13).

Decontamination processes should be chosen to be compatible with the Endoscopes to be processed.

2.2 Decontamination Life Cycle—Cleaning and Disinfection

Endoscopes and their accessories are classified as medical devices under the Medical Devices Regulation (MDR). 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 service users and/or compromise the quality of clinical samples.

The objective of this recommended practice 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.

Step 1: Pre-Cleaning at the Point of Use

- **Wipe the Insertion Tube**

  Immediately on removal of the Endoscope from the service user, 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 lint free cloth appropriately after use.

Figure 3: Wiping the Insertion Tube

- **Aspirate Enzymatic Detergent in Accordance with Manufacturers Recommendations 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.

  For Endoscopes with auxillary channels, manufacturer instructions, for additional pre cleaning steps at the point of use, must be followed.

Figure 4: Aspirating the Enzymatic Detergent Through the Suction/Biopsy Channel

- **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 5: Purging Air/Water Channels

- **Detach Removable Components**

  Remove the Endoscope from the light source.

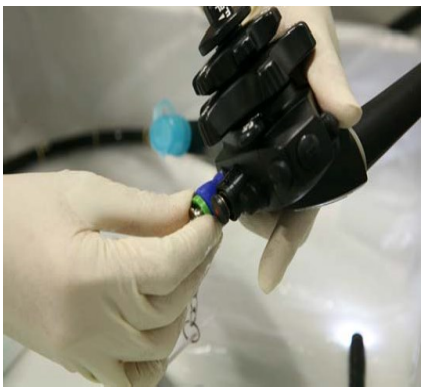
  Attach protective video cap (if using video Endoscope).

Figure 6: Removing the Endoscope From the Light Source

- **Removing Valves/Buttons/Caps**

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

Figure 7: Removing Valves/Buttons and Caps



(**Note:** *It is preferable to have extra valves/buttons/caps to allow for additional time to ensure that adequate cleaning is performed prior to disinfection/sterilisation however , additional valves/ buttons/caps remain with the scope as a unique set)*

(**Note:** *Accessories should not be interchangeable, extra sets should remain with scopes as a unique set for traceability purposes*)

Step 2: Transport of Endoscopes

Contaminated Endoscopes and accessories should be placed in re-usable, solid walled, leak proof container with a hard lid that completely enclosed the Endoscope/trolleys and transported to the 'dirty' area (receipt of contaminated Endoscopes) as soon as possible after use.

Transport containers should protect both the product during transit and the handler from inadvertent contamination.

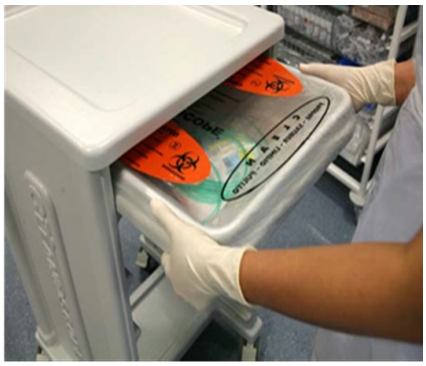
The container should be labelled as "contaminated".

Personnel should be trained to handle, collect and transport contaminated Endoscopes and accessories and should wear PPE in accordance with local safety policies, procedures, protocols and guidelines.

Policies, procedures, protocols and guidelines for transportation of contaminated Endoscopes (return of used items for reprocessing) and accessories should be developed, reviewed periodically, and readily available within the department.

Figure 8: Transport of Contaminated Endoscopes and Accessories

Figure 9: Transporting to the Cleaning Area



Step 3: Cleaning and Disinfection in the EDU

The objective of this recommend practice is to provide guidelines in relation to cleaning and disinfection of contaminated Endoscopes and accessories. Cleaning is the initial and most critical steps in breaking the chain of disease transmission.

- **Endoscope Leakage Testing**

  There are two types of leakage tests wet or dry.

  The Endoscope should be leak tested according to the manufacturers' instructions.

  All Endoscopes should be leak tested prior to immersion and between each service user usage.

  The leak test will detect damage to the interior or exterior of the Endoscope that may lead to cross infection associated with damaged Endoscopes.

  Perforated channels in Endoscopes are an infection control risk and damage may also occur to parts of the Endoscope not designed for fluid exposure.

Figure 10: Leak Testing

Wet Leak Testing

Attach the leak tester and pressurise the Endoscope. Some manufacturers specify removing detachable parts prior to leakage testing others do not. Immerse the Endoscope in the designated sink in water and observe for a continuous stream of bubbles. If the leakage 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 using the controls. 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.

Failure to follow manufacturer instructions regarding the disconnection of the leak tester, after the leak test has been performed, may cause damage to the Endoscope.

Dry Leak Testing

Follow manufacturers' instructions for connection and use of the dry leak tester. Do not immerse the Endoscope into liquid until the leak test has successfully been completed. Using the inflation bulb squeeze until the needle reaches the recommended level. If the needle stays in the advised position it is safe to proceed to the next stage of the decontamination process. If the needle falls below the recommended level a leak has been detected.

- **Processing Endoscopes that Fail the leakage 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.

- **Manual Cleaning in the EDU**

  The Endoscope is manually cleaned and then further cleaned and disinfected in an Endoscope washer-disinfector.

  Make up detergent solution to the manufacturers' instructions for reprocessing each Endoscope.

(**Note:** *An automated detergent dispenser with temperature monitor is preferred. The automated dispenser must be calibrated at least annually*)

- **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.

Figure11: Immersing the Endoscope:

- **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) should be carried out, in accordance with manufacturers' instructions.

  The Endoscope should be completely disassembled so that all surfaces may be reached for a thorough cleaning.

- **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, single use cleaning tools will prevent damage to the Endoscope.

  Single use soft brushes are useful to clean grooved control handles and to brush the distal tip.

  Valve sets and biopsy ports should be brushed using brushes which are designed for this purpose.

(**Note:** *Manufacturer approved single use brushes , chosen to clean the required channel diameter, should always be used*)

- **Brush and Flush 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.

  After brushing is complete, aspirate the detergent through the entire channel system in accordance with the manufacturers instructions for use. The detergent should be aspirated from a clean bowl, separate from the contents of the sink used for manual cleaning. This is to avoid the possibility of recirculation of tissue/protein removed from the channels.

  Endoscope manufacturers provide purpose-designed irrigation tube sets that connect with each channel to facilitate cleaning.

(***Note:*** *Some Endoscopes manufacturers require a suction arrangement for aspiration of the suction channels)*

Aspiration of air/water channels should be undertaken with a syringe of a size recommended by the endoscope manufacturer.

(***Note:*** *Automated aspiration systems that incorporate temperature monitoring and recording of the flushing process are now available. Before using such systems, the manufacturer of the endoscope should be consulted. These systems require periodic disinfection in accordance with the system manufacturers instruction*)

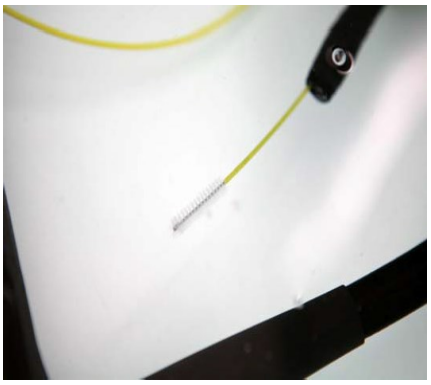
Drain water from the sink.

Curl Endoscope for transfer to a separate sink.

Discard the brush appropriately after use.

Traceability labels from the brushes should be maintained as a record.

Figure 12: Brushing Channels



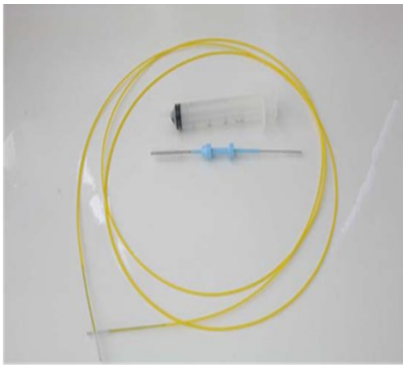
- **Brushes**

Cleaning brushes for all brushable channels should be purchased and used in accordance with scope manufacturers' recommendations.

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 13: Brushes



(**Note:** *Single-use brushes must be used*)

- **Rinsing**

  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 contamination.

  The amount of water required to thoroughly rinse the Endoscope after cleaning will vary according to the design and length of the Endoscope.

- **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.

Step 4: Automated Cleaning and Disinfection in the EWD

- **Use of EWD**

  An EWD provides an automated process with leak testing, cleaning, rinsing, disinfection and final rinse and drying stages. The Health Service Executive regards the use of an EWD to process flexible Endoscopes as mandatory. Unless specifically required by the Endoscope manufacturer it is not acceptable to carry out chemical disinfection manually.

The Endoscope should be transferred to the automated EWD in an appropriately sized receptacle so as to avoid contamination of the environment.

- **Use of Chemicals in the EWD**

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 Endoscope washer disinfector by the 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 required .

There should be a log of disinfectant batch numbers and expiry dates.

The water supplied to the Endoscope washer disinfector for the rinsing after the chemical disinfection stage should be purified water and should be free from microbial contamination.

- **EWD Procedure**

Determine the exact number of channels on the Endoscope to be processed.

Determine the number of irrigation ports available for use in the Endoscope Washer Disinfector EWD.

Ensure that the automated process on the EWD will irrigate, clean where relevant, and disinfect all channels (including auxiliary and elevator wire channels) on the Endoscope. Ensure that the EWD and all services are operational.

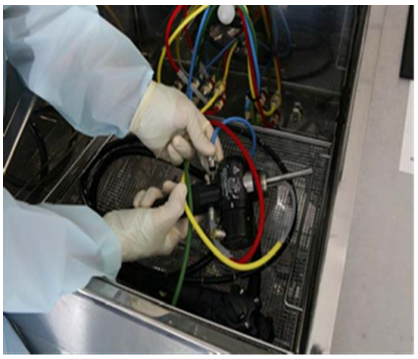
The EWD should not start if any anomalies are present.

Transfer the Endoscope(s) (that have been manually cleaned) to the EWD.

The channels of the Endoscope should be attached to the appropriate connection in the EWD to ensure the free passage of fluids through the channels during processing.

(**Note:** *Check that the attachment tubing is not kinked*)

Figure 14: Attaching the Endoscope Channels



Manual washing is required whether or not the EWD 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.

Check that the Endoscope blanks/caps, connectors are intact and secure.

Select appropriate cycle. The EWD cycle must be validated and manufacturer instruction must be followed.

- **Automated Endoscope Reprocessing**

Enter Endoscope code and user code.

Initiate EWD 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 15: Selecting the Cycle

Cycles which were aborted should be documented with the action taken in a log book.

- **Self-Disinfect Cycle**

  All EWDs should undergo a self-disinfect cycle preferably at the beginning of each day, or in accordance with the EWD manufacturers' recommendations. 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.

- **Documentation Required Post Automated Cleaning and Disinfection**

  - All documentation for automated cleaning and disinfection should contain the following information:
  - Endoscope Washer Disinfector (EWD) identification number or serial number;
  - Endoscope unique identification number;
  - cycle number;
  - type of EWD and type of cycle used;
  - date and time of start of cycle and load content;
  - critical parameters for the specific washer-disinfector cycle;
  - operators name;
  - results of washer-disinfector process;
  - signature of an authorised qualified person confirming whether or not the process has passes;
  - 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.

Figure 16: EWD Record

- **Drying**

The EWD provides a air purge stage after the final rinse 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.

Drying minimises staining and reduces the risk of recontamination during inspection and assembly of Endoscopes. Residual moisture can damage Endoscopes and allow biofilm formation.

When the purge cycle has been used, on removal from the EWD, the outside of the Endoscope should be wiped with a disposable sterile dry lint free cloth.

Step 5: Post Cleaning Inspection and Function Testing

- **Checking the Endoscope**

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

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, residue and there is free movement of all parts.

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.

Factors that may alter the efficacy of the decontamination process include staff training, age, type and model of the Endoscope.

(**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*)

(**Note:** *The use of sterile gloves should be considered when handling Endoscopes after they have been cleaned and disinfected to minimise the risk of recontamination of the disinfected Endoscopes*)

Step 6: Transport of Endoscopes to the Point of Use or Storage

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

The objective of this recommended practice is to provide guidelines in relation to the transportation of reprocessed Endoscopes and accessories.

Reprocessed Endoscopes and accessories should be transported in clean dry containers. Single use sterile tray liners with covers that denote cleanliness status of the Endoscope are required.

Endoscopes should be transported in 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 with a hard cover and should visibly state decontaminated Endoscope.

There should be an adequate number of transport containers and trolleys in the Endoscope reprocessing unit.

There should be documented cleaning and disinfection regime for all transport containers and trolleys between dirty and clean usage.

Step 7: Storage of Endoscopes

- **Detachable Components and Parts (including buttons and valves)**

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. 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.

- **Controlled Environment Storage Cabinets (CESC)**

The air filtered Endoscope storage cabinet should maintain the microbiological quality of the reprocessed flexible Endoscope and accessories for a predetermined period validated by and in accordance with the manufacturers' recommendations.

The drying process should remove moisture from and out of the Endoscope

Once placed in the cabinet, the endoscope should remain in place for the full duration of the validated drying stage.

(**Note:** *The drying stage is not the same as the validated storage period. The cabinet manufacturer can advise on the duration of the drying stage*)

After the drying process a conditioning process guarantees the Endoscope maintains its condition for up to 72 hours or as specified by the manufacturer.

(**Note:** *If the maximum storage time has elapsed a process alarm should advise that maximum time has exceeded, the scope should not be used until reprocessed again*)

When Releasing an Endoscope from a CESC

- ◊ visually check that the Endoscope is dry;
- ◊ confirm and verify by signature that the Endoscope was dry and the conditions when storage and drying were achieved.
- ◊ confirm that the maximum storage time has not been exceeded.

Remove the dry Endoscope and accessories from the cabinet and place in the designated trolley or container.

(**Note:** *The use of single use sterile tray liners and covers that denote the cleanliness status of the Endoscope are preferred*)

The cabinet should be electronically controlled and should be subject to validation and microbiological testing in accordance with manufacturers' recommendations. The cabinet should be routinely serviced in accordance with manufacturers' recommendations. The connection method for use should be determined by the scope manufacturer. The cabinet should have the capability to store process information and data.

(**Note:** *For each Endoscope series, there should be a set of connectors available for connecting all channels of the Endoscope to the air connector as specified by the manufacturer. These connector sets must be checked for functionality and intact*)

- ♦ **Endoscope Storage Cupboards**

If storage cupboards are used then Endoscopes should be stored hanging vertically in a designated dry and well ventilated storage cupboard.

Storage cupboards should be cleaned daily 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 needs.

- **Portable Storage Systems**

The portable storage system should maintain the microbiological quality of the reprocessed flexible Endoscope and accessories for a predetermined period validated by and in accordance with the manufacturers' recommendations. The protective container or bag must have a label affixed that states the expiry date after which the Endoscope cannot be used and should be reprocessed.

Prior to placing a reprocessed flexible Endoscope into a portable storage systems protective container or bag, the Endoscope should be subject to a drying process to remove moisture from and out of the Endoscope. Where Endoscopes need to be processed in a controlled environment storage cabinet first, to ensure they are dry before packing and storing, the User needs to secure clarification from cabinet manufacturers on the actual drying time required for each type of Endoscope.

- **When Releasing an Endoscope from a portable Storage System Protective Container or Bag**

  - visually check that the Endoscope is dry (if the system does not use a processes chemical to maintain the condition of the Endoscope);
  - confirm and verify by signature that protective container or bag was not broken, compromised or damaged in any way during the storage period;
  - confirm that the maximum storage time has not been exceeded.

Remove the dry Endoscope and accessories from the storage system container or bag only when the Endoscope is ready to be used.

The system should be electronically controlled and should be subject to validation and microbiological testing in accordance with manufacturers' recommendations. The system should be routinely serviced in accordance with manufacturers' recommendations. The system should have the capability to store process information and data and must be set up as part of the tracking system for full traceability.

(**Note:** *With respect to those portable storage systems that utilize a process chemical to maintain the microbiological quality of the Endoscope, for each Endoscope series, there should be a set of connectors available for connecting all channels of the Endoscope to the chemical delivery connector as specified by the manufacturer. These connector sets must be checked for functionality and intact*)

Step 8: Cleanliness and Functionality of Endoscopes Prior to Reuse

- **Cleanliness and Functionality**

  Endoscopes should be reprocessed before use if more than three hours has elapsed from the last decontamination process unless stored in a dedicated controlled environment storage cabinet that has been validated for more prolonged storage.

  Prior to reuse, all decontaminated Endoscopes should be inspected for cleanliness.

- **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, snares, 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.

(**Note:** *This should be carried out in a central decontamination unit and should be done in accordance with the manufacturer's instructions*)

Reusable water bottles should be sent to the central decontamination unit at the end of the session to be cleaned and sterilised in accordance with the manufacturers' instructions i.e. every 3 hours (BSG, 2017)

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.

Discard and replace reusable valves and distal tips regularly or if they become damaged during use.

Figure 17: Detachable Parts

Step 9: Low Temperature Sterilisation of Endoscopes

(**Note:** *See Part 1, section 3.6 and table 2 for guidance when sterilisation may be required*)

Guidance on the operation of low temperature sterilisers is given in Health Service Executive Standards and Recommended Practices for Central Decontamination Units.

Only low temperature sterilisation processes identified within the manufacturer's instructions should be used.

2.3 Transfer of Used Endoscopes to Third Parties—General Principles

Anyone who inspects, services, repairs or transports Endoscopes, either on healthcare organisation premises or elsewhere, has a right to expect that the Endoscopes have been appropriately treated so as to remove or minimise the risk of infection or other hazards.

General Principles

All Endoscopes intended for inspection, service, repair, or disposal must be decontaminated before despatch, unless the Endoscope cannot be reprocessed without further damage occurring to the Endoscope and procedures are in agreement with the Manufacturer/Supplier for the Endoscope.

In all circumstances the Endoscope must be accompanied by a certificate stating the status of the Endoscope i.e., contaminated or the method by which it was decontaminated.

If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, the recipient may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.

Endoscopes that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.

When Endoscopes are returned after being repaired, the Endoscope must be decontaminated prior to re use.

Each Endoscope should be checked for functionality prior to reuse post repair or service as per healthcare organisation policy, procedure, protocol and guideline.

2.4 Loaning and Borrowing Endoscopes

♦ General Principles

Endoscopes may be loaned to a healthcare organisation so that a particular procedure can be performed. The Endoscopes may be borrowed either from manufacturers or other healthcare organisation and are returned after use. This practice increases the risks associated with the decontamination and reprocessing of such devices because the organisation may not be familiar with the Endoscopes or the required decontamination process. Items on loan should be managed in line with HSE policy, procedure, protocol and guidelines. Loan Endoscopes should be tracked with the same level of detail as healthcare organisation owned Endoscopes. Required documentation stipulated by the Healthcare Products Regulatory Authority (HPRA) and EN policy, procedure, protocol and guidelines should be made available at each point of need within the decontamination process.

Borrowed Endoscopes must be accompanied by relevant reprocessing instructions (including dissemble and reassemble instructions where relevant) and a list of contents.

The supporting documentation relating to the Endoscopes must be in a form that can accompany the set throughout the decontamination cycle.

Each Endoscopes must be entered into the relevant tracking system to ensure that should an adverse incident occur, full traceability can be achieved.

The borrowed Endoscope must have the correct connection sets to allow it to be connected to the EWD and Endoscope Storage Cabinet.

Correct size brushes must be available. The Endoscope must be set up on the EWD and CESC system to allow for full traceability and correct decontamination and storage of the Endoscope.

Endoscope valves may be reusable or single use where deemed necessary.

All borrowed Endoscopes must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly.

Endoscopes on loan must be registered, including ownership, service history, current location, service responsibility and instructions for use.

It is the responsibility of the user to ensure that a full record of use for the Endoscopes will be available from the loan organisation, and that the usage history is both available and complete.

All requests for the loan of Endoscopes must be made directly by clinical manager of the unit intending to use the Endoscopes.

When agreement has been reached that the Endoscopes may be borrowed, the manager of the Endoscopy/decontamination unit that will be responsible for decontamination must be informed.

The Clinical Engineer should be informed of the loaner request to ensure appropriate tests can be performed to ensure full functionality prior to placing into service.

- **Documentation**

The owner of the Endoscopes being loaned is responsible for ensuring that the loaned Endoscopes are accompanied by the following documentation:

- ◊ The tray of Endoscopes or single Endoscopes is tracked using a globally accepted Global Standards 1 (GS1 code);
- ◊ content list;
- ◊ decontamination certificate;
- ◊ reprocessing instructions, including disassembly and reassembly, where relevant;
- ◊ instruction for use;
- ◊ the above data is presented in an accessible and appropriate manor so that it can be used throughout the reprocessing cycle.

- **Log book**

Details of all Endoscopes which are loaned to/borrowed from other institutions should be entered into a log book detailing:

- ◊ Name and description of the Endoscopes;
- ◊ Endoscopes identification / serial number(s);

- name of the person to whom the Endoscopes is being loaned to/borrowed from;
- identity of the institution providing/receiving the Endoscopes;
- identity of the person who is making the loan;
- date of loan;
- expected date of return;
- confirmation that the relevant supporting documentation required to track reprocess and use the Endoscopes have been received and are available to all person departments requirement that information;
- the unique identifier permitting traceability of the decontamination cycle(s) for the Endoscopes prior to use. Global Standard 1 (GS1) GIAI code;
- the unique identifier permitting traceability of the decontamination cycle(s) for the Endoscopes after use;
- confirmation that the owning institution has appropriate systems in place to maintain an effective loaning history for the Endoscopes.

♦ Arrangements for Return of Endoscopes

Arrangements for the return of Endoscopes must be made directly by the person who borrowed the Endoscopes within the defined time period agreed.

Responsibility for logging the safe and complete return of the Endoscopes rests with the designated person to whom the Endoscopes are returned.

The return date, the name of the institution and the person returning the Endoscopes should be recorded.

Documents to Access

Consult the Voluntary Healthcare Agencies Risk Management Forum Recommended Best Practice for Use of Reusable Invasive Medical Devices (RIMDs) on trial / or on loan to/from other Hospitals and/or Companies / Suppliers (2019).

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/vharmf-framework-for-loaning-and-borrowing-of-rimd.pdf

2.5 Action on Non-Conforming Product

To ensure service user safety and compliance with the Safety, Health and Welfare at Work Act, 2005 and the Medical Device Regulation 2017/745, the organisation must establish procedures to expedite the retrieval of reprocessed items that are suspected to be non-sterile, contaminated or otherwise defective and to ensure appropriate follow-up actions. Follow-up actions may include quarantine of the Endoscopes, notification of clinicians and surveillance of service users as well as remedial action to prevent any recurrence.

Written policies, procedures, protocols and guidelines for the recall of nonconforming product should be developed, available and implemented in the local decontamination facility.

Where any occurrence gives cause for concern that the required assurance of sterility, functionality and freedom from contamination has not been met, the microbiologist, infection prevention and control manager, risk manager and quality and patient safety manager should be notified so that follow-up surveillance of service users can be conducted and appropriate management of the incident is implemented.

Incident Management

It is the policy of the Health Service Executive (HSE) that all incidents are identified, reported and reviewed so that learning from events can be shared. Incidents will be disclosed in accordance with the requirements of the Department of Justice and Equality's Civil Liability (Amendment) Act 2017 and the National Open Disclosure Policy (2013) and related guidance.

To support services in complying with this policy and to promote a consistent approach to the management of all incidents, the HSE has developed the National Incident Management Framework and related Guidance documents. The Incident Management Framework sets out the principles, governance requirements, roles and responsibilities and process to be applied for the management of incidents in all service areas. The Framework is consistent with legislative and regulatory requirements.

The purpose of the Incident Management Framework is to provide an overarching practical approach, based on best practice, to assist providers of HSE and HSE funded services to manage all incidents (clinical and non-clinical) in a manner that is cognisant of the needs of those affected and supports services to learn and improve. The local quality and patient safety manager will advise in relation to reporting criteria

https://www.hse.ie/eng/about/qavd/incident-management/hse-2018-incident-management-framework-guidance-patient-staff-stories.ppdf

Operational Management of Device Recall.

Written policies, procedures, protocols and guidelines for the recall of nonconforming product should be developed, available and implemented in the healthcare organisation. Where any occurrence gives cause for concern that the required assurance of cleaning, disinfection, and or sterilisation, functionality and freedom from contamination has not been met, the consultant microbiologist, infection control nurse manager and risk manager should be notified so that follow-up surveillance of service users can be conducted if required .

The nature and seriousness of the fault and the risk category of the device will determine whether it will be necessary to issue an advisory notice or to institute a device or patient recall.

A recall policy, procedure, protocol and guideline should be written outlining the circumstances for issuing a recall and include the designated person(s) authorised to issue the recall and the designate person(s) responsible for reporting on the execution of a recall.

The product or device must be identifiable by the endoscope UDI/ serial number, lot number (example brushes) cycle number in the EWD and if required the sterilisation lot number. Identify the departments to whom the recall is addressed, identify and record the type and quantity of the devices to be recalled, specify the action to be taken by the person or persons receiving the order (e.g. destruction, return of device, patient recall).

Identify the circumstances that prompted the recall and specify immediate corrective action(s) to be taken to minimise patient harm.

Perform a root cause analysis to identify why the failure happened and how a recurrence may be prevented.

Ensure governance structures are in place to record, risk assess and escalate to the appropriate level in the organisation.

Reporting Concerns Relating to a Device:

The Healthcare Products Regulatory Authority (HPRA) are the competent authority regulating medical devices in Ireland . In the event that decontamination practitioners have concerns regarding devices including endoscopes, brushes, connector sets, EWD's CESC's etc., (concerns may also relate to decontamination instructions) users should complete the Medical Device Incident User Report Form which is available in the HPRA website www.hpra.ie

Appendix I: Top Ten Tips for Endoscope Decontamination

TOP TEN TIPS FOR ENDOSCOPE DECONTAMINATION		
1.	**Compatibility**	Ensure compatibility with the existing hospital decontamination processes, including compatibility with decontamination equipment. Do not reprocess single-use devices. Use pre-purchase questionnaires that require input and acceptance from decontamination and/or Infection Control Teams prior to purchase.
2.	**Instructions**	Ensure that all equipment is operated and controlled in accordance with the manufacturer's instructions, local Endoscope decontamination policy and associated risk assessments.
3.	**Identification**	Identify all Endoscopes and decontamination equipment used in the hospital to ensure they are being maintained and the correct decontamination process is being used. Ensure Endoscopes can be tracked through the decontamination process and traced to the patient on whom they have been used.
4.	**Channel Connection**	Check the number of channels in each Endoscope and ensure that they can all be connected to the EWD and CESC using correct connectors/ connection sets provided by the manufacturer.
5	**Manual Cleaning**	Ensure Endoscopes and reusable accessories are manually cleaned prior to processing in an automated EWD, including the flushing of all lumens even if they have not been used during the procedure.
6	**Chemical Compatibility**	Only use chemicals that are compatible with the Endoscope and its accessories and the EWD. Chemicals must be used at the correct concentration, temperature, and contact times as recommended by the manufacturer throughout the decontamination process.
7	**Recommended Practices.**	Endoscopes should always be decontaminated and maintained to a level specified in the HSE Endoscope Standards and Recommended Practices Documents. A continuous process of evaluation and improvement should be in place to progress towards locally determined best practice.
8	**Process Validation**	Use only validated processes following the manufacturer's instructions and the appropriate standards e.g. EN ISO 15883 series Washer-Disinfectors .
9	**Staff Training**	Ensure all staff, including new staff, involved in the decontamination process are fully trained and that this training is regularly updated as appropriate. Training should include Endoscope and decontamination equipment training provided by the manufacturer.
10	**Incident Reporting**	Report any problems relating to Endoscopes, EWDs or process chemicals, to a line manager and to the Healthcare Products Regulatory Authority when required. Report identified problems with any decontamination process to the local Microbiologist.
These Top Ten Tips take into account the broad approach taken in MHRA's Device Bulletin MDADB2002(05) – 'Decontamination of Endoscopes' and updated in 2013.		

Appendix II: Decontamination Recommendations for ERCP Procedures and On-Table Bile Duct Exploration

ERCP PROCEDURES AND ON-TABLE BILE DUCT EXPLORATION	
ERCP Procedures	Endoscopic retrograde cholangio – pancreatography (ERCP) is a procedure to diagnose and treat problems in the bile duct or pancreatic duct using a flexible Endoscope, appropriate single-use accessories and an x-ray detectable dye.
Decontamination Requirements	Because the Endoscope is passed down through the mouth, it does not need to be provided as sterile.
♦ Adherence to manufacturers' instructions at all times is essential. ♦ The Endoscope must go through a bedside pre-clean followed by a manual decontamination process and an automated cleaning and disinfection process. ♦ Pay particular attention to the elevator mechanism and the recess surrounding the elevator mechanism. ♦ The distal cover should be removed and the elevator should be raised and lowered throughout the manual cleaning process to allow brushing of surfaces that may be obscured by the raiser bridge. ♦ The elevator wire channel should be flushed with detergent during manual cleaning ensuring the correct sized syringe is used. If automated flushing systems are used for this stage of the process, staff should ensure that this channel is included. ♦ Following the manual process the duodenoscope should be reprocessed through an EWD using appropriate chemistries and adhering to the Endoscope manufacturer's instructions. Ensure the EWD is capable of decontaminating Endoscopes with wire-carrying channels. ♦ If stored in a controlled environment storage and drying cabinet, the elevator wire channel should be flushed with HEPA filtered air and the elevator wire channel connected to the cabinets air supply system along with all the other channels. If this channel is not flushed with air, the Endoscope should be used within 3 hours or the Endoscope reprocessed before patient use.	
On-Table Bile Duct Exploration	On-table biliary explorations are done in a theatre environment that involves intra-abdominal surgical intervention by a surgeon. It is either performed under aseptic conditions using a flexible choledochoscope passed via the cystic duct or performed as a choledochotomy either laparoscopically or at open surgery.
Decontamination Requirements	Since the choledochoscope has to enter sterile tissue, the scope needs to be provided as sterile. This is achieved with: a. manual cleaning process; b. then reprocessing through an EWD; and c. sterilisation using low temperature sterilisation procedures (for example, hydrogen peroxide).
Training	Staff should receive comprehensive training, and a record retained, on all aspects of the decontamination of Endoscopes.

Appendix III: Joint Advisory Group Decontamination Assessment Requirements

Joint Advisory Group on GI Endoscopy Ireland – Standards 9 Global Rating Scale for Decontamination Patient Equipment and Environment.

The purpose of this standard is to ensure that adequate resources are provided and used effectively to ensure a safe, efficient, comfortable and accessible service for staff and patients.

No	Measure	Guidance
9.2	Guidelines for Endoscope decontamination are available in the service in written and/or electronic format.	Decontamination equipment and associated machinery including Endoscope Washer Disinfectors (EWDs) reverse osmosis plants, Endoscope storage cupboards and HEPA filtered storage and drying cabinets etc. Testing and validation should be in line with current HSE Standards and Recommended Practices. Action is taken if necessary on results which fall outside the acceptable parameters including water quality, environmental, equipment, Endoscopes etc.
9.5	The service implements and monitors systems to ensure facilities and environment support delivery of the Endoscopy service. This includes annual completion of the Endoscopy environment checklist.	Mandatory decontamination assessment and audit by the Authorised Engineer for Decontamination AE(D) within 1 year of a JAG accreditation assessment, and yearly audits and actions for all other years is required.
9.6	There is a Decontamination Lead appointed by the Hospital who has overall responsibility for Endoscope Decontamination Practice.	The management lead for decontamination within Endoscopy must fulfill the role and requirements as identified in the respective national guidance. Where decontamination is undertaken outside Endoscopy, the nominated person must show how this links to the staff using the equipment within the Endoscopy service.
9.7	There is an Endoscopy management lead responsible for the Procurement and management of all Endoscopy equipment and consumables (including decontamination).	Where decontamination is overseen outside the service, or by another authorized Manager, procurement and management may fall within the remit of two people. The Decontamination Lead and Infection Prevention and Control Practitioners must be involved in the procurement process.
9.8	There is an annual Authorising Engineer report for decontamination.	Mandatory decontamination assessment and audit by the AE(D) within 1st year of a JAG Accreditation assessment, and yearly audits and actions for all other years is required.
9.9	There are systems in place to ensure that all areas within the Endoscope decontamination environment are well maintained.	There should be high standards of operational practice in all areas where Endoscopy procedures are undertaken e.g. main unit, radiology for ERCP and Decontamination.
9.10	There are systems in place to ensure that access to decontamination areas is restricted.	This should define the clinical environment from reception and decontamination Facilities.
9.12	There are systems in place to ensure the management and control of environmental conditions associated with decontamination facilities.	For example, temperature or ventilation controls.
9.13	There are systems in place to ensure the maintenance and quality assurance of all decontamination equipment with corresponding records.	For example tracking systems, effective recall procedures, unique device identification (UDI) for each Endoscope and reprocessing records, storage records etc.
9.14	The findings and recommendations of the annual Authorising Engineer report for decontamination are actioned and approved by the organisation.	Assurances are provided that practices are safe. A gap analysis identifies where improvements can be made and a Quality Improvement Plan supports and guides the development and implementation of improvement strategies.
9.15	There are systems in place to ensure that there is a planned equipment replacement programme for Endoscopes and decontamination equipment.	The Clinical lead, Decontamination lead and Service Nurse Manager highlight capital equipment needs for the service as part of annual service planning.

Summary of precautions advised for the use of flexible endoscopes in patients with CJD, presumed infected or at increased risk

The following applies where an invasive procedure has been carried out. For non-invasive procedures, endoscopes should be decontaminated normally.

	Status of patient				
	Symptomatic – diagnosed with or suspected of having a human prion disease			Asymptomatic: presumed infected	Asymptomatic: at increased risk
Tissue Infectivity and level of risk	Definite or probable: • Sporadic CJD • iatrogenic CJD • inherited prion disease	Definite or probable variant CJD	Possible CJD or diagnosis unclear[1]	At risk (blood*** recipient from a donor who later developed vCJD)	At increased risk of: • variant CJD • inherited prion disease • other iatrogenic CJD
High: • Brain • Spinal cord	Not covered by this guidance				
Medium: Olfactory epithelium*	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	Single use OR destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	Single use OR Quarantine pending diagnosis	Single use OR destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	No special precautions unless contaminated with olfactory epithelium* If contaminated: Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient
Medium: Lymphoid tissue**	No special precautions	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	No special precautions
Low or none detectable: All other tissues	No special precautions	No special precautions	No special precautions	No special precautions	No special precautions

Notes

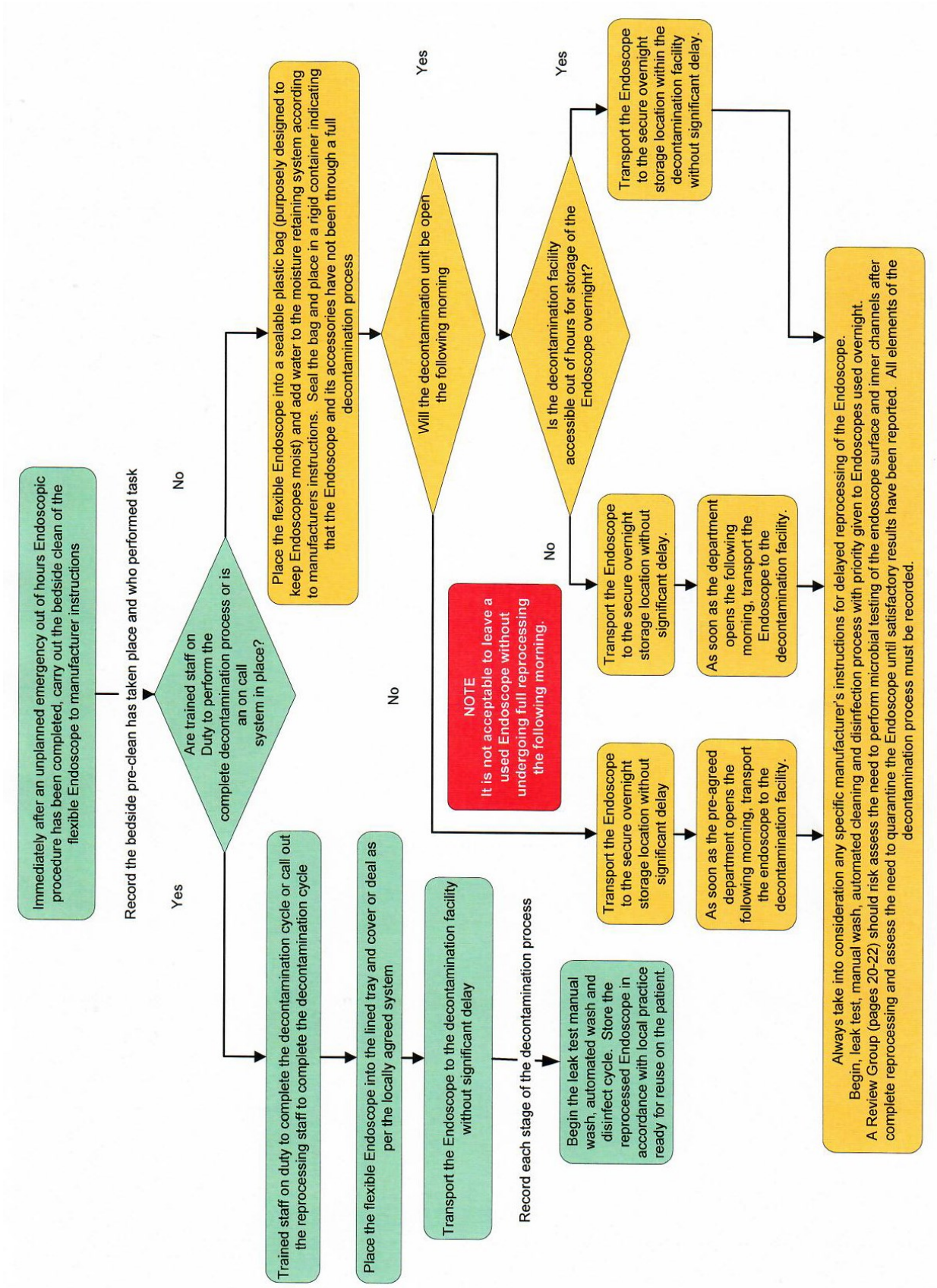
* The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues.

** For the purposes of this guidance, lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and the gastrointestinal tract sub-mucosa.

*** A small number of individuals are known to have received blood or blood components from a donor who later developed vCJD.

1. This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered (see also Annex B of the ACDP-TSE guidance).
2. Quarantined endoscopes may be re-used exclusively on the same individual patient if required.

Appendix V: Flowchart for the Out of Hours Unplanned Emergency Use of Flexible Endoscopes



Appendix VI: HIQA Self-Assessment Guide and Inspection Requirements

HIQA PCHCAI- Standard 2.9: Self-Assessment Guide			
2.9.1	The hospital has a named decontamination co-ordinator with responsibility for reusable invasive medical device reprocessing.	Yes	No
2.9.2	Decontamination of medical devices at the hospital is overseen by a decontamination committee.	Yes	No
2.9.3	The hospital has an inventory of all **critical and semi-critical devices** used in the facility that identifies areas in the hospital and services provided by the hospital where such devices are used.	Yes	No
2.9.4	Decontamination of critical items and semi-critical items is performed in a designated decontamination area in line with best practice guidelines.	Yes	No
2.9.5	The hospital has up-to-date policies and procedures for the reprocessing of all reusable invasive medical devices used in and by the facility in line with relevant national guidelines.	Yes	No
2.9.6	The hospital has a competency-based training program for reprocessing of **critical and semi-critical** devices.	Yes	No
2.9.7	There is a continuing programme of training and education for personnel involved in device decontamination.	Yes	No
2.9.8	The hospital regularly audits (monitors and documents) adherence to reprocessing procedures for **critical and semi- critical** devices.	Yes	No
2.9.9	The hospital provides feedback from audits to relevant personnel and hospital management regarding adherence to reprocessing procedures for **critical and semi-critical** devices.	Yes	No
2.9.10	Single-use devices (SUDs) labelled by the manufacturer for a single use are not reprocessed.	Yes	No
2.9.11	The hospital allows adequate time for reprocessing to ensure adherence to all steps recommended by the device manufacturer, including drying and proper storage.	Yes	No
2.9.12	The hospital has an adequate supply of instruments for the volume of procedures performed to allow sufficient time for all reprocessing steps.	Yes	No
2.9.13	The hospital has a service level agreement outlining governance and accountability arrangements with respect to external contractor's involvement in device handling and where decontamination services are outsourced.	Yes	No
2.9.14	The hospital has a standard operating procedure in place based on national guidelines if devices are loaned, borrowed or trialled to minimise the risk of infection to patients, personnel and others.	Yes	No
2.9.15	The hospital has a standard operating procedure in place based on national guidelines if devices are loaned, borrowed or trialled to minimise the risk of infection to patients, personnel and others.	Yes	No
2.9.16	Each step of the decontamination cycle is recorded, including the identity of the person undertaking each step.		

2.9.17	The infection prevention and control team is consulted whenever new devices or products are to be purchased or introduced to ensure implementation of appropriate reprocessing policies and procedures.	Yes	No
2.9.18	All reusable invasive medical device sets (e.g. surgical instrument sets) and Endoscopes can be traced through the decontamination process and linked to the patient on whom they have been used.	Yes	No
2.9.19	The hospital has policies and procedures outlining hospital response (i.e. risk assessment and recall of device, look back) in the event of a reprocessing error or failure.	Yes	No
2.9.20	The hospital central decontamination unit operates a quality management system in line with EN ISO 13485.	Yes	No
2.9.21	Endoscope and local decontamination units operate a quality system in line with the key elements of EN ISO 13485.	Yes	No
2.9.22	Personnel trained in decontamination practice are available to reprocess reusable invasive medical devices for out of hour's unplanned emergency procedures if there is a requirement to decontaminate the device immediately following use e.g. an Endoscope.	Yes	No
2.9.23	The hospital has up- to- date policies and procedures to minimise the exposure of patients and employees to transmissible spongiform encephalopathies.	Yes	No

Appendix VII: HIQA Documentation and Data Request

Sample Documentation and Data Request for Chief Executive Officer and or General Manager During Site Inspection	
1	Inventory of critical and semi-critical reusable medical devices at the hospital and the clinical area in which such devices are used.
2	List of current policies, procedures and guidelines relating to decontamination and reprocessing of reusable medical devices.
3	Terms of Reference and list of members by discipline for the decontamination committee.
4	Minutes of decontamination committee meetings for the last three meetings.
5	An annual decontamination report submitted to the hospital group CEO.
6	Decontamination-related risks on the current hospital risk register.
7	Number of decontamination related incidents recorded on the hospital incident management system in the past 12 months.
8	Reports of management of individual incidents or look backs in relation to decontamination failures for last 12 months.
9	Audits in relation to decontamination and reprocessing of reusable medical devices.
10	Examples of action plans to address required improvements identified through monitoring or audit.
11	List of content of decontamination education and training programme for staff.
12	Number of staff who carry out Endoscope decontamination who have received a Fetac Level 6 Minor Award in Decontamination.

Sample Documentation and Data Request for Local Decontamination Facility Manager	
No.	Documentation or data
1	Inventory of critical and semi-critical reusable medical devices used in the facility.
2	List of current policies, procedures and guidelines relating to decontamination and reprocessing of reusable medical devices.
3	Number of Endosocpy staff employed to work in the facility who have received a Fetac Level 6 Minor Award in Decontamination.
4	List of content of decontamination education and training programme for staff.
5	Audit of decontamination and reprocessing processes and results.
6	Examples of communication received in relation to medical device alerts.
7	Policy for Transmissible Spongiform Encephalopathies risk assessment.

Appendix VIII: Guidance on Training Requirements for Endoscope Decontamination Practitioners

Criteria	Rational	Confirmation of Competence Interview Observation or Documentation	Date	Assessor Name / Role
Section 1: Understanding legal/ regulatory/national and local policies relating to decontamination and Infection Prevention and control				
Locate and discuss the local Hand Hygiene and Infection Prevention and Control Policy.	Demonstrate knowledge of Infection Prevention and Control and associated risks to patient and staff and where this information can be accessed			
Discuss the protection of the healthcare worker (HCW) and the patient from cross infection.	Demonstrate effective Hand Hygiene technique . Select correct Personal Protective Equipment (PPE) for the task to be performed. Demonstrate awareness of the role of vaccination in protecting the HCW. Knowledge of sharps and splash injury procedure and First Aid Measures .			
Discuss management of the environment to prevent cross contamination.	Demonstrate knowledge of environmental risks associated with cross contamination and how these risk can be controlled.			
Locate and discuss Chemical Safety Data Sheets and management, storage and disposal of chemicals used in the EDU and procedure for chemical spills and use of respirator. Recording batch number, opening and expiry date.	Demonstrate understanding of the risks associated with chemicals used in the department. Demonstrate knowledge of chemical safety.			
Demonstrate awareness of regulatory / guidance documents and legal issues related to Endoscope decontamination e.g. HSE Standards & Recommended Practices for Decontamination, HIQA Standards, using Manufacturer Instructions etc.	Understands implications of non adherence to manufacturer instructions for Endoscope decontamination. Aware of the daily ,weekly tasks associated with the management of Endoscopes and decontamination equipment. Demonstrates knowledge of legal responsibilities such as signature on records, how to raise a concern regarding equipment . Understand HIQA's role.			
Competence achieved when the trainee can: ♦ Summarise good infection control practices relating to Endoscope decontamination and First Aid procedures for injury. ♦ Identify the Safety Data sheets for the chemicals used in their area and how to manage chemical spill. ♦ Identify correct storage and disposal procedures for the chemicals in use. ♦ Identify where to locate operational procedure for the use of chemical within the area. ♦ Identify the key requirements for the management of environmental hygiene. ♦ State where the relevant guidance documents/ policies/ procedures can be located in the department.				
Section 2: Understanding, managing and maintaining Endoscopes and associated equipment				
Discuss the structure of all the makes , models of Endoscopes to be used.	Understands the working mechanism of each type of Endoscope to be processed ,where potential problems may occur . Identifies the number of channels in each scope and the correct brush size, connector sets for the EWD and CESC, connection configuration and channel separators to be used.			
Discuss the visual inspection and leak testing process for Endoscopes .Demonstrate awareness of cracks/damage to the Endoscope which may harbour contaminated material.	Understands correct handling to minimise risk of Endoscope damage . Awareness of the correct procedures to be followed and personnel to be contacted in the event of Endoscope damage .			

Criteria	Rational	Confirmation of Competence Interview Observation or Documentation	Date	Assessor Name / Role
Discuss the visual inspection and leak testing process for Endoscopes .	Identifies the correct leak tester to use and demonstrates how it is used. Aware of repairs and maintenance protocols and procedures for Endoscopes			
Competence achieved when the trainee can: ♦ Correctly identify all channels of each type and model of Endoscope to be cleaned. ♦ Demonstrate knowledge of the correct brush sizes, connection sets, channel separators to be used for each Endoscope ♦ Demonstrate correct operation of all Endoscopy equipment (leak tester, light source and video connector). ♦ Demonstrates correct procedures to follow in the event that an Endoscope is damaged. ♦ Demonstrate correct packaging and transport requirements for Endoscopes that are to be sent for repair.				
Section 3: Understanding the process and stages of the decontamination life cycle .				
Discuss the decontamination life cycle from bed side pre-cleaning to transport , storage and re use.	To ensure safe and effective reprocessing of Endoscopes and accessories is performed. Demonstrate knowledge of the decontamination life cycle for Endoscopes. Pre-clean at the point of use, Transport to EDU, Leak Testing, Manual Cleaning, Automated Cleaning and Disinfection , Drying ,(Sterilization if required) Transport, Storage and reuse. Understands the procedures to minimising re contamination of an Endoscope prior to storage or patient use.			
Discuss the track and trace process for the Endoscope journey through to patient use including loan Endoscopes.	Knowledge of the role track and trace plays in the Endoscope and patient journey. Knowledge of the importance of keeping Endoscope and accessories as a unique set throughout the decontamination process. Knowledge of the process for ensuring loan Endoscopes are traceable through the decontamination process.			
Competence achieved when the trainee can : ♦ Identify each stage of the decontamination life cycle. ♦ Identify each step of the tracking process ♦ Identify the requirement for each Endoscope to have a unique tracking number and that this is linked to the Endoscope washer disinfector , the endoscope storage system and to the patient. ♦ Identifies the requirement for loan Endoscopes to tracked through the decontamination process.				
Section 4: Understand the workings of the Endoscope Washer Disinfection (EWD)				
Understands the purpose and demonstrate working knowledge of the basic functions and controls of the EWD. Understands the EWD cycle phases and parameters that has been set up by the EWD Manufacturer.	To ensure the operator of the equipment is competent , can perform daily , weekly maintenance and testing tasks, is aware of the parameters for each phase of the decontamination cycle and can identify if the EWD cycle has passed or failed. Can identify if the temperature, chemicals dosing, contact times for each cycle stage are met.			
Identifies correct connect or sets to connect the Endoscope to the EWD and checks “o” rings etc., for correct functioning. Aware of Daily weekly tasks to be performed	Understands risks of not connecting Endoscopes the EWD correctly. Knowledge of the factors affecting good connections. Ensures the correct operation of EWD by performing checks and tasks set out in HSE Standards and Manufacturer Guidance			
Competence achieved when the trainee can: ♦ Describe and demonstrate the operational functioning and key parameters of the EWD cycle				

Criteria	Rational	Confirmation of Competence Interview Observation or Documentation	Date	Assessor Name/Role
Section 5: Demonstrate ability to effectively decontaminate an Endoscope				
Leak Testing in the EDU Correct PPE is selected Sink is filled with clean water @ temperature no greater than 37 °c. All buttons etc are removed prior to leak test. Leak tester is checked for functionality and correctly attach to endoscope. The leak test is performed , note trainees observations, timing and what the action would be if bubbles are detected.	Leak testing demonstrates the integrity of the outer sheath of the Endoscope is intact and identifies Endoscope damage prior to the manual cleaning process.			
Manual Cleaning in the EDU Note preparation of detergents , temperature of the water, choice of brushes, removal of valves etc. Observe cleaning techniques and the order of cleaning are in line with manufacturer instructions, including , cleaning of biopsy port, valves, auxiliary channels elevator bridges if present, rinsing and Observe the rinsing process post cleaning.	Endoscopes must be manually cleaned in accordance with manufacturer instruction. Cleaning is the initial and most crucial step in breaking the chain of disease transmission. Knowledge of the importance of keeping Endoscope and accessories as a unique set throughout the decontamination process. Prevent recontamination of the Endoscope and carry over of detergent into the EWD by rinsing in accordance with manufacturer Instruction.			
Competence achieved when the trainee can : ♦ Identifies the correct process and sequence for manually cleaning the Endoscope . ♦ Correctly removes accessories and keeps with the Endoscope as a set and identifies accessories which need to be sterilised. ♦ Tracks the Endoscope through the manual cleaning process. ♦ Demonstrates effective infection control and health and safety practice.				
Section 6: Automated Endoscope Reprocessing				
Demonstrate working knowledge of the functions and controls of the EWD. Understands the EWD cycle phases and parameters that has been set up by the EWD Manufacturer. Checks connector sets , channel separators and connection sets and ports for condition. Correctly selects the appropriate configuration of connectors for the EWD.	To ensure the operator of the equipment is competent . Can identify if the temperature, chemicals dosing, contact times for each cycle stage are met. To ensure all channels of the Endoscope are exposed to the cleaning and disinfection process.			
Identifies if EWD daily tests have been performed and passed. Is aware of the current water quality status . The EWD process is tracked. On completion of the cycle the printout from the machine or IMS is checked against the original commissioning document to ensure all parameters are within specification. The print out is checked, signed if passed and records filed. Notification of appropriate personnel in case of cycle failure.	Ensures the correct operation of EWD by performing checks and tasks set out in HSE Standards and Manufacturer Guidance. Checks the parameters of the cycle to ensure all parameters have been met . Ensure the endoscope is tracked through the EWD process. Ensure product release is correctly monitored and documented.			
Competence achieved when the trainee can: ♦ Describe and demonstrate the operational functioning and key parameters of the EWD cycle. ♦ Demonstrate knowledge of correct connection to the EWD. ♦ Demonstrate cycle release procedure and notification process for failed cycles. ♦ Demonstrate knowledge of water quality and daily EWD testing regimes and outcomes.				

Criteria	Rational	Confirmation of Competence Interview Observation or Documentation	Date	Assessor Name/Role
Section 7: Controlled Environment Storage Cabinet Use				
Demonstrate working knowledge of the functions and controls of the CESC. Understands the CESC phases and parameters that have been set up by the CESC Manufacturer. Checks connector sets , channel separators and connection sets and ports for condition. Correctly selects the appropriate configuration of connectors for the CESC.	To ensure the operator of the equipment is competent . Can identify if the temperature (if applicable), air supply arrangements, drying and storage/conditioning times for each process are met. To ensure all channels of the Endoscope are exposed to the drying and conditioning process.			
Identifies if CESC daily checks have been performed and passed. The CESC process is tracked. On completion of the process the printout from the machine or IMS is checked against the original commissioning document to ensure all parameters are within specification. The print out is checked, signed if passed and records filed. Notification of appropriate personnel in case of cycle failure.	Ensures the correct operation of CESC by performing checks and tasks set out in HSE Standards and Manufacturer Guidance. Checks the parameters of the cycle to ensure all parameters have been met . Ensure the endoscope is tracked through the CESC process. Ensure product release is correctly monitored and documented.			
Competence achieved when the trainee can : Describe and demonstrate the operational functioning and key parameters of the CESC process. Demonstrate knowledge of correct connection to the CESC. Demonstrate cycle release procedure and notification process for failed cycles. Demonstrate knowledge of daily CESC check regimes and outcomes.				
Section 8: Portable Storage System Use				
Demonstrate working knowledge of the functions and controls of the system. Understands the system phases and parameters that have been set up by the Manufacturer. Checks connector sets (if applicable), bags, formers and protective arches. Correctly selects the appropriate configuration of connectors (if applicable).	To ensure the operator of the equipment is competent . Can identify if the correct packaging consumables (such as bags, formers and protective arches), vacuum/ pressure level (if applicable), chemical supply arrangements (if applicable), pre-drying and conditioning times for the process are met. To ensure all channels of the Endoscope are exposed to the conditioning process (if applicable).			
Identifies if the storage system daily checks have been performed and passed. The process is tracked. On completion of the process the printout from the system (if fitted) is checked against the original commissioning document to ensure all parameters are within specification. The print out is checked, signed if passed and records filed. Notification of appropriate personnel in case of process failure.	Ensures the correct operation of the storage system by performing checks and tasks set out in HSE Standards and Manufacturer Guidance. Checks the parameters of the process to ensure all parameters have been met. Ensure the Endoscope is tracked through the storage process.			
Competence achieved when the trainee can : Describe and demonstrate the operational functioning and key parameters of the process. Demonstrate knowledge of correct connection to the system (if connectors are required). Demonstrate process release procedure and notification process for failed processes. Demonstrate knowledge of daily system check regimes and outcomes.				

Appendix IX: Acknowledgements

Endoscope, Decontamination Standards Review Group

Ms Caroline Conneely	HSE Decontamination Advisor National Quality Improvement Team
Mr Wayne Spencer	Authorising Engineer for Decontamination - Technical Advisor to the National Decontamination Safety Programme
Ms Annette Cotter	Clerical Officer—Quality Improvement Team
Mr Mark Hichens	Environmental Microbiologist—Director Curam Medical
Ms Jacinta Nolan Burke	Decontamination Lead – Tallaght Hospital
Mr Damien Doherty	Decontamination Unit Manager—Children's University Hospital Temple Street
Mr John McNamee	Decontamination Supervisor—Galway University Hospital Clinical Sterilisation Service Department Manager
Ms Mary Scully	Clinical Nurse Manager 2—Endoscopy—Theatre Department Our Lady's Children's Hospital Crumlin
Ms. Niamh O'Callaghan	Decontamination Lead -South Infirmary-Victoria University Hospital Cork

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