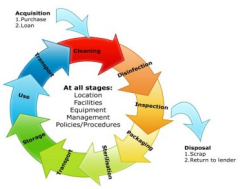
Health Service Executive Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Units

Tús Áite do Shábháilteacht Othar
Patient Safety First



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(**Note:** *This Standards and Recommended Practices 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

AD	Average Daily Demand
AED	Authorising Engineer for Decontamination
AP MGPS	Authorised Person Medical Gas Pipeline Systems
AHU	Air Handling Unit
AT	Available Minutes for Processing
BMS	Business Management System
CESC	Controlled Environment Storage Cabinets
COSHH	Control of Substances Hazardous to Health
CT	Cycle Time
EDU	Endoscope Decontamination Units
EWD	Endoscope Washer Disinfector
H	Hour
HCAI	Healthcare Associated Infection
HEPA	High Efficiency Particulate Filtered Air
HIQA	Health Information Quality Authority
HSE	Health Service Executive
ICU	Intensive Care Unit
JAG	Joint Advisory Group
N	Number of Machines
PCHCAI	Prevention and Control for Healthcare Associated Infections
PD	Peak Demand
PPE	Personnel Protective Equipment
RIMDs	Reusable Invasive Medical Devices
RO	Reverse Osmosis
SC	Scopes per Cycle-number of Endoscopes that can be processed per cycle
TDS	Total Dissolved Solids
TOC	Total Organic Carbon
TR	Time Required
TVC	Total Viable Count
UDI	Unique Device Identification
UPS	Uninterruptible Power Supply

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Part 1
Introduction
Standards and Recommended Practices

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 termolabile 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 Units.

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

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

Purpose of the Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Units

This document has been developed to support best practice in the planning, design and development of Endoscope Decontamination Services and is written to reflect the need to continuously improve outcomes in terms of patient safety, clinical effectiveness and patient experience.

It reflects the need to ensure that the environment in which decontamination procedures are carried out is fit for purpose ensuring 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, HBS Estates and Facility Managers, Endoscope Decontamination Unit (EDU) Managers, Infection Prevention and Control Specialists (IPC), Microbiologists, Theatre Managers, Health and Safety Managers, Risk Managers, Capital Planning, Design Teams, suppliers of specialised equipment and Authorising Engineers for Decontamination (AED) when planning and designing an EDU.

The design of a decontamination facility critically impacts on the safe effective management and control of environmental, infection and cross contamination risks associated with the decontamination of Endoscopes. The design of decontamination facilities and services in Ireland must include mechanisms which support business continuity so that patient safety, in terms of service delivery, is ensured.

Planning and design of an EDU requires input from relevant experts in the field. The following personnel must be included in any planning and design process:

Design and Planning Team

- Group CEOs/Hospital Managers;
- Authorising Engineers for Decontamination;
- Building and Design Engineers;
- IPC representative and Microbiologist;
- Procurement;
- The Users of the service/Theaters/Day Surgery/Endoscopy;
- 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.

How should we read this document? This document is provided in two parts:

- **Part 1** provides you with key aspects which influence the design and delivery of safe reliable EDUs;
- **Part 2** provides guidance on the key Infection Prevention and Control design features which meet with HIQA Standards for the Prevention and Control of Healthcare Associated Infection(2017). There are four elements to this section which link with HIQA Theme 2 Safe Care and Support –Standard, 2.6, "***Healthcare is provided in a clean and safe physical environment that minimise the risk of transmitting HCAI***".

(***Note:*** *Authorising Engineers, who are involved in the planning or design of EDUs in Ireland,* ***must*** *use this document as a template to ensure compliance to HSE Standards for Facility Design and Equipping of EDUs)*

1.2 Aim of the Standards and Recommended Practices for Facility Design and Equipping of EDUs

The overall aim of facility and service design Standards and Recommended Practices 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, the HSE Standards and Recommended Practices for Endoscope Decontamination Units and the Health Information Quality Authority (HIQA) Standards for Prevention and Control of Healthcare Associated Infection 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.

Design Requirements Associated with the Regulation

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).

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

Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed o the market and remain so under the transport and storage conditions specified by the manufacturer (Annex I, Chapter II paragraph 11.3).

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).

(***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. Disinfection must be achieved by using an appropriate validated method and undertaken in an appropriately controlled environment.*

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

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 Endoscope Decontanination Units?

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.

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 are the Standards that are most applicable to Facility Design and Equipping of Endoscope Decontamination Units.

2. Endoscope Decontamination

Risk Factors for Healthcare Associated Infection

Flexible Endoscopes are complex Reusable Invasive Medical Devices (RIMDs) that require unique consideration with respect to decontamination. Decontamination is the combination of processes (including cleaning, disinfection and sterilisation) used to render RIMDs safe for handling by staff and for use on patients. Effective decontamination of Endoscopes, performed in appropriate purpose built facilities is an essential component in the prevention and control of healthcare associated infection.

It is estimated that approximately 260,000 flexible channelled and non channelled Endoscope procedures are performed annually, across all disciplines, in Ireland (HSE, 2015). Evidence suggests a year on year rise in activity of approximately 10-15% for GI Endoscope procedures alone (HSE, 2011), correlating to the introduction of cancer screening programmes, and greater public awareness of the benefits of early detection of bowel cancer, with publications in Scotland and UK estimating a similar rise in the need for Endoscope services (NHS Improvement, 2012).

Most recent data (Eurostat, 2016) identifies that colonoscopy is the second most common type of procedure performed across Europe. Ireland the UK and Malta record the highest frequency of colonoscopy procedures at 1,400 procedures per 100,000 inhabitants. The frequency of diagnostic bronchoscopy with or with biopsy is above 286 procedures per 100,000 inhabitants.

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

2.1 Development of a Centralised Model for the Design of EDUs

Historically, the development of Endoscope decontamination services has been fragmented. The HSE Decontamination Service Survey (2015) highlighted the need for renewed focus on the provision of appropriately designed Endoscope decontamination services, to improve patient safety and minimise the risk of infection transmission. Whilst, considerable improvements have been made in terms of Endoscope decontamination services, over 50% of decontamination activity is performed in multi-satellite units scattered throughout the organisation, rather than in centralised specialist units as recommended in the HSE Decontamination National Audit Report (2007).

The introduction of the Endoscope JAG Accreditation process for Bowel Cancer Screening Services (2011) has been an important step forward in terms of accrediting Endoscope decontamination practices in Ireland. However, it is important to note that where multiple EDUs exist within a hospital (satellite units which decontaminate bronchoscopes, cystoscopes, and nasendoscopes), JAG will currently only accredit the unit which processes GI Endoscopes, potentially creating a two tiered system of accreditation for service delivery.

Of note, studies by Kimmey, (1993) and Seoane-Vazquez, (2006) identify that centralisation of Endoscope services can reduce the risk of infection associated with Endoscope Decontamination by 91%. In addition, the cost associated with duplication of equipment, validation of multiple facilities, equipment, servicing, staff training and staffing costs, needs to be considered, with synergies and efficiencies in all areas maximised through centralisation of activity.

Lastly, Berwick's (1991) model for quality improvement in healthcare, centers around the need to standardise and control variation in practice, service design and service delivery. In practice, centralisation of Endoscope decontamination services is critical to providing quality assurance, consistency of practice and value for money across the system (Bonner, 2007, Alexander, 2012).

3. Essential Design Considerations

With regard to the Mechanical and Electrical services design for Endoscope Decontamination Units, it is essential that all calculations associated with equipment design, layout and throughput are integrated.

- A system wide review should be performed by the design, planning and project teams, (see page 2) prior to any tenders being issued. This should be taken as an opportunity to identify any design shortfalls, capacity planning changes, gaps in the process, plant capacities, equipment layout, flow patterns and any other ambiguities.
- Selection of plant and equipment must be from the HSE National Frameworks where available and include an evaluation of lifecycle costs. Lifecycle costs should include chemicals, operation (including energy), maintenance and validation of all specialist plant and components and spare parts/consumables.
- Consideration needs to be given to the method of equipment supply and whether this is via a turnkey type arrangement or individual contracts for supply of each item of equipment.
- The requirements for Building Management System (BMS) control links should be identified early in the process including details of cabling system for BMS connections, Uninterruptable Power Supply (UPS), IT tracking systems data network hubs and telecommunications.
- It's essential that mechanical and electrical/control wiring schematics are developed early in the design process. Designs must incorporate easy access for maintenance of the equipment and services once the department is operational.
- Consideration must be given to the insulation of systems that support business continuity in the event of service failure or 'for example' water supply/quality failure.

3.1 Elements which are critical to support the design and development of a safe quality assured Endoscope Decontamination service include:

- Centralisation of all Endoscope decontamination activity;
- capacity planning, consider potential growth over time, turnaround times, activity/sessions;
- facility Design/Workflow;

- water Quality;
- ventilation;
- compressed Air;
- IT Systems, electricity supply points and emergency stop locations;
- equipment Procurement, Installation, Commissioning and handover;
- use of Chemicals;
- transport;
- business Continuity and;
- delivery of Equipment.

3.2 Additional Requirements for Sterilization of Surgically Invasive Flexible Endoscopes.

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

4. Centralisation of Endoscope Decontamination Activity

A centralised model of Endoscope service delivery will minimise variation in practice, maximise patient safety, provide a safe environment for staff, improve efficiency, facilitate effective implementation of standard practices and facilitate meaningful audit and quality assurance of the Endoscope decontamination life cycle. When looking at a model for best practice in Endoscope decontamination service delivery, it is critical to evaluate the decontamination activity associated with the use of all Endoscopes, assigned to each specialty, in the service.

There are 3 key categories of Endoscopes:

- Channelled Endoscopes, e.g. bronchoscopes, gastroscopes, colonoscopies deuodenoscopes etc.;
- non channeled nasendoscopes;
- *transoesophageal Probes, Transvaginal Ultrasound Probes/Transrectal Ultrasound Probes.

*(***Note:*** *Health Service Executive Guidance for Decontamination of Semi Critical Ultrasound Probes; Semi Invasive and Non –Invasive Ultrasound Probes was published in 2017)*

5. Capacity Planning Considerations

It is critical to determine patient throughput now and for the future. The proposed lifespan of any solution must be considered and growth evaluated for the whole of that period. When interim solutions are being designed, growth will accordingly be more certain and easier to estimate however, for long term solutions, beyond 5 years growth, estimated growth risk becomes unreliable. Consideration should be given to previous growth patterns, established trends, growth from other similar projects nationally, the impact of national programmes (such as cancer screening) and any forthcoming technology developments. For designs other than short-term interim solutions, five years growth in service demand with due regard to the care pathways and quality standards in use, is the minimum that should be considered. In addition, all activities relating to the use of all three categories of Endoscopes, must be evaluated when planning any decontamination services.

The design team should calculate growth on a compound basis for example, 5% year on year growth in a 5 year project will not equate to 25% growth rather it is calculated as 28% growth. Therefore, seemingly small amounts of growth in latter years of a project plan can be hugely impacted by large growth in the early years. The longer the project evaluation period, the more difficult it is to estimate growth on a reliable basis. However, using the compound model, large amounts of early year growth will often dictate overall growth amounts when smaller, conservative, uncertain estimates are used for later years. It is therefore important to get early year growth as accurate as possible particularly when this is forecasted to be greater than 5%.

A sense check against previous HSE/hospital projects should be considered. Service providers who are aware of the impact of an undersized solution may concede to the temptation to overestimate growth as a "safeguard" to the future. However, the compound calculation means total project growth can escalate dramatically particularly over project periods of 10 years or more. Design teams should be aware that this could result in unnecessary costs when the project is implemented, larger operating costs and options being discarded due to space shortfalls that could otherwise have been utilised.

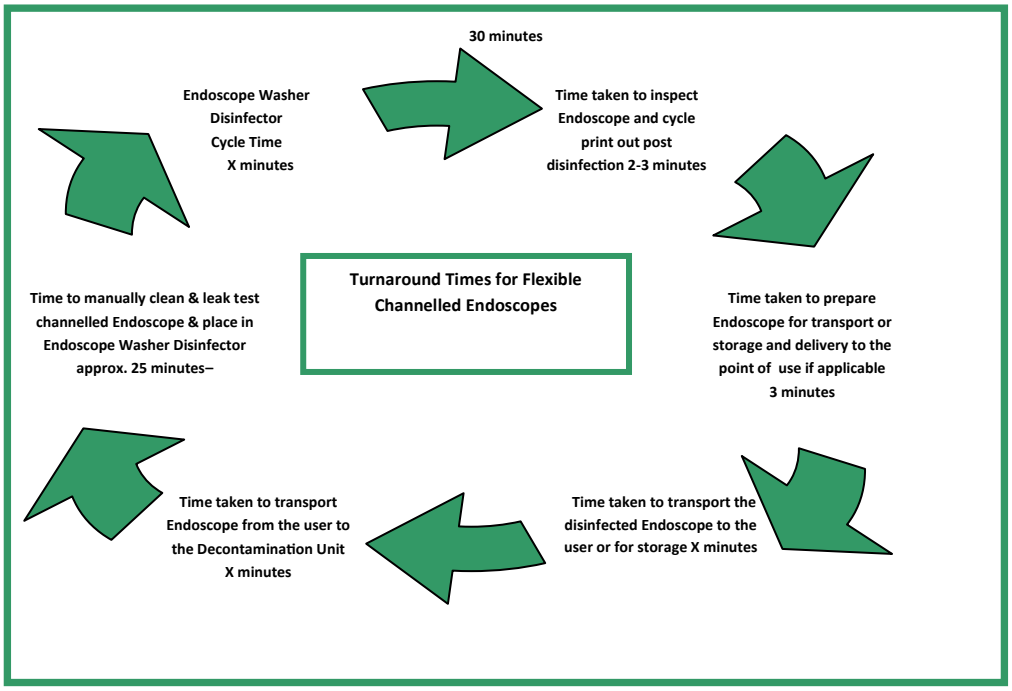
Because of the uncertain nature of growth it is important that design teams should undertake sensitivity analysis on a range of growth scenarios. This can be undertaken by creating several different growth models and checking their impact on final department size/services capacity and equipment numbers. However it should be noted that due to the coarse nature of EWD sizes, small fluctuations in growth may not matter nor affect required equipment numbers, when planning smaller departments.

5.1 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 PPE, preparation of solutions for cleaning, scope tracking, scope examination, connection of the Endoscope to the EWD etc.

Figure 2: 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 needs to be considered.

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)*

5.2 Endoscope Capacity

Factors such as EWD cycle times, Endoscope decontamination facility location and its proximity to the user, human resources, availability of decontamination equipment and other priority requests in the system may impact on turn around times and therefore additional scopes may need to be purchased as part of the facility development.

A robust evaluation of the number of Endoscopes, required to deliver the service, must be performed as part of the overall service plan, with additional Endoscopes included in the business case for service development, if required. Work load, will determine the number of EWDs required to ensure service user needs are met within the operational hours of the EDU.

5.3 Automatic Endoscope Decontamination Capacity

Work load (e.g. the number of Endoscopes requiring reprocessing), is the primary factor in determining the number of EWDs required to ensure service user needs are met within the operational hours of the decontamination unit.

Additional factors which determine choice of EWD:

- EDW cycle/process time;
- maximum number of Endoscopes which can be processed in the machine during a cycle;
- EWD utilisation factor (discussed below);
- time taken to load the machine and;
- design of the EWD i.e. single or double chamber.

All of this information will allow the number of Endoscopes which can be processed in a day to be calculated. In addition, factors such as cycle faults, which are common features of day to day Endoscope reprocessing, and may be due to failure from incorrect loading (these should be managed with appropriate training), faulty Endoscopes and machine breakdowns, may affect turnaround times.

It should be noted that industry standards recognise a utilization factor 60% for EWD's. This utilization factor accounts for maintenance, periodic testing, validation downtime and breakdown. The user must also factor in daily and weekly testing regimes which will impact on the availability of decontamination equipment and will impact on production.

The storage solution to be used will also impact upon the EWD numbers required. Historically, Endoscopes processed at the end of a working day would need reprocessing at the start of the next day whether or not they have been used. This often resulted in a large peak demand at the commencement of each day. Controlled Environment Storage Cabinets (CESC) can reduce the number of EWDs required, by eliminating the need to reprocess time expired Endoscopes, before the start of each clinical session. Endoscopes which are infrequently used will also require less EWD processing. As these cabinets are a lower capital cost than an EWD, incorporating them into service design may give a more cost effective solution (see 5.4, 5.5, 5.6 and 5.7).

When planning smaller departments, 100% standby may be required in a department that theoretically only needs one EWD, based on capacity requirements alone. Alternative formal contingency arrangements will need to be put in place with other departments or hospitals.

In addition, the selection of a number of smaller machines (for single scope processing) may allow more flexibility than fewer larger machines (for multiple scope processing).

Whilst the utilisation factor of 60% is relevant to machine overall availability, the capacity calculation should also allow for machines to be taken off-line for maintenance and validation purposes for up to 2 days at a time. Water test failures may also lead to situations where machines are limited to processing certain Endoscope types only (for example, mycobacteria failures leading to restrictions on the ability to process bronchoscopes). In a department with many machines, the 60% utilisation factor is often sufficient to meet service needs. However in facilities where only 1 or 2 machines are installed, spare capacity should allow for continued function of the department and the above testing etc. to take place.

In total, the range of information which should be considered includes:

- Number of Endoscopic procedures carried out per session/per day;
- type of Endoscopic procedures carried out i.e. gastroscopy, bronchoscopy, colonoscopy, sigmoidoscopy, etc.;
- number of operational hours per day for the department in which the EWD is located and;
- machine utilisation factor expressed as a percentage of the number of operational hours;

- Endoscope throughput profile per day;
- Endoscope inventory and time between use;
- scale of Endoscope reprocessing required at the beginning of the day;
- trends in the increasing number of Endoscopes requiring reprocessing;
- machine's location and the transport time to the processing area;
- staff availability for loading and unloading;
- are the staff who operate the machine dedicated to the operation of the EWD, or is the operation of the EWD only part of their duties?;
- planned and breakdown maintenance time;
- routine, periodic and annual testing including the impact of failed water tests;
- availability of Controlled Environment Storage Cabinets;
- availability of validated systems to extend Endoscope storage and;
- out of hours provision requirements.

5.4 Example Calculation for Normal Demand

The following shows a method of calculating the number of Endoscope reprocessors required. The figures are for example **only** and do not represent a solution to any particular throughput numbers or reflect machines that are available in the market.

Example:

The GI Endoscope Decontamination department is processing 9,000 Endoscopes per annum. The hospital also processes 2,000 bronchoscopes in theatres, 1,000 ENT nasendoscopes in outpatients and 1,000 urology Endoscopes in various other locations. It wishes to create a new decontamination unit to reprocess all the demand.

The total workload of the new department will therefore be 13,000 Endoscopes per annum giving an average weekly demand of 250 Endoscopes per week. This presumes a flat rate across the year. However, if there are known to be definite, reoccurring peaks in any individual week or period, the peak weekly demand should be used. In this example the department will operate 5 days a week giving an average daily demand (AD) of 50 Endoscopes per day.

The Endoscope users will be operating 5 days a week. This equates to an average daily demand (AD) of 50 Endoscopes to be processed per day.

The preferred choice of EWD has 40 minute cycle time including time taken to load and unload the chamber/bowl (CT).

From this information the processing time required each day in minutes (TR) to process the daily demand can be calculated:

TR = average daily demand X machine cycle time;

TR = AD X CT;

TR = 50 X 40;

CT = (Cycle Time) 2,000 minutes.

Next the number of available minutes for processing in a day (AT) needs calculating. The new department intends opening from 9am to 5pm giving an 8 hour day or 480 minutes day. With 60% utilisation there are 288 minutes available each day for processing (480 X 0.6). Therefore in this example AT = 288.

The number of machines required (N) is then calculated using the following formula:

CT Is the cycle time required each day;

AT Is the available minutes for processing;

SC Is the scope capacity i.e. the number of Endoscopes that can be processed per cycle in the machine.

(***Note:*** *When calculating SC, a two bowl machine whereby the chambers take 1 scope each but operate each chamber independently would be an SC of 2. Likewise a machine with a larger chamber which takes 2 scopes within the same chamber that doesn't operate independently would also be 2)*

N = CT/(AT X SC)

N = 2,000/(288 X 2)

N = 2,000/576

Therefore N = 3.47 which equates to 4 machines.

If several different machine suppliers are being considered, the equation will have to be repeated for machines with different cycle times (by adjusting CT) or scope numbers (by adjusting SC).

As discussed earlier in section 5.1 capacity growth, whilst critical to floor space and staffing numbers, may make little difference to the number of machines required. The example above shows a requirement for 3.47 machines. Obviously, machines can only be purchased in whole numbers and in the example above, 4 machines would be required. If the unit was to add 15% growth into the equation they would still only require 4 machines (see examples A and B page 17).

Table 2 **Example A** Endoscope Washer Disinfector Calculation

Growth	0	5%	10%	15%
Current annual procedures	13,000	13650	14300	14950
Weekly procedures	250.0	262.5	275.0	287.5
Days working per week	5			
Average daily procedures (AD)	50.0	52.5	55.0	57.5
Machine cycle time and loading/unloading time (CT)	40			
Processing time required each day (mins) (TR)	2000.0	2100.0	2200.0	2300.0
Working day length (Mins)	480			
Utilisation factor (testing, maintenance, sampling time)	60%			
Available time in working day (AT)	288			
Scopes per machine (SC)	2			
Minimum machine numbers required for flat demand only (N)	3.47	3.65	3.82	3.99

Table 2 **Example B** Endoscope Washer Disinfector Calculation

If the initial demand was for 14,000 Endoscopes per year, 15% growth would tip the number of machines required from 4 to 5:

Growth	0	5%	10%	15%
Current annual procedures	14,000	14700	15400	16100
Weekly procedures	269.2	282.7	296.2	309.6
Days working per week	5			
Average daily procedures (AD)	53.8	56.5	59.2	61.9
Machine cycle time and loading/unloading time (CT)	40			
Processing time required each day (mins) (TR)	2153.8	2261.5	2369.2	2476.9
Working day length (Mins)	480			
Utilisation factor (testing, maintenance, sampling time)	60%			
Available time in working day (AT)	288			
Scopes per machine (SC)	2			
Minimum machine numbers required for flat demand only (N)	3.74	3.93	4.11	4.30

The calculation method discussed in this document applies a flat demand and makes little allowance for excessive peaks and troughs unless the average daily demand is adjusted prior to using it in the formula. If the equation is created in a spreadsheet then the impact of different growth and increases in peak daily demand can be modelled in a matter of seconds. An example of such a spreadsheet is available from the HSE website:

Capacity planning Tool for EDU

Available at:

http://www.hse.ie/eng/about/Who/QID/nationalsafetyprogrammes/decontamination/

5.5 Example Calculation for a Large Peak Demand

In situations where controlled environment storage cabinets are not used and there is a large Peak Demand (PD) immediately before services commencing then a sense check of the required machine numbers can be made by the following formula:

N = (PD X (CT/H))/SC

PD = Peak Demand

CT = Cycle Time

H = 60 minutes/hour

SC = Scope Capacity

For example, a hospital with 4 treatment rooms requires 1 nasoendoscope to be available for the commencement of service in each room. Two further procedures will have been undertaken before the EWD has completed a second cycle. Therefore the hospital requires 12 Endoscopes at the start of a morning session to be available across all its ENT Endoscopy treatment rooms (3 scopes per room multiplied by 4 rooms). This gives a Peak Demand PD value of 12.

The hospital is proposing to purchase a machine with a cycle time (including loading and unloading) of 40 minutes. This gives a Cycle Time CT value of 40. The EWD can process 2 scopes at once giving a SC value of 2. Therefore:

N = (12 X (40/60))/2

N = (12 X 0.666)/2

N = 8/2

N = 4

Four machines would be required.

However this presumes that the department would be open for a sufficient period of time, prior to service commencing so that the EWDs could be loaded with the Endoscopes. The equation offers a balance between machine numbers and this pre-service open time.

5.6 Endoscope Washer Disinfectors

The design of the EWD can often impact on the capacity of the proposed department to meet service demands. Machines that incorporate the processing of several Endoscopes at once may take up less space if they are of an upright single chamber design. However these type of machines require all the scopes to be processed at once during a single cycle. Conversely, machines designed with separate bowls for each Endoscope may take up greater floor space but offer greater flexibility with respect to running cycles independently of one another. This type of arrangement can give greater flexibility in departments.

The design of the EWD will also impact on the time it will take to validate the machine. Single chamber multi-scope EWDs will have common chamber parts and may take less overall time to validate. However, when they are being validated, the reduction in capacity is greater than double basin EWDs. Double basin types may allow for each basin to be validated independently, giving flexibility to the user during validation, but taking longer overall to validate as separate dosing systems and cleaning efficacy tests will need to be undertaken.

5.7 Endoscope Storage Systems

All items should be stored in such a way that the microbial quality of the scope 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. The storage of reprocessed flexible Endoscopes must be clearly separate from the clinical procedures area to reduce recolonisation of decontaminated Endoscopes and accessories. There are three options for storage of flexible Endoscopes post-decontamination; Sterilisation, (this document does not cover the processing of flexible Endoscopes used to examine sterile body tissues, these Endoscopes should be sterile) Controlled Environment Storage Cabinets or Portable Storage Systems.

5.8 Controlled Environment Storage Cabinets

Controlled Environment Storage Cabinets (CESC) allow processed Endoscopes to be stored for extended periods whilst maintaining their microbial quality. As discussed previously, CESCs can reduce the number of EWDs required by eliminating the need to reprocess 'time expired Endoscopes' before the start of each clinical session. Infrequently used scopes will also require less EWD processing. The design of the CESC will impact on the number and type of Endoscopes which can be stored. The number of CESCs available and their location will also impact upon the number of EWDs required and the staff numbers required within the reprocessing department.

(***Note**: CESCs must not be located in a clinical treatment area. Supplying CESCs with air from the hospital medical air supply must be avoided. Where a connection to the Medical Air supply is to be considered a rigorous risk assessment must be undertaken by (or involving) the Authorised Person (MGPS), as this may compromise the capacity of the medical air system to supply critical areas such as ICU or Theatres. The preferred solution must be to install a CESC which provides its own air supply from an integral/integrated compressor. Where the Hospital Medical Air supply is to be used the Quarterly Quality Controller (QC) test reports for medical air should be incorporated into the quality records for the CESC)*

5.9 Positioning of CESCs

Correct positioning of cabinets, in a clean environment, is critical to maintaining the cleanliness of the stored Endoscopes. Prolonged storage of Endoscopes within dedicated cabinets is designed to deliver High Efficiency Particulate filtered air (HEPA) to the internal channels of the Endoscope at the appropriate temperature and flow rate.

Excessive environmental contaminants have the potential to reduce the life of the HEPA filters, and lead to a failure to maintain the appropriate environment within the CESC. It is acceptable to include space for Endoscope storage in the clean room of the decontamination facility, or in theatres etc. Departments that require out-of-hours or unscheduled activity may need access to reprocessed Endoscopes at all times of the day. This will mean that a CESC may need to be accommodated as close to the point of use as possible. A pass through model or single ended model may be used depending on the design template used. See Figures (4,5,6 and 7).

The environment where such equipment is installed should be controlled, and in rooms designated for 'clean' activity. The room should not be open for common access, must be controlled by either access code or key, and should not present an opportunity for recontamination as a result of other activities within the room. CESCs must never be installed in dirty utility rooms or rooms for waste/bodily fluid disposal.

There should be enough space around the cabinet to ensure that there is adequate access to open the doors and position Endoscopes in/out of the cabinet. If an UPS is required, it should be securely positioned in accordance with the manufacturer's recommendations. CESCs should be fitted securely in a stable position and tethered (if recommended by the manufacturer).

Whenever CESCs are positioned away from the centralised reprocessing area, consideration needs to be given to the transportation systems that will be used. Transport system design and access to/from the reprocessing area will be crucial to maintaining the integrity of the decontaminated product.

5.10 Prolonged Storage Using Vacuum Systems

New systems are being developed to support prolonged storage of flexible channelled Endoscopes. These systems will allow the User to have an Endoscope at the point of use in areas where regular usage may not be a requirement (e.g. ICU, Out Patient Clinics). The majority of these systems operate on a partial vacuum packing method.

There are two types of vacuum systems that are currently available:

1. Vacuum systems which require that the external surfaces of the Endoscope are dry prior to storage. These vacuum systems provide a means of purging the internal channels of the Endoscope.
2. Vacuum systems which facilitate extended storage and require that the external surface **and the internal channels** of the Endoscope are fully dried prior to storage. **This type of system requires the Endoscope to be dried in a CESC prior to vacuum storage**.

A robust mechanism to validate the prolonged storage times of each Endoscope type must be in place where these systems are to be used. The validation process must be recommended by the manufacturer of the vacuum system and evaluated by the design and planning team to provide assurances to the user that this method of prolonged storage will not comprise the disinfection efficacy of the Endoscope/Endoscope type to be stored in their department/hospital. This process must be repeatable to provide continued assurances of the efficacy of the storage system. All packaging should be visually inspected for damage prior to use.

(***Note:*** *Where Endoscopes need to be placed in a CESC as a first step, (to ensure that they are completely dry) prior to packing and storing using a vacuum system, the User needs to secure clarification from the cabinet manufacturer on the actual drying time for each type of Endoscope)*

*(**Note:** All elements of the decontamination life cycle, cleaning, disinfection, transport, handling and location of Controlled Environment Storage Cabinets will impact on the efficacy of storage times. It should be borne in mind that successful storage is event related and not necessarily only time based. Manufacturers instructions relating to the duration of the length of storage must be validated in local practice taking into consideration the frequency of insertion and removal of Endoscopes into/from the CESC as this can increase the risk of Endoscope contamination. Retesting is required if a new type of Endoscope is added to the process.*

It is recommended to keep prolonged storage times to a minimum for safety. All new Endoscope storage systems must be set up to interface with the National Fingerprint Track and Trace System)

5.11 Business Continuity Considerations

Business continuity and future service capacity planning may require purchase of additional EWDs, CESCs or portable storage systems or the design team may provide additional space (with services) to allow for installation of additional EWDs, sinks or CESCs at a later stage.

Consideration should be given to provision of an UPS to ensure IT information systems such as the Fingerprint National Track and Trace System and the Endoscope CESCs are supported in the event of a loss of power supply to the department. The Endoscope decontamination facility should be backed up with a Standby Generator in the event of loss of power supply. Critical alarms such as loss of power to the facility (including plant room) shall be connected to the Business Management System (BMS) and telephonist switchboard to facilitate timely reconnection.

Duplex Reverse Osmosis systems must be installed to ensure business continuity and continuous service delivery.

Consideration must be given in installing duplex systems including pumps, softeners, within the plant room to ensure business continuity.

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 to facilitate recall/withdrawal of potential faulty or contaminated Endoscopes from use. In addition, the system must facilitate timely identification of service users exposed to specific Endoscopes, 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, "ScopeTrack" for the recording of the decontamination process and storage of flexible Endoscopes within the EDU.

The objective of the National ScopeTrack system is to ensure that there is effective audit trail in place which can track the Endoscopes 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 (GSI);
- 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*)

6.1 Equipment Interface Functionality with the Track and Trace System

The HSE require interface functionality of the EWD and CESC or vacuum systems used to prolong Endoscope storage , with the National Endoscopy tracking software system “ScopeTrack”. This requirement is to afford data generated by the EWD and CESC or vacuum system to be accessed directly by “ScopeTrack”. The direct interface functionality will streamline the operational processes in EDU’s, reduce time and provide the decontamination parametric release report for archiving within “ScopeTrack” and make this information available for archiving within the patient file via an endoscopy reporting system.

The primary aim of interface functionality is to deliver:

- Accurate data recording of parametric release;
- accurate EWD cycle recording;
- accurate EWD and storage system data archiving within “ScopeTrack”;
- accurate EWD and storage cabinet data archiving within the Endoscopy reporting system;
- central reporting and time efficiencies in operational processes within the EDU.

The minimum requirements the interface will provide are:

- Automatic Parametric Release: the independent monitoring system data is made available to “ScopeTrack”, facilitating automatic cycle pass or failure recording;
- accurate start and stop data is obtained directly from machines to ensure no time parameters are in-advertently exceeded;
- information that is generated and accessed by the machine manufacturers is made available to “ScopeTrack” for combined reporting;
- to facilitate a single scan processing capability for “ScopeTrack”, the EWD and CESC or vacuum systems.

2

Part 2
Facility Design Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Units

1. Design and Layout of an EDU

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.

Features of a service meeting this HIQA Standard include:

2.6.1 A physical healthcare environment that is planned, designed, developed and maintained to facilitate effective cleaning and compliance with Infection Prevention and Control best practice.

- It is essential that decontamination facilities are appropriately designed, maintained and controlled to reduce the risk of cross-contamination and to provide a safe place of work. The design must ensure complete physical separation of 'dirty' and 'clean' activities providing, at minimum, separate 'clean' and 'dirty' rooms with use of pass through EWDs.

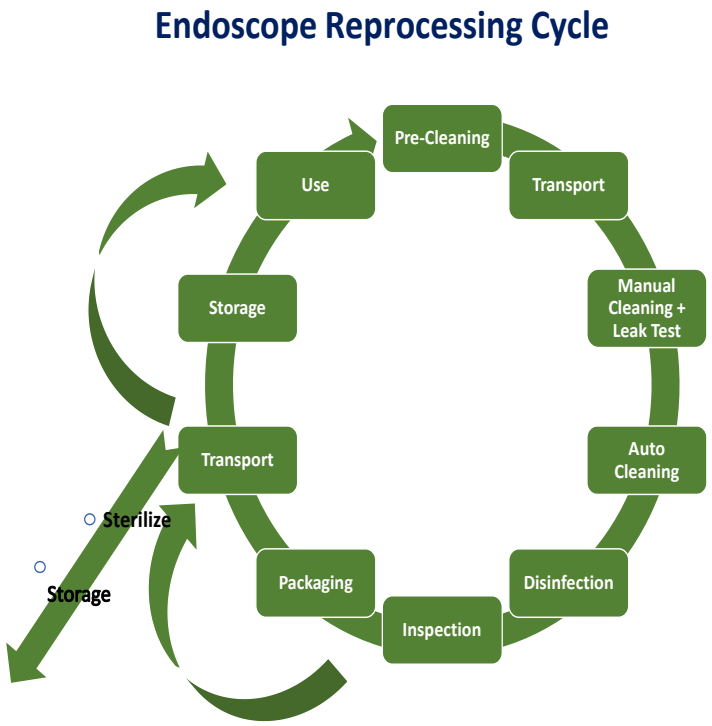
2.6.2 The size, complexity and specialties of the service are considered when planning the design and layout of the facility.

- The department must not be used for any other purpose or used as a thoroughfare or part of any service user treatment area.
- There is a changing area for donning work wear which includes shower, toilet facilities and lockers in proximity to the decontamination area.
- Controlled access to the washroom and clean room is through separate gowning rooms provided with hand hygiene facilities.
- The wash room and clean room are designed to minimise the ambient sound levels within the room. This will require attention to the installation of equipment, building finishes etc.
- The flow of equipment within the EDU department is from dirty to clean areas to minimise the risk of cross-contamination.

2.6.3 The service complies with the relevant legislation and national and international best practice recommendations for the infrastructure of the facility including the building, water supply and ventilation;

- 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 service, are critical if decontamination is to be fully effective and safe for staff and users;
- 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. Example layouts have been included (see Figure 4,5,6 and 7).

Figure 3: Endoscope Reprocessing Cycle



The following example design templates have been devised to support the development of Endoscope decontamination facilities. These design templates are not to scale. Variations on the layout of the facility may be incorporated into the design brief on the proviso that key concepts regarding work flows remain.

Figure 4: Design Template Large EDU

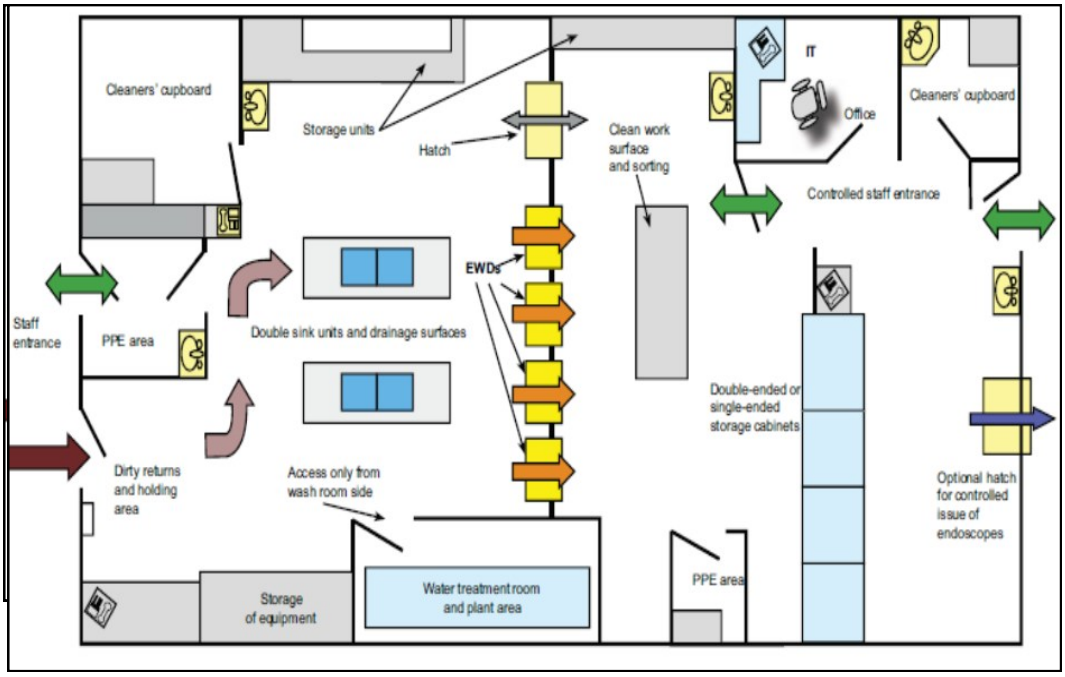
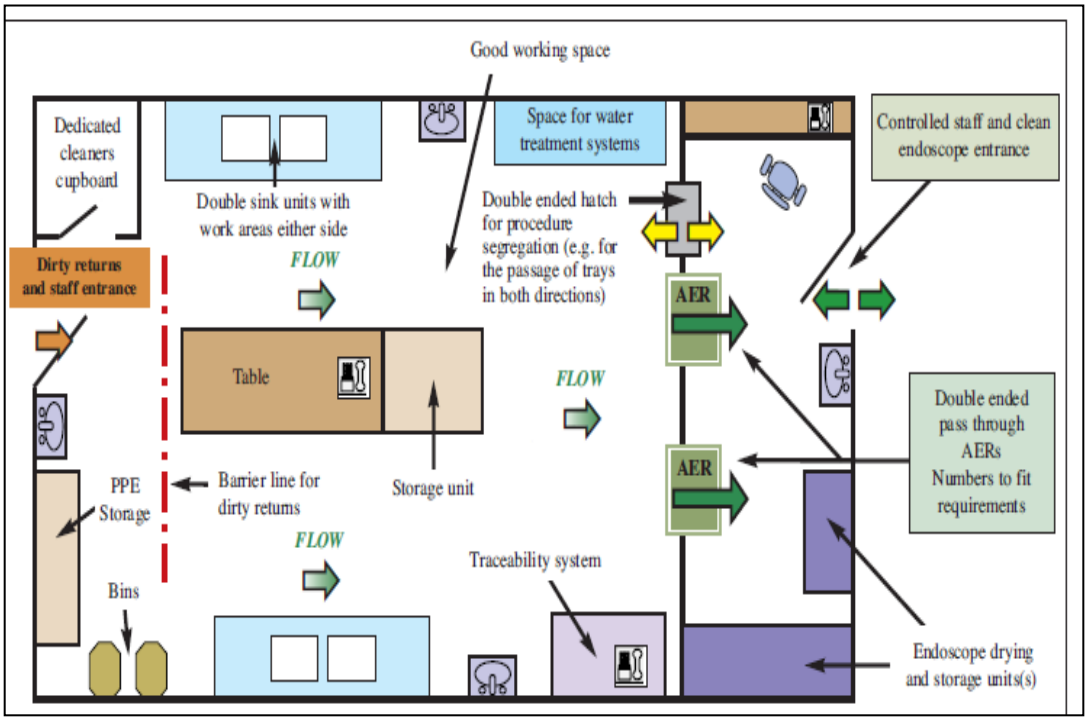


Figure 5: Design Template Medium to Small EDU



Design Template for an EDU Supplying Adjacent Treatment Rooms

Figure 6 shows the interrelationship between the EDU and two adjacent treatment rooms. This design concept can be adapted to serve more than two treatment rooms, however, the return of contaminated Endoscopes needs to be considered to ensure the 'clean' and 'dirty' workflows are not compromised.

Figure 6: Design Template for an EDU Supplying Adjacent Treatment Rooms

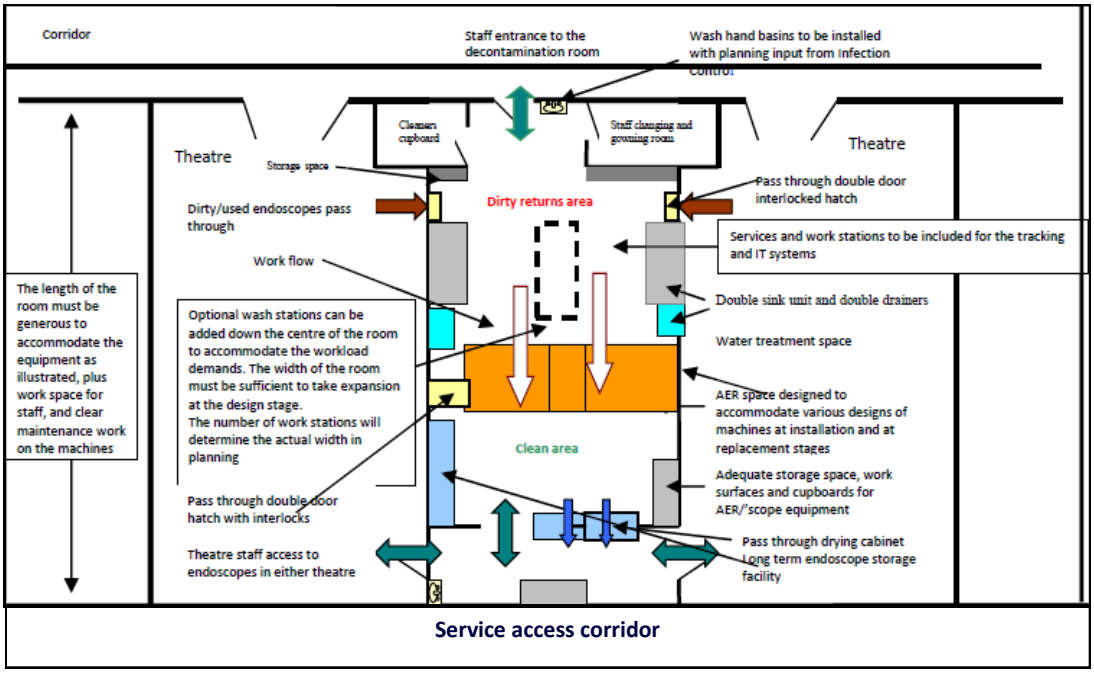
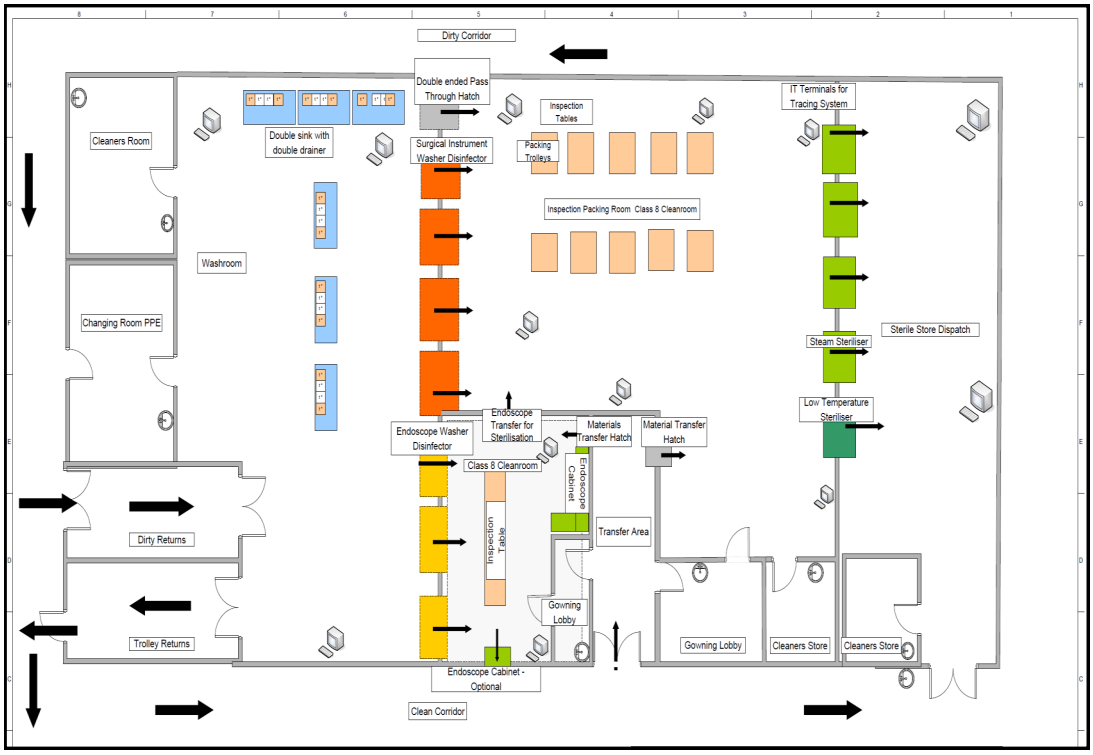


Figure 7: Design Template for a Large Centralized CDU and EDU



Summary Considerations Regarding Footprint of the EDU

The footprint of the Endoscope decontamination unit must take into consideration the following:

- Current Endoscope activity/projected growth;
- number of personnel working in the area;
- need for, at minimum, a twin basin sink in the dirty room with set down areas on either side of the sink. The sink must be sized to accommodate an Endoscope in each basin;
- hand hygiene sink in the decontamination room, and a separate hand hygiene sink external to the clean room;
- the number of an type of EWDs and Endoscope storage cabinets required;
- identify if Endoscopes will be stored within the clean area of the decontamination unit;
- separate cleaners cupboard for 'clean' and 'dirty' areas;
- storage requirements for chemicals, (such as disinfectants which must be stored in a dedicated facility external to the 'clean' and 'dirty' rooms of the EDU) consumables, PPE and Endoscope transport cases if required;
- IT requirements for each room, PC and space for IT stations, printers and hand held scanners, networking of the equipment and tracking system onto local and national HSE servers;
- ancillary areas such as changing-room facilities, rest rooms etc.;
- the Plant Room shall be sized to accommodate RO Duplex System, water softeners, heater units, Air Handing Units, air compressors and allow for easy access by service providers to plant equipment;
- electrical requirements for decontamination, storage equipment including consideration of the method used to heat water, electrical installation requirements according to ET101 (2009) (with attention paid to phase requirements for EWDs) and isolator locations need to be agreed and advised for all electrical components;
- all data signal cabling between plant, equipment, BMS and the hospital data network hubs need to be identified early on;
- it is preferable to locate services that require routine access for maintenance within the plant room space or corridor ceiling void;
- compressed air requirements for decontamination and storage equipment;
- Uninterruptible Power Supply unit (UPS).

2. Design of Ventilation Systems for an EDU

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.

Features of a service meeting this HIQA Standard include:

2.6.10 The ventilation system is planned, designed, maintained and monitored to mitigate the spread of Healthcare Associated Infections, in line with best practice and relevant legislation:

- Endoscope decontamination and storage facilities are workplaces, and it is a legal requirement under the Building Regulations that they be ventilated;
- to meet this legal requirement ventilation systems must function;
  - to maintain a comfortable working environment for the staff,
  - to remove airborne hazards arising from the decontamination process including chemical vapours/odours,
  - to preserve the quality of Endoscopes that have been decontaminated.

Ventilation and Temperature

All rooms in the department must be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures are controlled between 18-22 degrees Celsius and relative humidity is controlled within the range 35-60%).

A two room Endoscope decontamination facility is required and as a result the ventilation system can be better defined and managed. In the wash room, there needs to be consideration of the need to protect healthcare workers who are handling and manually washing contaminated Endoscopes as well as protecting them from the hazards of the chemicals used in this area.

Air will need to be introduced and removed so as to efficiently ventilate the entire workspace with air flowing from the cleaner areas to the less clean areas of the facility. The ventilation system should be designed and operated to ensure that contaminants arising from the decontamination process are removed within the facility, and that airborne contaminants are excluded from the point that the decontaminated Endoscopes are stored. These objectives will be achieved both by supplying filtered air to the 'clean' areas, and maintaining them at a positive pressure with respect to surrounding areas, and by extracting air from the less clean areas, and maintaining them at a negative pressure with respect to surrounding areas.

Contaminants arising from the decontamination machines themselves must be as far as is practical, captured at source, and removed before they enter the workplace. Ventilation should be provided by an Air-Handling Unit (AHU) that conforms to the standards set out in the UK Health Technical Memorandum 03-01. A dedicated AHU is required for EDU.

The Air-Handling Unit should have the facility to heat, cool, and filter the air delivered to the working space.

If the AHU does not supply air of the correct quality, then an additional filter may be required in the branch duct to achieve the quality required. Air should be filtered by an 'F7 type' filter. An extract system should be provided with energy recovery between the extract and the supply via the insertion of a plate heat exchanger or run-around coil, a thermal wheel should not be used. The decontamination facility will need 10 air changes per hour to dilute possible airborne contamination.

Additional Requirements for Sterilisation of Surgically Invasive Flexible Endoscopes

Where decontamination units need to sterilise Endoscopes, the environmental conditions under which packing and sterilisation occur should be no different to those within a Central Decontamination Unit.

Therefore the requirements for clean rooms can be divided across three delivery scenarios:

Scenario 1: Stand alone EDUs that do not need to sterilise surgically invasive flexible Endoscopes. The units should have a clean room with air supplied via an F7 filter. They should have minimum of 10 air changes per hour and a pressure differential with adjoining rooms of + 5 Pascals.

Scenario 2: Stand alone EDUs that sterilise surgically invasive flexible Endoscopes. These units should have a clean room that meets the requirements of ISO 14644 Class 8 at rest. In many cases this could be achieved using F7 filtration but may need HEPA filtration in some locations. They should have minimum of 20 air changes per hour and a pressure differential with adjoining rooms of + 10 Pascals.

Scenario 3: EDUs that are co-located with Central Decontamination Units (and share clean room facilities). These units should have a clean room that meets the requirements of ISO 14644 Class 8 when at rest. In many cases this could be achieved using F7 filtration but may need HEPA filtration in some locations. They should have minimum of 20 air changes per hour and a pressure differential with adjoining rooms of + 10 Pascals.

Risk from Chemicals

Health and Welfare at Work Acts 2005 and 2010 require employers to ensure, as far as is reasonably practicable, the health, safety and welfare of all employees. The Act also requires employees to comply with the precautions established to ensure safe working. The Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 require employers to assess the risk to the health of staff by exposure to hazardous chemicals to minimise and to avoid such exposure where this is reasonably practicable, and otherwise to ensure adequate control. Engineering methods of control must be used in preference to personal protective equipment.

There may be a risk to staff from chemicals used in the process, such as detergents and disinfectants, which may include components of peracetic acid, chlorine dioxide, hydrogen peroxide, and enzymatic detergents, some of which have occupational exposure limits. EWDs employing chemicals that are volatile require exhaust ventilation to maintain the environmental concentration below any limit specified for occupational exposure and to ensure that the discharge is to a safe place.

In preventing exposure to harmful substances in the workplace, there is a hierarchy of control measures that must be considered, commencing with the elimination or substitution of the hazard or, where these options are not possible, the hazard must be controlled by engineering means. Local exhaust ventilation (LEV) is one such engineering control measure. LEV is an engineering system designed to reduce employee exposure to airborne contaminants (dust, mist, fume, vapour, gas) in the workplace by capturing the emission at source and transporting it to a safe emission point or to a filter/scrubber. Employers need to work with designers, suppliers, installers and employees to effectively control exposure to airborne contaminants. Suppliers must provide LEV that is fit for purpose, is shown to work and continues to work. The employer (the LEV owner) must ensure controls are adequate. Everyone, including suppliers and facilities department, must be competent in the use of the LEV system for further guidance please review the Health and Safety Authorities Guidance for Local Exhaust Ventilation (LEV) Systems (2014).

An EWD will always leave some residual chemical in the bottom of the detergent and disinfectant containers when empty which can pose an exposure risk to staff when they are changing the containers. The exposure risk to the chemicals and any fumes should be addressed by the department in consultation with the hospital appointed Dangerous Goods Advisor, Health & Safety Officer, the supplier of the detergent and disinfectant and the chemical safety data sheet. EWDs not equipped with an air extraction system may require and extraction device to be mounted above the door or lid to reduce chemical vapors entering the workplace.

Air Flow

With a two-room layout, air will be supplied to the clean room/clean Endoscope storage room through a ceiling-mounted diffuser, and pass through to the wash room via a high level pressure stabiliser mounted in the adjoining wall.

Air is extracted from the washroom preferably at low level behind the sinks, where the Endoscopes are washed prior to being placed in the EWDs. Air should be extracted directly from the EWDs during the process cycle (Figure 8). The operational success of this facility will be dependent on the detail of its design and construction.

The following points must be observed:

- Advice should be sought from the EDU Design and Planning Team (see page 2) regarding suitability of the ventilation system to meet the current and future needs of the EDU (Table 3);
- all decontamination equipment, such as softeners, Reverse Osmosis (RO) water units, or water filtration, should be located outside the clean area, preferably within a dedicated nearby plant room;
- the EWDs should be installed so that all parts that need to be routinely inspected or serviced are accessible from the wash room side. The principal extract position in the wash room should be on the wall immediately behind the wash (manual cleaning) sinks. The Endoscope clean room/storage room should have a solid ceiling;
- the clean Endoscope room ceiling void should not contain any equipment that requires routine servicing or maintenance;
- the ventilation ductwork passing through the clean Endoscope ceiling room void should not contain any branch trimmer heaters, cooling coils, humidifiers, or filters;
- the isolation/fire dampers mounted in the wall should be installed so that access for annual testing is from the corridor side;
- the room doors must be fitted with automatic door closers;
- the clean Endoscope room should be maintained at + 5 Pascal, and the wash room at - 5 Pascal with respect to the surrounding areas. A pressure stabiliser fitted in the wall between the rooms should be set to open at 10 Pascal;
- there should be a note on the location of the supply and extract grilles;

- a local control facility to regulate the temperature of the working area between 18-22 degrees Celsius will help with comfort conditions. A room air pressure monitoring panel should be provided external to each room and in the EDU office indicating "healthy" & "outer limits" in green and red LED light respectively. A facility to monitor and modify the temperature of each room is required.

Note regarding refurbishment

If a refurbished area has an existing tiled ceiling that cannot be removed, then the tiles should be sealed in position. The ceiling should be able to withstand cleaning, and have a completely sealed finish to maintain microbiological cleanliness. If hatches are unavoidable they should be of the sealable type.

A summary of the ventilation requirements are included in the table below:

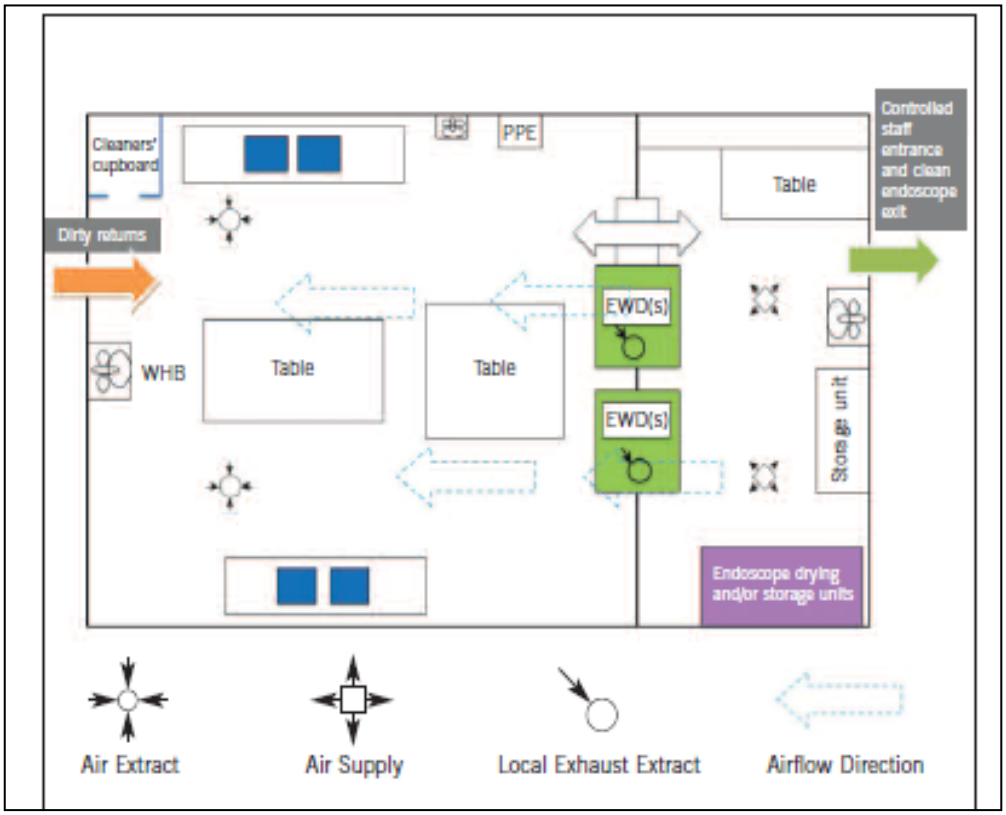
Table 3: Summary of the Ventilation Requirements

Application	Wash Room	Clean Room	Clean Room with Low Temp Sterilisation of invasive Endoscopes
Ventilation	Extract	Supply	Supply
AC/hr	>10	>10	>20
Minimum Air Flow Rate	6L /second of fresh air per person working in the room	6L /second of fresh air per person working in the room	6L /second of fresh air per person working in the room
Pressure (Pascals)	Negative -5Pa to surrounding areas	Positive +5Pa to surrounding areas	Positive +10Pa to surrounding areas
Supply filter	-	F7	Sufficient filtration to achieve ISO 14644 class 8 at rest
Temp (°C)	18-22	18-22	18-22
RH	35-60%	35-60%	35-60%

Users should also ensure that:

- The ventilation within the decontamination environment complies with all relevant building notes and National Standards;
- ventilation requirements include consideration of the thermal load within the decontamination room;
- the ambient temperature within the decontamination area allows users to work within the environment with all doors and windows closed;
- there is a local method of checking both incoming air and extraction (i.e. magnahelic gauges);
- ventilation requirements are assessed/reassessed when there are any changes in room use, including installation of new EWDs;
- staff working within the area are aware of, and adhere to, all relevant health and safety policies regarding safe working practices, including those relating to the number of personnel working in the area, and the wearing of PPE;
- there is a documented process in place for dealing with ventilation problems in a timely manner;
- decontamination audits include assessment of the function, efficiency and effectiveness of the room ventilation and;
- ventilation installation and maintenance is only undertaken by competent persons with a working and up-to date knowledge of the requirements within a decontamination environment;
- all new and refurbished installations must be validated by a Competent Person independent from the contractor on behalf of the client. Annual verification of the functioning of the ventilation system must be performed by a Competent Person independent of those carrying out the maintenance of the ventilation system.

Figure 8: Airflows and pathways in a pass through EDU.



Additional Notes

(Installation of RO plant, ventilation plant , EWDs and Endoscope Storage Cabinets should be carefully considered to avoid unnecessary disruption to services. Pathway for delivery of this equipment should be measured to ensure delivery and installation of large bulky equipment is not hindered. The design team must liaise with the EWD, Reverse Osmosis, Ventilation and Endoscope Storage Manufacturer to plan spatial requirements for engineering access. ***Ideally all access for repairs should be performed in the dirty area and not the clean room****. The use of flexible hoses should be avoided. Water treatment plant space for filters and specially designed units will also require adequate space for installation and access for maintenance)*

3. Water Quality for Endoscope Decontamination

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.

Features of a service meeting this HIQA Standard include:

2.6.9 The water system is planned, designed, maintained and monitored to mitigate the spread of Healthcare Associated Infections, in line with national guidelines and relevant legislation including the Health Protection Surveillance Centre Guidelines for the Prevention and Control of Infection from Water Systems in Healthcare Facilities (2014).

2.6.10 Measures are in place to control the risk to the microbiological safety of water in the facility in line with relevant national guidelines.

Water Quality

The quality of water used at all stages of the decontamination process is critical to the successful outcome of the process, as the water is the last product to make contact with the scope prior to the service user procedure.

The objective of this recommended practice is to provide guidelines in relation to provision of water of optimum quality for each stage of the decontamination process.

Analysis of the existing water supply for the building should be taken and recorded at design stage. The pre treatment plant for the RO system should be designed based on the condition of the existing water supply.

At each stage in the decontamination process the water quality should be compatible with:

- The materials of construction of the EWD;
- the RIMDs to be processed;
- the process chemical to be used;
- the process requirements of each particular stage of the cycle.

Incoming Water Supply

Water is derived from a number of sources including lakes, reservoirs, rivers and underground aquifers. Water has the natural ability to dissolve or suspend nearly all chemical compounds present in the environment and the geographical region and seasonal variation will affect the quality of the water. The water passes through a number of treatment steps before distribution and supply. The quality of treated "mains" water although regulated by national and local regulations may vary considerably.

The quality of the mains supplied water, with respect to suspended particles, dissolved inorganic and organic compounds, microbiology and dissolved gasses, may have significant effect on the application including Endoscopes and EWDs. Determine the quality of water coming into the hospital and whether the existing hot and cold supplies in the hospital can serve this new facility without depriving other units/areas of their supplies. Identify if water softening systems are required, the pressure flow and temperature of incoming water must be determined as this will impact on the EWD requirement on maximum demand.

*(**Note:** In theory only the final rinse of the automated Endoscope decontamination process requires water at the quality identified in Table 4 and 5. However, in practice the consensus is that using purified water for the entire automatic decontamination process is the option which delivers a consistent level of water quality as the quality of incoming mains water can vary from time to time)*

The provision of high quality water, free of contaminants, is essential to support safe, reliable reprocessing of Endoscopes. The following points must be considered:

- Although the incoming water may be capable of achieving, as a minimum, national and local guidance levels for chemical and microbial quality, the contractor and/or estates should evidence the quality of water, which may vary considerably throughout the year, by analysis over an extended period of time;
- water from the public supply has a microbial content that should free from pathogenic organisms, but may contain organisms that could cause opportunistic infections in immunocompromised patients, if allowed to grow to high numbers. In addition high microbial loading may impact on the water treatment process;
- water from the public supply has a chemical content that may impact on the cleaning and disinfection process;
- volume, type (storage tank, direct mains, borehole) pressures, temperature and flow of the intended water supply;
- investigate secondary treatment policies within the hospital i.e. chlorine dioxide, copper silver ionization etc. Additional free reactive chlorine will cause rapid deterioration of Reverse Osmosis membranes and active carbon filtration may be required;
- the manufacturer/contractor should undertake chemical and microbial analysis of incoming water over an extended period of time to determine the quality of the water and justify the water treatment plant design and installation and provide assurances of efficacy following commissioning. Maintenance and servicing following commissioning should include provision of water testing to confirm effectiveness during the life span of the equipment in accordance with the specification provided at the outset.

This as a minimum shall include sampling during commissioning, periodically thereafter and immediately prior to and following maintenance or servicing;

- the design and planning stage should identify the positioning of accessible sampling ports, both upstream and downstream of the water treatment plant;
- careful consideration should be given to positioning of the water treatment plant and pipework to ensure direct access to or within the Endoscope department so that servicing and maintenance of water treatment plant can, where possible, be carried out easily without disruption to the unit;
- design and planning of drainage is critical and full consideration should given at the outset to adequacy and siting (page 55).

Water Quality Specifications

Water is used for dilution of chemicals, initial rinse-water; intermediate rinse-water and final rinse-water. The provision of high quality water assists in ensuring:

- That, with sufficient volumes of water, chemicals, matter and microorganisms are readily removed during the washing, disinfection and rinsing stages;
- that chemical agents are readily dissolved in the water (without inhibition) and acting to the manufacturers specifications and;
- chemicals employed in the cleaning, disinfection stages, that may pose a risk to patients, are readily removed especially during the rinse stages, so as to prevent contact with patients.

Final rinse-water provided by a water treatment system should meet the guidance levels described in Table 5 and contain low levels of chemical contaminants as shown in Table 4 and Table 5.

Key Indicators Affecting the Quality of Water Required to Safely Reprocess Endoscopes.

The following physical, chemical and microbiological factors are considered important in assessing and maintaining the quality of the final rinse water and indicating the quality of water emanating from the water treatment plant:

- Appearance;
- water hardness;
- temperature;
- ionic contaminants (e.g. heavy metals, halides, phosphates and silicates);
- microbial contamination expressed e.g. TVC as CFU/100mls;
- bacterial endotoxins;

- *Pseudomonas aeruginosa;*
- environmental Mycobacteria and;
- pH and conductivity.

Appearance

Water supplied to an Endoscope department may well contain deposits originating from the water treatment plant or distribution system and may affect Endoscope cleaning and disinfection efficacy or cause blockages. These deposits can be removed by filtration.

The appearance pre and post treatment should be clear, colourless and free of particulate material.

Water Hardness

Hard water is caused by the presence of dissolved salts of alkaline earth metals (principally calcium, magnesium, barium and strontium), which have low solubility and deposits as lime-scale when water is heated or evaporated. The deposition of lime-scale on electrical heating elements or heat exchange components, within pipes and around the edges of spray nozzles will seriously impair the performance of the RO system and the EWD.

Using hard water in the final rinse stages of an EWD cycle is one of the major causes of deposits on load items and cause damage to Endoscopes. Deposits may act as a focus for soiling, biofilm formation and recontamination of the item in use. Deposits may seriously impair the utility of the Endoscope, particularly the optical system. Hard water may cause scaling on the edges of spray nozzles even when fed with only cold water. Many detergents and disinfectants are seriously impaired in their activity by hard water and sequestering agents may be required to prevent inactivation of these chemicals.

Table 4: EWD Water Hardness Requirements

Application	Requirements
Initial flush	Hardness less than 200 mg/L preferably 50 mg/L CaCO3
Intermediate flush	Hardness less than 200 mg/L preferably 50mg/L CaCO3
Water for diluting disinfectants and detergents	Hardness less than 50 mg/L CaCO3
Final rinse-water	Hardness less than 50mg/L CaCO3
Note: If any of the above parameters for the final rinse-water are above the stated limits, additional water analysis will be required to determine the source of the problem (for example, pH, chloride, heavy metals etc.).	

Temperature

The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process. Water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to "fix" proteinaceous soil to the surface of the load items. The inflowing water should be maintained at a temperature low enough to preclude the occurrence of protein coagulation.

The activity rate of chemical disinfectants generally increases with increased temperature.

Water at too low a temperature during the washing stage of the cycle will often impair the ability of detergents used, to remove soils composed of fats, oils or grease, and will cause failure to achieve the required microbial inactivation. However, too high a temperature with particular compounds can lead to degradation of the active components, evolution of toxic vapours or damage to the Endoscopes being processed. The maximum temperature of rinse-water should be compatible with the items being processed; flexible Endoscopes are temperature-sensitive and may be damaged by temperatures above 60ºC.

pH

The relative acidic or alkaline level of a solution is measured by pH. The pH is a measure of hydrogen ion concentration in the water. A pH of less than 7.0 is acidic and a pH of more than 7.0 is alkaline. The pH for a washer-disinfector should be between 5.5 and 8.0, any outlining values may indicate deterioration of the water quality or the presence of residual detergent or disinfectant.

Ionic Contaminants

Ionic contaminants in the water may react with materials such as stainless steel, causing discoloration and may result in damage to equipment including Endoscopes. Ionic contaminants such as silicates, phosphates, heavy metals and iron (ferrous iron compounds) may encourage corrosion and or deterioration of Endoscope components. Maximum guidance levels are shown in Table 5.

Ionic contaminants conduct electricity, because pure water has a high resistance to electrical current, the measurement of electrical conductivity can provide an assessment of ionic concentration. There may be organic components or suspended solids that contribute to conductivity levels. Conductivity is described in microsemiens and is measured by a conductivity meter and probes. In Endoscope decontamination, the guideline limit for conductivity is no greater than 30 microsemiens.

Table 5: Design Requirements for Water Quality: Final Rinse and Process Water .

Determinant and Unit Maximum Permitted Values		
	Final rinse	**Other stages**
Appearance	Clear, colourless	
Degree of acidity (pH)	5.5 to 8.0	
Conductivity at 25ºC (uS/cm)	30	
Total dissolved solids (mg/100 mL)	4	
Total hardness, CaCO3 (mg/L)	50	200
Chloride, Cl (mg/L) 10 120	10	120
Heavy metals, determined as Lead, Pb (mg/L)	10	
Iron, Fe (mg/L)	2	
Phosphate, P2O5 (mg/L)	0.2	
Silicate, SiO2 (mg/L)	0.2	
Total organic carbon (mg/L)	1.0	
Total viable count (TVC) at 30ºC	<10	
Bacterial endotoxins (EU/mL)	0.25	

Chlorides

Chloride concentrations greater than 240 mg/L can cause corrosion pitting of some stainless steel and plastic components water used in the cleaning and disinfection of flexible Endoscopes should have a chloride concentration between 0 and 120 mg/L chlorine.

Water used for the final rinse should have a chlorine level no higher than 10 mg/L. Chlorine levels exceeding this level should be reduced using a carbon filter.

Conductivity

A measure of the ionic contamination of water can be gained by the measurement of conductivity (Table 5). If it is suspected that specific chemicals may be present in the water source, at a concentration that could be detrimental to the process, specific tests for individual chemical compounds can be carried out. The limit for conductivity should be less than 30us/cm.

Total Dissolved Solids (TDS)

Although there is an association between conductivity and total dissolved solids the relationship is not necessarily direct. TDS gives a measure of total contaminants in the water (dissolved and suspended solids) and elevated concentrations may provide indication of contaminants other than those described in Table 5.

Total Organic Carbon (TOC)

The presence of high concentrations of Total Organic Carbon (TOC) in the water may cause a reduction in the efficacy of detergents and disinfectants, cause foaming of detergents and promote of growth of microorganisms.

Organic material may be introduced to the water at point of supply from the national water distribution and local pipework systems. In addition, the presence of biofilm in pipework, storage tanks and point of use filters may contribute to the organic loading of the water supply. Therefore, a TOC test at commissioning and installation can provide a useful guide to the quality of the final rinse-water:

- A maximum TOC concentration of 1 mg/L is acceptable.

If the EWDs self-disinfection cycle is demonstrated to be effective (for example by TVC monitoring), TOC testing will not be required.

Microbial Contamination

The purpose of the decontamination process is to remove soiling and reduce the microbial contamination to an acceptable level for the intended use of the items to be processed. The nature and extent of the microbial contamination in the final rinse-water should not present a potential hazard to the patient, either through infection or by leading to an erroneous diagnosis.

The microbial population in the water used in the Endoscope Washer-Disinfector, particularly in the final rinse stage of the process cycle should not increase the bioburden of the load items.

(***Note:*** *Sample tests for these parameters should be taken from the aseptic sample point on the RO loop prior to the EWD and the final rinse-water taken from the EWD chambers or bowls)*

Microbial Contamination – *Pseudomonas aeruginosa*

Pseudomonas aeruginosa is ubiquitous to water, readily forms biofilm and is a potential secondary pathogen particularly in immunocompromised patents.

Water treatment plant shall be designed to supply water with no *Pseudomonas aeruginosa* detected in a 100 ml sample.

Microbial Contamination – Environmental Mycobacteria

Final rinse residual water may be present on instruments used to take tissue samples. If this water is contaminated with environmental mycobacteria, these organisms will appear similar to *Mycobacterium tuberculosis* and may lead to misdiagnosis.

Other mycobacteria that occur in water, for example *Mycobacterium kansasii* and *Mycobacterium chelonae*, are opportunistic pathogens. Testing should be carried out in a suitably accredited laboratory.

Water treatment plant shall be designed to supply water with no environmental mycobacteria detected in the 100 ml sample.

Bacterial Endotoxins

Bacterial endotoxins are thermostable toxic compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse effects. They are not readily inactivated by chemicals or removed by bacteria-retentive filters. Control of endotoxin exposure is important to patient outcomes and the care experience.

Water treatment plants intended to be used for EWDs shall be designed to supply water with endotoxin levels of less than 0.25 endotoxin unites/ml and routine testing is required.

Water Treatment Plant

The nature and extent of treatment will depend in part on the quality of the local water supply. Therefore when a new installation is being planned, analysis of the water supply will provide a useful guide for the plant and equipment required to treat the water and may include a water softener.

The contractor should provide evidence of the quality of the supply water and justify the required water treatment plant, prior to installation and provide, as part of the maintenance regime, details of ongoing sampling to confirm water treatment systems are operating to specification. This will include the water treatment system storage and downstream pipework which should be designed to allow for adequate disinfection and prevention of microbial colonisation i.e. thermal disinfection which is the preferred HSE option.

Water Softeners, or "Base-exchange" (ion exchange) Softeners.

Water softeners consist of an ion exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. Water softeners are prone to bacterial colonisation and may significantly increase the planktonic (free) bacterial counts.

Water softeners are simple to operate with an automated in-line system and will handle water with varying levels of hardness, and are safe to regenerate. After regeneration, however, high levels of chloride ions may be present in the initial output from the softener. Mechanisms should be in place to ensure water softeners are sanitised on a regular basis.

Reverse Osmosis (RO)

RO treatment plants remove almost all (95%) dissolved inorganic contaminants (chemical contaminants) by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will also remove a high proportion of organic material, bacterial endotoxins and microorganisms.

Reverse Osmosis (RO) usually requires a carbon filter to be fitted ahead of the RO unit to remove traces of chlorine from the mains water supply. Pre-filtration to remove larger particulate matter may be required up stream.

Measures are required to maintain the microbial quality of water during storage and distribution. The retention of this water quality requires a high level of understanding and maintenance. The microbial quality of the water can deteriorate following storage due to the proliferation of bacterial species. Appropriate measures to minimise risk include:

- A continuous recirculation water system;
- water filtration, e.g. through a 0.03 micron UF filter to remove microbial contaminants and endotoxins;
- treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited and regular disinfection of the loop tank and pipework and by the use of UV irradiation (wavelength 254nm).

The RO system and associated pipework need to be sanitised regularly and routine maintenance and membrane replacement need to be undertaken periodically. Additional water treatment may be required depending on the quality of the mains water supply. Other requirements include:

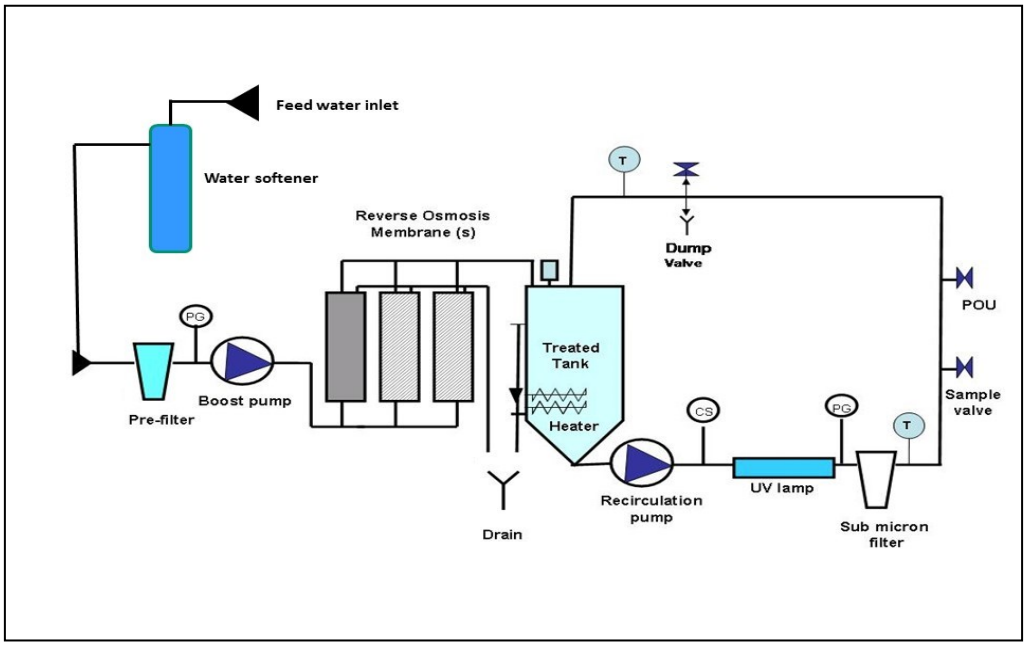
- The installation of Duplex RO systems capable of delivering water of the quality recommended in this document and being thermally sanitised at temperatures above 80°C whilst achieving an A0 value of 600 throughout the system are required for water treatment. Redundancy relating to pumps on the pre-treatment plan are also recommended;
- aseptic sample points should be installed on the RO pipework ring after the plant and on the return before the RO plant;
- RO specialist to provide warranty details, service and maintenance requirements.

Pipework Water Supply and Distribution

The design of the pipework, tanks and sanitary fittings should avoid dead-legs. The pipework used to supply the water should be designed to minimise the risk of microbial growth and appropriate to the quality of water carried in the system. The preferred option for RO systems is orbitally welded 316 stainless steel or cleanPEX piping. Fittings and pipe connectors used to deliver the final rinse-water should have minimal dead space, capable of resisting frequent disinfection and capable of withstanding temperatures of 80 degrees Celsius and above, required when thermally disinfecting the RO loop and pipework.

- All pipe work should be installed with a continuous fall towards the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.
- Regular disinfection of the storage and distribution system should be undertaken and the efficacy of such control procedures should be subject to microbiological testing.
- If a bacterial count is obtained from test water the identification of bacterial species is advised and the results presented to the Microbiologist or Infection Prevention and Control team for consideration.
- This information may aid identification of the contamination source and assist with any subsequent advice.

Figure 9: Example of RO Plant Supplying EDU



Filtration

When water is treated by filtration (for example, through a 0.22 µm filter to remove microbial contaminants), rigorous controls are needed to ensure that the system works effectively. This should include:

- Maintain the pressure drop across the filter throughout its working life—a decrease in differential pressure being cause for rejection of the process cycle and a change of filter. In the event of concerns in this area, a service agent should be consulted;
- a continuous recirculation system for RO water supplies. For a bank of filters, intermittent chemical disinfection is appropriate to prevent a bioburden build-up; or
- treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited either by use of elevated temperature (for example, greater than 60ºC), filtration through a suitable fine filter or by ultraviolet irradiation (wavelength 260 ± 10 nm; >2 J/m2) or chemical biocide.

Biofilms

As a survival strategy, bacteria, algae, fungi and protozoa, found free floating or swimming in water, will attach to both inert and living surfaces. Adhering to the surface the microorganisms produce an extracellular polysaccharide (i.e. slime) in which the organisms become imbedded. As the biofilm develops the aggregation of organisms and extracellular polysaccahide provides protection against physical and chemical treatment. As the biofilm matures bacteria may be sloughed from their surface and rapidly populate surfaces downstream of the original biofilm.

Traditional chemical and physical treatments may only remove or kill part of the biofilm. The remaining biofilm will quickly recover and the surfaces will become repopulated. Biofilms found in water storage tanks, water distribution network pipes and associated equipment including valves, pumps, particulate filters, water softening resins and carbon filter matrices or in EWDs, can act as a source of potentially pathogenic bacteria.

Even in well maintained water systems, the quality of the water can deteriorate rapidly due to the formation of biofilm and subsequent release of bacteria into the water supply. The development of biofilm, containing opportunistic pathogens (i.e. *Pseudomonas aeruginosa)* , has been implicated in numerous reported cases of infection. (HPSC, 2014).

Pseudomonas aeruginosa is the most commonly reported organism responsible for transmission of infection during endoscopy. Nelson (2006) identified that Pseudomonas infections resulting from an Endoscope procedure were most commonly related to inadequate cleaning of the Endoscope, the use of inadequate disinfectants or colonization of the water supply used to decontaminate the Endoscope. The ability of bacteria to form biofilms in the internal Endoscope channels can contribute to failure of the decontamination process. Once established, the removal of biofilm from the internal surfaces of small diameter tubing within Endoscopes presents a difficult challenge, due to poor access and the chemical sensitivity of the many surfaces within these complex instruments. (Kovela et al., 2013).

Biofilm formation in Endoscope channels, resulting from a failure in the cleaning and disinfection stages of the decontamination process, can create a cycle of growth, disinfection, partial killing or inhibition and regrowth of a biofilm. Patients who undergo Endoscope interventions with a biofilm-containing Endoscope are at risk from an Endoscope related infection.

Biofilm Prevention

The propensity for growth of biofilms in water systems has a significant impact on the quality of water supplied to decontaminate Endoscopes and thus may impact on patient outcomes.

Biofilm can form in the crevices of valves and pipe junctions and particularly plastic. Therefore, the inside of an EWD should have no dead spaces where biofilm can form. A delay in delivery of an EWD after manufacture and testing will allow biofilm to form within the machine. This may require the replacement of all the flexible pipework when first commissioned to allow the bacterial count in the final rinse-water to pass.

All EDU Design teams must consider the installation of RO systems which have a Hot RO loop. This system when appropriately managed will minimise the risk of biofilm formation. The use of cold RO systems require regular chemical sanitisation, with biofilm build up a constant concern. The literature identifies that once biofilm builds up in a cold RO pipework system, that regular change in chemicals used, may be necessary to combat biofilm resistance to disinfectants. The current HSE tender specification, for purchase of RO systems for EDUs requires the instillation of a hot RO loop.

(***Note**: All EWDs must run at least once a day, using at minimum, the self-disinfect cycle to prevent bio-film formation in pipe work and internal circulation systems. This factor must be considered during the period between installation and hand over.*

As there is a gap between installation commissioning of Endoscope decontamination equipment and hand over to the user (e.g. whilst waiting for Environmental *Mycobacterium water results) the hospital and the equipment supplier must ensure that during the "waiting time" all EWDs are run on a daily Monday to Friday basis. Weekly water samples must be taken from each sampling point on a weekly basis during this waiting time)*

Additional Water Supply Considerations

- In areas where high levels of silicate exist which are not adequately filtered by the RO system, consideration should be given to installing a twin pass system if the silicate levels regularly exceed maximum levels identified in Table 5. Consideration may be given to regular replacement of RO membrane as a less expensive alternative. Advice should be sought from AED and RO supplier.
- Volumes of water used for each phase of the EWD cycle need to be identified and the number of cycles for each machine to be run on a daily basis will provide the RO supplier with the information to calculate the RO make up requirements. Maximum demand at any one time, i.e. all machines running needs to be calculated.
- How many water inlets are required by the EWD manufacturer. Is a boiler needed to heat water?
- Additional contingency should be built into the RO capacity if activity/demand is projected to increase.
- RO sample points must be easily accessed at the point of use, with sample points installed along the RO loop, pre and post tank, post softener etc.
- Identify the location of the water treatment plant. The plant must be located external to the decontamination working rooms.
- Maintenance and breakdown regimes need to be considered.
- A data logger on the hot RO system must record at minimum, conductivity, time, date temperature of each thermal sanitisation process.

(***Note:*** *Best practice in terms of overall management of the decontamination lifecycle is that data is collected from the Hot RO loop via a data logger and networked to the PC in the decontamination room, where it can be downloaded reviewed, and saved to the organisations server, providing evidence to the user that the sanitisation process has taken place)*

Drainage

The position of drains in the floor of a room will, to a degree, dictate where the EWDs can be sited. Therefore it is important to establish the ideal position for the EWDs at an early stage of design to allow the drains to be sited correctly. To move drains can be a major problem, so care in their position is important. Drainage should not be run in ceiling voids over the 'clean' and 'dirty' area. It is preferable to locate such services that require routine access for maintenance within plant-room space or corridor ceiling void.

The discharge of soil from EWDs should be regarded as being no more, but no less, hazardous than the discharge from any other sanitary appliance (for example, a WC). The discharge of process chemicals, including detergents and disinfectants, may require special attention. The local water company should be consulted before such chemicals are discharged into the drainage system, as it may be necessary to neutralise or inactivate them before discharge.

In considering drainage of EWDs the following should be noted:

1. The maximum flow of effluent to the drain;
2. The maximum temperature of the effluent on leaving the EWD. If thermal self-disinfection is used, the discharge temperature from a EWD may be as high as 85ºC. The materials used for the construction of the discharge system should be chosen to withstand temperatures up to 100ºC;
3. The maximum effective diameter of the discharge orifice from the EWD chamber;

Effluent from EWDs should pass via an air break into a tundish or tank before being discharged to drain (or by the inclusion of a check valve and a vacuum breaker). The air break should be preserved at all times to prevent the EWD and its associated pipework being contaminated by reverse flow from the drainage system. When a tank supplies water to a pump on the EWD, the overflow discharge from the tank should also include an air break.

A sealed and vented drain may need to be used for the discharge of chemicals with a significant vapour pressure – determined at the maximum attainable temperature of effluent in the drain – which may be hazardous to health or a nuisance. The manufacturer of the EWD and the chemical should be consulted on this issue. In all cases the discharge of toxic gases from the drain system and toxic gases being liberated into the atmosphere into the work area should be avoided.

The drainage system from the installation should be trapped and designed to pass the flow-rate of water, air or condensed steam specified by the manufacturer, with account taken of the peak output during the operating cycle. The drain system will need to withstand the action of chemicals used in the EWD process. RO water used in the final rinse stage may also corrode some materials.

4. Physical and Environmental Hygiene and Safety

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.

Features of a service meeting this HIQA Standard include:

2.6.1 A physical healthcare environment that is planned, designed, developed and maintained to facilitate effective cleaning and compliance with Infection Prevention and Control best practice.

2.6.5 Arrangements and documented specifications are in place for cleaning and disinfection of the physical environment, in line with best practice guidance.

Environmental Control

Decontamination facilities are designed, constructed, maintained and controlled to provide effective segregation of 'clean' and 'dirty' activities. This design provides an environment that minimises the risk of adventitious contamination of clean and disinfected Endoscopes. The facility must decide how dirty Endoscopes are to enter the decontamination room and how clean Endoscopes are returned to the User without possible contamination transfer.

Other Design Requirements:

- The department must be designed so that it is physically separate from all other work areas and is not part of any service user treatment area;
- the department must not be used for any other purpose or used as a thoroughfare. Entry to the EDU must be restricted to authorised personnel only;
- a changing area for donning work wear which includes shower facilities, toilet facilities and lockers, in proximity to the decontamination area, must be provided, with access to the wash room and clean room through a separate dedicated gowning room provided with hand hygiene facilities;
- positive pressure air-lock lobbies with interlocking doors must be provided at the entry and exit points to the decontamination room and clean side/sterile store. A dedicated entrance/exit lobby is required for staff entering/or leaving the department. This entrance/exit lobby must be separate to the equipment entrance /exit pathway;
- staff movement between dirty and clean areas must not possible without passing through a clothing change and hand wash area;

- the wash room and clean room must be free from “opening” windows, ledges and uncleanable areas;
- the wash room and clean room must be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation equipment, building finishes etc.);
- surfaces in contact with Endoscopes and their components or those likely to be contaminated should be impervious, easily cleaned and be able to withstand disinfection;
- the finishes on the walls and other surfaces must be flush, smooth, non-linting, non-porous, water resistant and able to withstand frequent cleaning;
- the junction between walls and floors must be coved and flush;
- the fitments where possible must be flush with wall surfaces;
- floors must be covered in a washable non-slip material which is securely sealed;
- all work surfaces, fittings, fixtures and furniture must be made of easily cleanable non-porous robust material that will withstand regular cleaning and disinfection regimes;
- the workstations must be of adequate size and are equipped for the preparation and inspection of all Endoscope types and are height adjustable where possible. There must be adequate space between workstations for equipment and staff movement;
- the shelving in storage facilities must be manufactured from non-shedding material, easily cleanable and with a smooth surface that will not damage packaging;
- the shelving must be of sufficient depth for all the materials to be held and must not be more than two meters high, unless special provision is made for loading and un-loading higher shelves;
- there must be adequate lighting to permit good working practices and visual examination of Endoscopes and adequate task lighting and magnification for inspection of Endoscopes;
- the lighting in the EDU should be of good quality (750 lux);
- dedicated cleaning provision (both equipment and storage) must be provided for both the wash room and the clean room.

Storage Facilities

Safe storage facilities must be provided for process chemicals used to decontaminate Endoscopes. Chemical storage must be provided external to the working areas in the decontamination facility. Guidance for provision of appropriate chemical storage must be sought from the hospital appointed Dangerous Goods Advisor, Health & Safety Officer, supplier/manufacture of the chemicals to be used and associated chemical safety data sheets, during the design phase.

- The storage area is required to house a chemical spillage kit that is suitable for use in EDUs. This spillage kit should contain as a minimum the following components:
  - absorbent granules/powder, to absorb liquid spills,
  - absorbent containment sausage/sock, to contain liquid spills,
  - absorbent sheets and plastic spill proof disposable bag and,
  - plastic apron, gauntlets and respirator/mask.

(***Note:*** *Staff working in the area must have access to a respirator which has been fit tested for each individual working in the area, if deemed necessary by the Health & Safety Officer, Dangerous Goods Advisor or chemical supplier*)

Other considerations for storage include:

- Facilities for Endoscope transport trollies for 'clean' and 'dirty' areas;
- facilities for bulk items external to the wash room, and clean room;
- facilities for reprocessed Endoscopes and accessories prior to dispatch;
- storage for Personal Protective Equipment (PPE) and easily accessible in each of the work areas;
- storage for Endoscope connectors and connector sets used in the wash room (Figure10) and;
- storage for Endoscope protective cases and Endoscope transport carts must be considered as these items require considerable storage space.

Figure 10: Example of Connector Set Storage

Endoscope Wash Room Sinks

A stainless steel double sink designed to wash flexible Endoscopes and accessories is required in the EDU washroom. Care should be taken to ensure that an ergonomic assessment is undertaken and that the protection of the health and safety of staff/operatives of variable stature or height is considered. A specification for variable height sinks is available from HSE Decontamination Procurement (where variable height sinks are used, the possibility of trapping hazards should be recognised and appropriately controlled.

Requirements for wash room sinks include:

- There should be two separate sink bowls in each height adjustable sink unit, one for washing and one for rinsing the washed Endoscopes and accessories;
- the sink should be of sufficient size to permit immersion of the Endoscopes with adequate put down spaces along side and between the sinks;
- the units should be constructed with a 320 grit polish on 316 stainless steel to EN 14401 standard; have raised edges to the front and side and a up-stand to the rear to ensure liquids are contained. The sink unit should have a 300mm high splash back;
- the drainers on each side of the bowls need to be constructed to allow free drainage of all liquids from the drainer into the bowls to prevent pooling of water on the drainers; the unit should have the option of a leak tester shelf;
- the bowls must have a minimum depth of 200mm. Each bowl must be fitted with a waste outlet, located at opposite sides of the bowls to allow for the insertion of independent traps to prevent back flow of contaminated water into the rinse sink. The base of the bowls must be tapered towards the waste outlet to ensure complete drainage of all liquids;
- each sink bowl must have a pair of pillar, hot and cold, lever control mixer taps with a central swivelling spout which can rotate up to 180 degrees (the mixing taps must be equipped with long adjusting arm);
- the units are to be designed to take a chemical dosage pump fitted to the sink which can be calibrated to deliver one shot of the chemical and a means of monitoring the temperature of liquids in the sink;
- the bowls must be supplied with a high level weir overflow stand pipe and be clearly labelled in litre measurements to suit the bowl volume so that the operator is able to measure the quantity of liquids in the bowls;
- consideration should be given to the provision of dedicated sink units for cleaning and disinfection of Endoscope transport trays. This unit does not need to be height adjustable.

(***Note***: *Sinks used for manual cleaning should be supplied with water directly from the main supply if possible. Tank water can often be contaminated and the cleaned Endoscopes will then contain bioburden from retained water. Branches and dead legs in the supply system will also allow biofilm to form in the pipes. The use of jet washers is discouraged)*

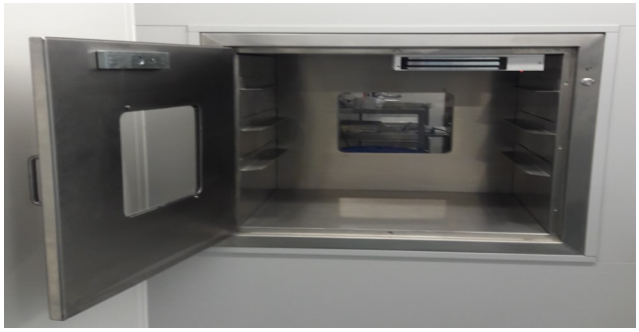
Figure 11: Example of a Stainless Steel Sink

Stainless Steel Pass-through Hatches

A pass-through hatch may be required by the EDU, the HSE have a specification to support the design process:

- The pass-through hatch must have a door interlock system so that only one side can be opened at one time;
- the hatch should be constructed using 320 grit polished over 316 stainless steel to EN 14401 standard;
- there should be no inaccessible recesses, rough surfaces or connections, projections, sharp edges, unnecessary joints or exposed threads etc. which may retain dirt, snag cleaners hands or equipment;
- the doors must have 10mm toughened glass door with stainless steel frame with pivot hinge;
- the doors should be mechanically interlocked and close against magnets or solenoids;
- the hatches are to be supplied with installation flanges to secure them in the wall and be fitted flush on the washroom side and protruding on the clean side if necessary;
- the option of an integrated buzzer or intercom system should be considered.

Figure 12: Example of Pass through Hatch



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Appendix I: Acknowledgements

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