NHS National Services Scotland

Decontamination Facilities

Scottish Health Planning Note 13

part 3 - Endoscope Decontamination Units (EDUs) in NHSScotland

SHPN 13 part 3

Draft 1.2 - July 2024

Contents

Disclaimer

The contents of this document are provided by way of general guidance only at the time of its publication. Any party making any use thereof or placing any reliance thereon shall do so only upon exercise of that party's own judgement as to the adequacy of the contents in the particular circumstances of its use and application. No warranty is given as to the accuracy, relevance or completeness of the contents of this document and Health Facilities Scotland, a part of NHS National Services Scotland (NSS), shall have no responsibility for any errors in or omissions there from, or any use made of, or reliance placed upon, any of the contents of this document.

Executive Summary

This Scottish Health Planning Note (SHPN) 13 Part 3 provides guidance to help plan and design a new or an upgrade to an Endoscope Decontamination Unit (EDU) processing flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes ready for next use on patients.

This SHPN is a full technical revision of the first version produced in 2010. Main changes include consideration of the new best practice decontamination guidance Scottish Health Technical Memorandum (SHTM) 01-06 v1: 2023 series, new processing and equipment standards, increased detail on business case stages, lessons learned in EDU build projects, stakeholders' enquiries, sustainability matters, and the Post Occupancy Evaluation (POE).

Four layouts of an EDU department are outlined. The preferred options for new builds or upgrades are:

- for small/ medium sized units adjacent to clinical units the two room endoscope decontamination unit with ante rooms
- for centralised services, the two room endoscope decontamination unit with ante and other support rooms

The option appraisal exercise should determine which model is appropriate. This guidance outlines the two interconnected workstreams that require to be resourced and controlled over the project of delivering a new/ upgraded EDU. The Validation Master Plan (VMP) identifies the activities in the validation workstream and the build workstream includes the business case stages, construction, procurement, and handover. The User Requirement Brief (URB), required at the start of the project, provides input to both workstreams, and is used to inform any bidders and the chosen principal contractor.

The Design Qualification (DQ) report for the facility and its site should be completed and approved by the Health Board before commencement of the construction and procurement stages. Over the construction phase there should be verification activities including Installation and Operational Qualifications (IQ/ OQ).

The Performance Qualification (PQ) of the facility is conducted after the handover from the principal contractor.

After start-up, routine production and maintenance of the facility and its service to Users is described in this guidance.

A substantial definitions section is included in this guidance.

1. Introduction

Scope and purpose

1.1. As is standard with best practice guidance it is not intended to be applied retrospectively. It provides guidance to help planners, estates and facilities managers, Endoscope Decontamination Unit (EDU) managers, capital planning and design teams to plan and design an EDU. Scottish Health Planning Note (SHPN 13) Part 3 should be cited in each stage of any business case and used throughout the design/ construction/ start up and operation of an EDU. The SHPN is cited within GUID 5013 v3 the Compliance Requirements for EDUs published by Health Facilities Scotland (HFS) in 2024. Version 1 of SHPN 13 part 3 published by HFS in 2010 is superseded. The best practice guidance Scottish Health Technical Memorandum (SHTM) 01-06 'Decontamination of flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units (EDU)' was first published in 2023. It introduced decontamination requirements for a range of decontamination equipment over its five part series.

1.2. The SHTM 01-06 v1: 2023 series comprises of five parts with the following titles:

- part A - management
- part B - general requirements for decontamination equipment and test equipment provision
- part C - dry and wet leak testers and manual clean flushing unit equipment
- part D - automated endoscope washer disinfectors (EWDs)
- part E - storage cabinets and packing systems for containment of disinfected endoscopes

1.3. This SHPN contains information on the building and operating principles for four main models of Endoscope Decontamination Units where both lumen and non-lumen flexible heat-labile endoscopes and TOE ultrasound probes are decontaminated (including non-lumen nasendoscopes used in examination clinics). The four models (see Appendix A to D) follow.

1.4. For centralised services:

- two room endoscope decontamination unit with ante and other support rooms

1.5. For small/ medium sized units adjacent to clinical units:

- two room endoscope decontamination unit with ante rooms
- two room endoscope decontamination unit
- single room endoscope decontamination unit

1.6. These facilities produce product (processed endoscopes) for a range of specialities (see Table 1.1) and some TOE ultrasound probes where applicable as manufacturer's instructions.

Table 1.1 - Endoscopes and their associated clinical specialities

Endoscope	Speciality
Bronchoscope	Respiratory
Colonoscope	Gastroenterology
Cystoscope	Urology
Cystoscope Ureteroscope	Urology-urethra and bladder
Duodenoscope	Gastroenterology/ Hepatobiliary
Endoscopic ultrasound	Respiratory/ Gastroenterology
Flexible sigmoidoscope	Gastroenterology
Gastroscope	Gastroenterology
Hysteroscope	Gynaecology
Intubating bronchoscope	Anaesthetics
Laryngoscope	Ear, Nose and Throat
Nasendoscope	Ear, Nose and Throat
Small bowel enteroscope	Gastroenterology
Choledochoscope	Sterile - General surgery
Cystoscope	Sterile - when used for examination or treatment other than the Urethra and Bladder Sterile
Neuroscope Sterile	General Surgery Neurosurgery
Thoracoscope	Sterile - General surgery
Cysto-nephroscope	Sterile - Urology- surgical treatment of kidney

Not in scope

1.7. This SHPN does not specify the space requirements for an EDU to deliver a given production throughput. Capacity planning and the option appraisal exercise have not been addressed in detail in this version of the document. Throughput calculations taking account of current, and any future needs will be required in order that the size of the facility can be determined. Currently, different manufacturers' EWDs have considerable differences in overall cycle time. A detailed study of machine throughput is key to the size of the EDU and the inventory of endoscopes required to meet clinical needs

New considerations in this first revision

1.8. New considerations since the previous version of this guidance are outlined below:

- use of the SHPN 13 part 3 version one guidance during new build projects (post project evaluation), new best practice decontamination guidance SHTM 01-06: 2023 series has been published, enquiry questions on the guidance, incidents and lessons learned have all provided some input to inform this revision. Quality control of documentation is addressed in detail to aid design control throughout the project. Some new definitions are introduced for clarity purposes
- sustainability matters have become of major importance further to the announcement of the climate emergency. Sustainable design and construction guidance, Scottish Health Technical Note (SHTN) 02-01: 2021 is considered in this guidance.
- URB and subsequent DQ
- a large range of standards have been revised/ released since 2010 and these are considered in this guidance as applicable
- inclusion of the requirement for Post Occupancy Evaluation (POE)

Background

1.9. This SHPN provides information to assist individuals and organisations make informed decisions on the provision of endoscope decontamination services.

1.10. The Sterile Services Provision Review Group in 2003 established that there was a lack of guidance on the provision of endoscopy decontamination facilities. An interim guidance document 'Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management'- Health Protection Scotland, was prepared and made available to the service in December 2004. This was replaced by the best practice guidance SHTM 01-06 'Decontamination of flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units (EDU)' published in 2023.

1.11. Endoscopes and their accessories are classified as medical devices under the 2002 Medical Devices Regulation S.I. 2002 no. 618 and the Medical Devices (Amendment) (Great Britain) Regulations statutory instrument 2023 no. 627 with the requirements:

- devices and manufacturing processes should be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties
- devices should be designed, manufactured, and packed in such a way to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage, and use of the devices and to the patients

Legislation, compliance requirements and guidance

Primary legislation

1.12. The Medicines and Medical Devices Act 2021 came into effect in 2021. This established a GB market as opposed to a UK market for medical devices.

Secondary legislation

1.13. The Medical Devices (Amendment) (Great Britain) Regulations statutory instrument 2023 no. 627 became effective in July 2023. This modified the 2002 medical device regulation statutory instrument 2002 no. 618.

Compliance publication

1.14. The HFS compliance document GUID 5013 v3: 2024 sets the technical requirements for EDUs to follow.

Guidance

1.15. The best practice guidance SHTM 01-06 v1: 2023 five part series covers decontamination in the EDU focussing on the decontamination equipment.

2. Planning - Business case stages and the Validation Master Plan (VMP)

2.1. An important point to grasp is that the various stages within the business case development can take several years to complete and be approved. Those involved in its development may not be around at later stages of the project such as during the construction stage. At the time of publication in 2024 there had been very few EDUs built in the previous ten years. Based on those that had been built in that timeframe indicated some four to five years are required from the development of Initial Assessment (IA) business case through to validating the performance of a new facility as satisfactory. There have been discussions about use of certain construction methods, such as modular construction, which may allow improvements in build timelines. New factors now require to be considered in planning. Supply chain issues are now more significant. Excessively long lead times on components during the construction stage of build projects have resulted in design changes during construction with the resultant considerable additional workload/costs of managing change control late on in a project.

2.2. Each of the business case stages can involve multiple meetings as well as workshops with associated preparation time for/ from each. Some of the project teams may be dedicated/ contractors but others will be operational mangers running an existing service while expected to contribute time to all these stages.

2.3. The Scottish Capital Investment Manual (SCIM) outlines a number of stages in business case progression. "…*processes and techniques to be applied in the development of all infrastructure and investment programmes and projects within NHSScotland*." The principles set out in SCIM are applicable to the development of all infrastructure and investment schemes regardless of their size or complexity and should be applied by all NHSScotland Bodies.

2.4. Scrutiny of the business case stages should be conducted by the National Design Assessment Panel (NDAP) facilitated by Health Facilities Scotland (HFS)/ NHSScotland Assure and its Principal Architects. The NDAP reviews are provided to the government.

NHSScotland Design Assessment Process (NDAP)

2.5. NHSScotland NDAP has been an integral part of the SCIM since the 1 July 2010.

2.6. NDAP support commences at the end of Initial Assessment (IA) and runs through-out Outline Business Case (OBC) and Final Business Case (FBC) stages. Board/ Client submits their business case to Capital Investment Group (CIG) only following appropriate consideration of the formal NDAP responses. CIG approval is conditional on the level of support verified in the formal NDAP report sent at OBC or FBC submission. Feedback at Project Monitoring and Evaluation should ensure continuous improvement.

2.7. The purpose of the NDAP is to promote design quality and the service outcomes realised through this. It does this by mapping design standards to the key investment deliverables plus Scottish Government objectives and expectations for public investment, then demonstrating their delivery via self, and independent, assessments. NDAP supports continuous investment improvement, through sharing design standards and learning from comparable projects, thus building upon the best of what has gone on before.

Achieving excellence design evaluation toolkit

2.8. The Achieving Excellence Design Evaluation Toolkit (AEDET) evaluates a design by posing a series of clear, non-technical statements, based on three key criteria: Functionality, Build Quality, and Impact. The use of a Design Quality Indicator Tool such as AEDET is a mandatory requirement of the NHSScotland NDAP under NHS Chief Executive Letter (CEL) 19 (2010) - A Policy on Design Quality for NHSScotland.

2.9. To satisfy SCIM, it is anticipated at least one AEDET workshop (depending on the scale and complexity of the project) should be held at the following key stages, and submitted via NDAP:

- use AEDET generic question set only
- IA - Target (and Benchmark) score(s)
- use combination of AEDET and project specific Design Statement (DS)
- OBC
- FBC, or Standard Business Case (SBC)
- Post Occupancy Evaluation (POE)

Key Stage Assurance Reviews (KSAR)

2.10. Government letter Director Letter (DL) (2023) 03 NHSScotland Assure: Key Stage Assurance Reviews (KSAR) - Commissioning and handover covers the commissioning, completion and handover part of the process and notifies that all building projects going through a KSAR, should not open to patients or the public until a ‘supported status’ is received from NHSScotland Assure. Project teams should liaise with their NHSScotland Assure KSAR team to ensure that their capital projects are completed satisfactorily to ensure that supported status is achieved. Any additional actions/ conditions included within the KSAR ‘supported status’ report for Commissioning and Handover should also be completed within agreed deadlines. Non-compliance with these requirements will deem the new facility as not appropriate for public/ patient occupation. When a supported status has been achieved, and the local NHS Board is content for the building to open, the Senior Responsible Officer should send a copy of the report to the Chair of the NHS Capital Investment Group for information.

Strategic assessment

2.11. This should:

- describe the scope of the new proposal
- inform government of the project
- gain consensus and support from stakeholders
- demonstrate priority over competing projects
- highlight service need and benefits

Programme initial agreement

2.12. In Feb 2024 via letter DL (2024) 02 NHSScotland: Whole System Infrastructure Planning replaced the requirement for IA to be submitted for individual capital investment projects. The new approach to strategic infrastructure planning and investment was via the PIA.

2.13. Each NHS Board requires to prepare and submit to government, a Programme Initial Agreement (PIA) which sets out a deliverable, whole-system service, and infrastructure change plan for the next 20 to 30 years. The PIA would also constitute the first step in the business case process, thus enabling individual capital investment projects to proceed straight to OBC stage, once agreed with government. SCIM requires that projects over 5 million pounds require a design statement to be included in the IA. Also, AEDET workshops are required at IA development stage.

2.14. NHS Boards were required to submit their Do Minimum Business Continuity Option to government by 31 January 2025. The preferred way forward stage within the PIA specifies that decontamination needs to be embedded into whole-system plans for change, with a clear indication of its local, regional, and national relevance.

Outline business case

2.15. The OBC requires several and different types of workshops to source information and make decisions on options.

2.16. The OBC should:

- confirm the status of the strategic case
- provide economic appraisal of alternative options for implementing the preferred strategic/ service solutions(s)
- identify a preferred and affordable option
- set out arrangements for delivering the preferred option and realising benefits
- confirm a readiness to proceed to procurement

2.17. Organisations can determine the most suitable means of providing decontamination services by undertaking an option appraisal exercise, whereby they quantify the required annual production throughput and where possible value the costs, benefits, risks, and uncertainties associated with each of the following options:

- procure a new build either within an existing hospital complex or outwith the hospital complex on a dedicated site
- upgrade existing facilities of an existing hospital building or outwith the hospital complex or obtain services from a third party

2.18. The User Requirement Brief (URB) should have been developed at this stage.

Final business case

2.19. The FBC should:

- confirm that management, commercial, funding, and financial arrangements are in place to deliver the project
- set out the contractual details of the project which the Board is being asked to sign-off
- identify and allocate resource for quality control checking of documentation both at design stage and construction stages where design changes may be required

2.20. The URB should have been agreed and signed off during/ on completion of the FBC.

2.21. During the final business case development, there should be a procurement process to select the construction company for the build. This may involve looking over different designs presented as part of the bidding process. The selected bidder is commonly referred to as the Principal Supply Chain Partner (PSCP). At the start of the project the procurement activities focus on the building and later there will be procurement processes to follow for decontamination equipment such as the washer-disinfectors and sterilizers.

2.22. NDAP support commences at the end of IA and runs through-out OBC and FBC stages. Board/ Client submits their Business case to CIG only following appropriate consideration of the formal NDAP responses. CIG approval is conditional on the level of support verified in the formal NDAP report sent at OBC or FBC submission.

Validation Master Plan

2.23. There should be a VMP for the project which will define the qualification exercises required for the Design Qualification (DQ), Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) of the facility. The DQ requires input by way of a clear URB that is prepared during the Business Case development. Ensuring compliance with the VMP, which is generated and approved by the design team, is critical to the delivery of an Endoscope Decontamination Unit (EDU) that is fit for its intended purpose.

The requirement for a VMP and the resulting resources required should be made clear to those responsible for producing the business case.

The user requirement brief and version control

2.24. The URB, which is part of the Validation Masterplan process should be prepared at an early stage in the business case stage (IA/ OBC). The URB should be agreed and signed off by relevant stakeholders at/on completion of the OBC.

2.25. It is likely that several iterations of the URB will be produced as progression through the OBC to FBC occurs. It may be that discussions with preferred bidders at FBC may result in modifications to the Users requirements. The version of the URB that is signed off by the health board for the appointed principal contractor to consider should be the version that is checked against the design prepared by the principal contractor. This is done at the DQ stage. The URB will be informed by engagement from a range of stakeholders. This should include clinical input as service users defining their expectations, the decontamination management and their expectations, senior management expectations and the board's Authorising Engineer (Decontamination) (AE(D)).

2.26. The URB should state it is a controlled document and should be managed as such in line with the EDU's quality management system (QMS). Change management should be included. The URB should state the requirement to follow the current version of guidance GUID 5013 (v3:2024) Requirements for compliant EDUs. This includes reference to the principal planning note Scottish Health Planning Note (SHPN) 13 Part 3: version 2 - 2024. An outline of the commitment of the EDU service and the level of service given to service users should be outlined.

2.27. URB details, addressing capacity and capability, should include and define:

- service strategy and service objectives
- the specialities to be provided for and the range of packaging systems to be accommodated, that is the range of thermolabile flexible endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes including the manufacturer's instruction for use
- the daily throughput required, and the annual throughput required
- the opening hours, expected number of shifts and number of staff
- the range of decontamination equipment/ furniture required
- the core production rooms and define the supporting rooms required
- any room being specified for use that is not in the planning note
- approach to duplexing of utilities
- other required infrastructure on the site external to the building
- an outline of allowances to be made for future increase in demand from service users

- an outline of whether/ or not there is to be allowance for a defined level of support to other boards during a contingency event.
- whether there is a preference to have the EDU and support areas all at ground level or leave for the bidders to interpret and provide design proposals
- flows for product - from receipt of soiled to dispatch of disinfected product including storage requirements
- flow of received raw materials and distribution within the facility as the process requires including storage requirements
- flow of staff
- flow of waste

2.28. In the case of a new build, the EDU should be built at ground level where possible. This is to assist with operational, construction and maintenance operations. The building design should be able to support the mechanical and electrical plant together with cable trays and trunking for cable support. If lifts are required to service, the EDU they should be dedicated.

2.29. A risk assessment should be carried out to inform the EDU design. This will include the consideration of the need for duplex systems.

2.30. The principle of designing in duplex systems and back-up systems for critical plant/ services to minimise production downtime should be considered. This should include water, Reverse Osmosis (RO) water, steam, electricity, compressed air, Heating Ventilation and Air Conditioning (HVAC), decontamination equipment and Information Technology (IT) systems.

Note 1: Systems have been sold as ‘duplex’ but still share common elements, for example control panels or storage tanks. The health organisation needs to carefully evaluate, and risk assess not only the security of supplies but also capacity, condition, and remaining life of the hospital services infrastructure.

2.31. There may be circumstances where it is desirable to have the processing capabilities provided by a Central Decontamination Unit (CDU) and an EDU within the same location in a hospital. For example, a limited staff resource where staff would be trained to work in both types of facilities and move between these as the workload demands.

Location of the EDU

2.32. When choosing the location of the EDU the following should be considered:

- availability of space
- distance from clinical units
- revenue and capital costs
- transport costs
- turnaround time

- inventory of endoscopes and their accessories
- quality and capacity of engineering services for example power, water, and drainage
- IT infrastructure
- personnel issues
- planning permission
- building warrant-environmental impact study
- fire certificate
- service development strategy
- fire precaution requirements
- safety policy
- structural survey
- potential for water leakage
- security and controlled access

2.33. When choosing the location of the EDU, consideration should be given to the long-term strategy for the service, EDU location, space required for the new service, and the size and condition of the building (if applicable). Regard should also be paid to the orientation and the aspect of the building. In addition, the following issues may be taken into consideration when determining the location:

- availability and cost of site/ premises
- site and site utility services are of sufficient size to accommodate the requirements of the EDU service
- consideration of risks to the service from an incident associated with local high risk areas such as railway lines or whisky bonds
- distance and travel routes from main users
- revenue and capital costs of providing and operating the facility
- transport requirements/ constraints (public transport availability)
- parking availability and vehicular access (including bulk tankers/ fire appliances) and effective delivery to and collection from the site
- turnaround time (including collection and delivery access to sites)
- instrument inventory
- quality, quantity and location of engineering services and technical support
- personnel issues, including proximity to local workforce
- security issues
- planning permission requirement
- customer base

- healthcare providers' strategies
- geographical and environmental constraints
- service and maintenance issues
- transport vehicle purchase and driver training

Service strategy considerations

2.34. The provision and maintenance of a compliant EDU is a significant, high cost and ongoing responsibility. The provision of an EDU should therefore only be considered following a detailed option appraisal. All aspects should be considered including costs, benefits, risks, uncertainties, and value for money.

2.35. When planning and designing an EDU there should be a clear understanding of the requirements. This includes the under noted information:

- operational policy
- process map
- throughput calculations (for decontamination equipment capacity)
- details of clinical activity (sessions per day, patients per session) and types of procedures performed
- required inventory of endoscopes and their accessories
- potential future demand
- consumable costs

2.36. Maintaining the delivery of a high quality decontamination service is of paramount importance. Anything that could affect quality, efficiency, and provision of clinical activity, should be considered, and addressed at the design stage. Examples of issues to be considered include:

- operational policy including contingency planning
- capacity requirements
- quality and reliability of utilities and building services
- acquisition, delivery, and storage of raw materials
- transport of clean/ disinfected items to the clinical area and/ or to the storage area
- return of used items for reprocessing
- equipment down time including maintenance and testing
- availability of staff trained in decontamination processes
- ongoing training needs and staff development

Service objectives

2.37. Before embarking on a design and development project for an EDU it is essential to have a clear understanding of the service objectives. These should be documented in a decontamination operational policy. Having established the principles, the formulation of a process map describing the flow of devices, staff, transport, waste, and consumables through the EDU will allow understanding of the stages within the process and the development of a design that is fit for purpose. These would include:

- decontamination to a level compatible with the intended use of the device such as high level disinfection
- minimisation of adventitious contamination through control of the environment and materials, products, coupled with appropriate staff training
- production of reprocessed devices that are fit for purpose
- ensuring that the decontamination process, or the way in which devices and process chemicals are handled and stored, has no adverse effect on the clinical environment, patients, staff, or other medical devices
- adequate throughput capacity provision to meet clinical need
- ensuring the EDU provides a high quality and cost-effective service
- providing adequate labelling for safe use. It should be clearly evident which devices are clean/ disinfected
- ensuring automated equipment is validated, maintained, and tested and the process is controlled and monitored
- generation and retention of maintenance records including equipment breakdown details to demonstrate compliance and traceability requirements

Service requirements

2.38. The HFS compliance document GUID 5013 v3: 2024 sets the technical requirements for EDUs to follow. This consists of requirements covering facilities, equipment, management, and process.

Options appraisal

2.39. The board should determine the most suitable means of providing decontamination services by undertaking an options appraisal exercise, whereby they quantify the required annual production throughput and where possible value the costs, benefits, risks, and uncertainties associated with each of the following options:

- procure a new build either within an existing hospital complex or outwith the hospital complex on a dedicated site
- upgrade existing facilities of an existing hospital building or outwith the hospital complex

2.40. Direct purchase or long term lease may prove an advantage in some circumstances.

2.41. The preferred options for new builds or upgrades are:

- for small/ medium sized units adjacent to clinical units the two room endoscope decontamination unit with ante rooms (see model layout shown in Appendix C)
- for centralised services, the two room endoscope decontamination unit with ante and other support rooms (see model layout shown in Appendix D)

2.42. The option appraisal exercise should determine which model is appropriate.

3. Planning - Assessing bidders and appointment of principal contractor

Assessing bidders

3.1. The various bidders should have reviewed the version controlled User Requirement Brief (URB) and produced their response to it. This may involve a number of passes and further requests for information to inform their return. Once finalised the returns from each bidder will be presented to the board for their consideration. The National Design Assessment Panel (NDAP) should review the returns and comment. There may be workshops used in order to facilitate this process. The Endoscope Decontamination Unit (EDU) manager should be involved in this exercise, which may take several months. Therefore, at the outset, arrangements should be made to ensure this is possible, allowing for the fact that the EDU Manager may already be responsible for managing and operating an existing decontamination service. Decontamination technical advisors should also be involved in these assessments.

Appointment of the principal contractor

3.2. The board should notify the principal contractor once the Final Business Case (FBC) submission has been given Capital Investment Group (CIG) approval. Once the principal contractor is selected, work should begin on working up the more detailed documents required for the project. The documentation will likely require multiple iterations before arriving at an agreed package at this stage in the process. Again, this will be a time demanding exercise for the EDU manager. The board's project management and the principal contractor should be made aware and acknowledge the validation requirements for the projects at the earliest opportunity. The board's designed person for validation of the project should have established contact at the start and maintain this throughout the project. All involved should be clear as to the handover process and the validation process. As some elements of the performance qualification are carried out when the facility starts up, all involved should be clear that the handover of the facility to the board does not indicate that facility is satisfactory and fit for purpose. The performance qualification is the method employed to confirm the facility meets requirements and is satisfactory for use.

4. Planning - Design qualification of the EDU and its site

The project team

4.1. Some of those involved in the business case stages will remain and be part of the project team engaged in the detailed design. The project team may comprise of the Endoscope Decontamination Unit (EDU) manager, a board project manager, construction company project manager, an architect, associated contractors Mechanical and Electrical, procurement staff, theatre manager, infection control, estates staff, technical advisors (decontamination) and Authorising Engineers Decontamination (AE(D)s). The identified roles should be maintained throughout the project and where possible handovers when new staff are introduced to the team.

The project meetings

4.2. Over the duration of a project there may be a range of sub groups established to focus and progress on specific work items such as technical groups, delivery groups and commissioning groups. Regardless of the name of the group(s) there will likely be several hundred meetings for the EDU manager to attend. An awareness of how this can be managed at the same time as running an existing service should be discussed at the User Requirement Brief (URB) stage. Consider seeking assistance from other boards' EDU managers.

Upgrades

4.3. The principles that apply to new builds should also be considered on upgrade projects.

4.4. A checklist of physical and other aspects of existing buildings should consider:

- the space available
- the type of construction used in the existing building
- the type of thermal and sound insulation in use
- the general condition of the building fabric
- the life expectancy and suitability of existing engineering services
- any changes to floor or ceiling heights
- fire safety
- locations of load bearing walls
- assessment of load bearing capability of floors

- the Disability Discrimination Act requirements

4.5. Having decided that an upgrade is the best option, the main requirement will be to assess how the facility can be adapted to best fit the design principles of the models presented. An upgrade project should of course address all current legislation. The upgrade work should minimise the disruption to existing services, with a clear segregation between construction work and the departmental operations. Dust and debris control with regular cleaning during and after completion of the building project is essential. Refer to Scottish Health Facility Note (SHFN) 30: part A Manual 2014 and part B Healthcare Associated Infection Systems for Controlling Risk in the Built Environment (HAI-Scribe): 2014 for further details regarding protection of sensitive areas during construction work.

Sizing the department

4.6. The size of an EDU and the site where it is located is based on the architect's interpretation of the requirements stated in the URB agreed before completion of the business case stages and addressing the design principles outlined in this guidance.

4.7. The URB should detail all the rooms required in the facility and also which rooms are not required. The architect should determine which of these rooms/ plant rooms are to be located at ground level, or at an upper level or whether some plant is located external to the EDU. The core production rooms should be located at ground level, with flexibility as to where the support rooms are located, unless the URB specifically identifies where they should be located. The URB should identify any requirements for the EDU to provide contingency support to other EDUs. If so, an indication of the level of support should be specified in order that the architect can make allowance in sizing certain rooms.

4.8. As each board's URB content will be different, it is clear that there will not be one size of EDU and its site to deliver a given output. A range of formats are possible and compliant with the design principles outlined in this guidance. There may also be restrictions to consider that will impact on the size of the facility. This can include the situation where a given area is provided and the EDU has to be located within this. Examples include locating the EDU inside an existing building or a new build where the EDU is part of a multifunctional healthcare facility. A risk assessment should be carried out to inform the EDU design. At an early stage in this exercise the design team should review the intended workload and maximum throughput possible covering trauma/ urgent surgery, elective/non-urgent surgery, primary care, private sector, and clinics. This will inform the design rationale when considering the impact of production downtime. The design team should also consider if there is a requirement for contingency arrangements with other EDUs. This may occur due to a range of reasons including utilities failure, Reverse Osmosis (RO) plant failure, upgrading of EDU, staffing problems, breakdown of endoscope washer disinfector (EWD), steam problems, waiting times initiatives and capacity issues.

4.9. The principle of designing in duplex systems and back-up systems for critical plant/services to minimise production downtime should be considered whilst ensuring that the required quality of these services is unaffected. This should include water, RO water, steam, electricity/ gas, compressed air, heating ventilation and air conditioning (HVAC), decontamination equipment and Information Technology (IT) systems.

4.10. The design team and those responsible for the business case should be clear that an accurate specification of the production throughput is critical to ensuring an under provision or overprovision is avoided. The size of the EDU facility such as the building and its site, the engineering services and the equipment required in both capital and revenue terms may be considerable.

4.11. Increasing the size of the EDU will increase the scale of support services required. Some of these support services, such as water, steam, air ventilation plant may come from areas not shown in the model layouts in the appendices of this document. If further support rooms, not shown in the model examples in the Appendices (A to D), are required in the provision of an endoscope decontamination service, consult Scottish Health Planning Note (SHPN) 13 part 1: 2024 which provides details covering design, finishes, mechanical and electrical and equipment/ furniture/ fittings. These details are presented in the form of room data sheets. If the EDU is to be built within an existing hospital complex consideration of the impact this will have should be carried out. This may include the possible impact on for example storage, portering, transport, waste handling and supplies.

4.12. Where works are to be undertaken in existing hospitals, the design team should ensure the local Estates and Facilities Manager is represented on the team. This individual will have significant input into the discussion of the condition and current capacities of existing services and to the evaluation of the demand load anticipated from the new EDU. As part of the project management, permit to work systems will be required. These will detail the where, when, and how in a documented protocol, the isolation and reconnection of hospital services will be managed.

4.13. The size of the EDU whether a Single Room, Two Room, Two Room with Ante Rooms or Two Room with Ante and other support rooms model (see Appendices A to D) will be determined by selecting the individual components as required from Table 4.1. (and allowing for access/ maintenance) to accommodate the throughput.

Table 4.1 - EDU area/ item or equipment and example of its dimensional length

Area/ item or equipment	Length (metres)
Door	0.9
Wash hand basin (could be in ante room)	0.6
Dirty set down area	1.4
Test sink with draining board	1
Wet leak tester	0.3

Area/ item or equipment	Length (metres)
Wash sink with draining board	1
Manual clean flushing unit	0.3
Detergent pump (under wash sink)	not applicable
Pre rinse set down area	1.4
Rinse sink with draining board	1
Post rinse set down area	1.4
EWD	0.9 to 1.5
Interlocked pass-through hatch (for 2 room model)	0.5
Post wash set down/ inspection area	1.4
Endoscope storage cabinet/system	1.7
Packing system for containing disinfected endoscopes (vacuum pack or positive pressure pack)	0.6
Dispatch area	0.6
Water treatment unit (could be under bench or on a wall in the Single Room EDU or the Wash Room of the other EDU models). It may also be installed in the Plant and Chemical Storage room.	0.9
Administration area	1.0
Personal Protective Equipment (PPE) storage (could be on a wall)	0.5
Waste storage (could be under bench)	0.5

4.14. Other areas or rooms are required to support the first three models, for example Domestic Services Rooms (DSRs) and trolley parking. The requirements for the Plant and Chemical Storage room would be assessed during the option appraisal process.

4.15. Where available floor space is limited, consideration should be given to placing certain components under the bench or on the wall to ‘double up’ components in the same area or having the PPE storage located on a wall. However, this should not be to the detriment of providing a continuous forward process flow from dirty to clean for example not arranging a clean process above a dirty process or vice versa. Adequate working space should be allowed between opposite sides of the room/ benches.

4.16. Storage requirements, outwith the EDU, for the transport containers should be considered. Plant space should be identified for chemical storage and compressors.

4.17. A dedicated DSR outwith the EDU, or a dedicated space within a general DSR, should be provided to support the cleaning activities in the EDU models as Appendices A to C. The room should be sized to accommodate a low-level bucket sink, wash hand basin, stainless steel sink with draining board and equipment storage/ hanging facilities. In the Two Room

with Ante and other support rooms model (see Appendix D) a separate DSR will be directly connected to the areas where clean and dirty endoscopes are processed.

4.18. The number of each type of component can only be determined after capacity demands on the EDU have been assessed. This will require detailed assessment of the clinical activity (sessions per day, patients per session, number, and type of procedures per patient, devices required for each type of procedure per day) the number of user units to be served and the types of procedures performed. Both current and likely future demands should be considered. Throughput calculations, for decontamination equipment capacity, also need to be established. In addition to meeting the capacity requirements the requirement for segregation of clean and dirty processes will also influence the size of the facility.

4.19. The building design should be able to support the mechanical and electrical plant together with cable trays and trunking for cable support. If lifts are required to service the EDU, they should be dedicated.

4.20. It is essential to specify the department's required production throughput to aid assessment of the physical size of a new-build EDU. This allows planners and designers to:

- calculate the optimum capacity of an EDU before bottlenecks start occurring
- model the overall installed production capability of an EDU
- assess the potential effects on throughputs and turn-round times (both for fast track and normal deliveries) due to
- change the number and size of processing equipment
- downtime for planned inspection/ servicing plant
- downtime for breakdown of plant/ equipment
- change number of staff

4.21. Consideration should be given to the long-term strategy for the service, EDU location, space required for the new service, and the size and condition of the building. Regard should also be paid to the orientation, the aspect of the building and the adequacy and location of all necessary support services. Consideration should be given to the totality of the impact of choice of location based upon factors including:

- instrument inventory to suit processing turnaround time
- transportation facilities
- staffing issues
- availability and cost of land
- service and maintenance issues
- considerations in selecting the location of the EDU

4.22. When choosing the location of an EDU, consideration should be given to the long-term strategy for the service, EDU location, space required for the new service, and the size and

condition of the building (if applicable). Regard should also be paid to the orientation and the aspect of the building.

4.23. In addition, the following issues may be taken into consideration when determining the location:

- availability and cost of site/ premises
- site and site utility services are of sufficient size to accommodate the requirements of the EDU service
- consideration of risks to the service from an incident associated with local high risk areas such as railway lines or whisky bonds
- distance and travel routes from main users
- revenue and capital costs of providing and operating the facility
- transport requirements/ constraints (public transport availability)
- parking availability
- vehicular access (including bulk tankers/ fire appliances) and effective delivery to and collection from the site
- turnaround time (including collection and delivery access to sites)
- instrument inventory
- quality, quantity and location of engineering services and technical support
- personnel issues, including proximity to local workforce
- security issues
- planning permission requirement
- customer base
- healthcare providers' strategies
- geographical and environmental constraints
- service and maintenance issues
- transport vehicle purchase and driver training

The EDU data sheet

4.24. The design requirements should be informed by the User requirements, including operational policies for the new facility, duplexing considerations, contingency measures, sustainability, and the requirements outlined in the EDU data sheet (see Table 4.2) of this guidance.

Table 4.2 - EDU data sheet

Subject	Requirements
Walls	Surface to be smooth, intact, easy to clean, able to withstand frequent cleaning, not shed particles and be fluid impermeable. Pipe-works or cables within the decontamination room should be boxed in. Gaps around installed equipment such as an EWD or pass through hatch, penetrating the wall, should be sealed. Edges where the wall meets the ceiling should be coved. Examples of suitable wall finish include elastomeric vinyl compound, epoxy coating, Poly Vinyl Chloride (PVC) with welded joints and acrylic paint. If plasterboard is used it should be moisture resistant and all exposed edges sealed. Suitable wall protection from trolley movement should be considered, that is mid height crash rail, durable materials on lower part of walls, protective corners, and coved skirting.
Floor	Surface to be level, hardwearing, smooth, intact, easy to clean, able to withstand frequent cleaning, not shed particles and be fluid impermeable. The flooring should be securely anchored and turned up at the junction with the walls in an integral coved skirting. In Two Room models, with pass through washer disinfectors, to prevent water spillages moving between rooms, a kerb (100-150mm in height) should be installed. The floor coving should be continuous against this kerb. For Single Room EDU, flooring should be non-slip. In Two Room EDUs the wash room flooring should be non-slip. Examples of floor finish include: slip resistant PVC sheet with welded joints and slip resistant resin based flooring. For EDU located above ground floor level: • consult a structural engineer for assessment of load bearing capability • a water catchment system is required to contain equipment leaks. Other protection systems could be considered
Ceiling	Surface to be continuous, smooth, intact, easy to clean and resistant to humidity. Examples of finish include elastomeric vinyl compound, epoxy coating, PVC with welded joints and acrylic paint. Light fittings should be flush-mounted, recessed and any cable entry system sealed with silicone sealant or similar to prevent insect infestation. If suspended ceilings are required, ensure the correct grade of ceiling tiles is selected (refer to Scottish Health Technical Memorandum (SHTM) 60: 2009 'Ceilings') and that all tiles/ hatches are sealed during installation and after any subsequent maintenance activity

Subject	Requirements
Doors	Surfaces to be hardwearing, smooth, intact, easy to clean, able to withstand frequent cleaning, not shed particles and be fluid impermeable. Door handles should be smooth. A vision panel should be provided where visibility is required. Security access by way of code, lock or supervised reception is required. Door protection could include protective plates and buffer rails mounted vertically at door edges. Door closers should be recessed or located on the dirty side. The EDU should have no external doors, except fire exits where unavoidable. The direction of door opening when passing through an ante room will be determined by a number of factors, including building control, the fire officer advice, space constraints and air pressure regimes.
Lighting	Enclosure intact, easy to clean and rated at Index of Protection (IP) 54, that is dust protected and protected against splashing water. The frame should be sealed to the ceiling. Light level 500 lux at workbench level supplied by ceiling lighting.
Electrical power	The electrical power supply should be designed specifically for the installation and should be served from a point where the system to which it is connected remains in compliance with SHTM 06-01: 2015 series, it should not cause overload in the supplying system. An enhanced power supply may be required for EWDs. Sufficient appropriately placed power points should be provided at a minimum of 150mm above bench level and IP55 rated.
Compressed air	Consult equipment manufacturer for details.
Medical grade air	Consult equipment manufacturer for details. If required, the air should be compliant with SHTM 02-01 part A: 2012. This would include the connections. Only Medical grade air is suitable for processing endoscopes. Consult an Authorising Engineer (Medical Gas Pressure Systems) (AE(MGPS)).
Air conditioning/ ventilation	Mechanical ventilation required for all models of EDUs. Certain manufacturers of storage cabinets may require a room air supply of a specified number of air changes per hour (AC/h). Ensure the air intake/output of the storage cabinets/ systems does not interfere with the room air ventilation. Ensure supply and extract grills or pressure relief dampers are kept free of obstructions.

Subject	Requirements
	Guidance for all room models- maintain an average room temperature between 16 to 21ºC and average relative humidity of 40 to 70%RH. **Two Room EDU with Ante Rooms** (see Appendix C) • **Wash Room** - supply a total of 7 AC/h to the Wash Room and its ante room (based on each individual area). Extract 10 AC/h (based on the combined wash room and its ante room area) directly from the wash room. Re-circulation of the supply air back into the Wash Room is not permitted. Wash room to be negative pressure with respect to adjoining areas. • **Inspection/ Storage/ Dispatch Room** - supply 10 AC/h to the Inspection/ Storage/ Dispatch Room (based on the combined Inspection/ Storage/ Dispatch Room and its ante room area). Extract a total of 7 AC/h from the Inspection/ Storage/ Dispatch Room and its ante room (based on each individual area). Inspection/ Storage/ Dispatch Room to be positive pressure with respect to adjoining areas. **Two room EDU with ante and other support rooms** (see Appendix D) • **Used Goods Reception** - supply 7 AC/h and extract 10 AC/h from the Room. Re-circulation of the supply air is not permitted. Used Goods Reception to be negative pressure with respect to adjoining areas. • **Wash Room** - supply 7 AC/h to the Wash Room and its ante room (based on each individual area). Extract 10 AC/h (based on the combined Wash Room and its ante room) directly from the Wash Room. Re-circulation of the supply air back into the Wash Room is not permitted. Wash Room to be positive pressure with respect to Used Goods Reception and negative pressure with respect to all other areas. • **Wash Room DSR** - to be negative pressure as Wash Room. • Wash Room Ante Room - to be negative pressure with respect to the corridor. • **Inspection Room** - supply 10 AC/h to the Inspection Room. Extract a total of 7 AC/h from the Inspection Room and its ante room (based on each individual area). Inspection Room to be positive pressure with respect to adjoining areas. • **Inspection Room DSR** - to be negative pressure with respect to Inspection Room. • **Storage and Dispatch Ante Room** - to be negative pressure with respect to the Storage and Dispatch Room and positive pressure with respect to the corridor. • **Storage and Dispatch Room** - supply 10 AC/h to the Storage and Dispatch Room. Storage and Dispatch Room to be negative pressure with respect to the Inspection Room and positive pressure with respect to all other areas.

Subject	Requirements
	Two Room EDU (see Appendix B) • **Wash Room** - supply 7 AC/h to the Wash Room and extract 10 AC/h from the Wash Room. Re-circulation of the supply air back into the Wash Room is not permitted. Wash Room to be negative pressure with respect to adjoining areas. • **Inspection/ Storage/ Dispatch Room** - supply 10 AC/h to the Inspection/ Storage/ Dispatch Room and extract 7 AC/h from the Inspection/ Storage/ Dispatch Room. Inspection/ Storage/ Dispatch Room to be positive pressure with respect to adjoining areas. **Single Room EDU** (see Appendix A) - supply 7 AC/h and extract 10 AC/h. No recirculation of the supply air back into the room is permitted. Room to be not positive pressure with respect to adjoining areas.
Windows	Windows should have intact seals and should be kept closed when the room is in use. Surfaces should be smooth, intact, and easy to clean. There should be no internal ledges. Window blinds should be permitted only if integral within double-glazing. No curtains should be used.
Horizontal surfaces	All horizontal surfaces to be smooth, intact, easy to clean, able to withstand frequent cleaning, resistant to mechanical damage and not shed particles. Edges to be coved where they meet the wall.
Work units	Work unit surfaces should be continuous, easy to clean, able to withstand frequent cleaning, be fluid impermeable and not shed particles. If joints/ cut edges are unavoidable in the work unit surface they require to be sealed with silicone, smooth, intact, easy to clean, able to withstand frequent cleaning, resistant to mechanical damage and not shed particles. Where laminated worktops are used, the laminate should be returned under the leading edge by at least 25mm. If stainless steel is being considered for the worktop, consult the manufacturer to confirm the grade of steel is suitable.
Test, wash and rinsing sinks	Dedicated rectangular stainless steel sinks with draining boards are required, one for leak testing, one for manual washing and one for rinsing. Any associated seals should be smooth and intact. A suitably sized waterproof splashback is required at each sink. Each sink should have single taps or a mixer tap, which is lever operated. The sinks should have no overflow and the taps should not discharge directly into the drain. The running trap should be remote from each sink and allow service access outwith the room. Each sink will require an upstand overflow tube plug. A spray gun may be required at the wash sink. The spray gun should be installed with suitable back flow protection that is related to the risks involved with the waste fluid

Subject	Requirements
	generation. A detergent pump, fitted under the wash sink, could be considered. To install this would require a small electrical supply and an injector to the sink.
Wash hand basin	A separate dedicated wash hand basin is required with taps, which are elbow, foot, or automatic sensor operated. The tap should be mixer or thermostatically controlled. There should be no overflow or plug; taps should not discharge directly into the drain. The running trap should be remote from the hand basin. A handwash solution dispenser should be wall-mounted near the wash hand basin. The handwash solution in the dispensers should not be refillable but be of a disposable, single cartridge design. A dispenser for disposable paper hand towels should be fitted above the sink. Dispensers should be easy to clean. Wash hand basins to be sited as per room layouts. (see Appendices A to D). In the Two Room model (Appendix B) there is no wash hand basin installed in the Inspection/ Storage/ Dispatch Room in order that water aerosolisation is minimised and operational misuse (such as Washing devices) of the sink is prevented. In this model a wall mounted alcohol based hand disinfectant dispenser should be fitted close to the entrance within the Inspection/ Storage/ Dispatch Room. Staff hands should be socially clean prior to entrance to the room.
Storage cabinet	To be smooth, intact, easy to clean, able to withstand frequent cleaning, resistant to mechanical damage and not shed particles. Cabinets/ systems may be fitted with a high-efficiency particulate air (HEPA) filtered air drying system. The air movement in/ out of the cabinet should not interfere with the room air ventilation.
Packing system	To be smooth, intact, easy to clean, able to withstand frequent cleaning, resistant to mechanical damage and not shed particles.
Admin area	This area is used to manage the decontamination documentation. A computer may be used. In the Single Room EDU, a single administration area is required. In the Two Room EDUs an administration area is required in both the Wash Room and the Inspection/ Storage/ Dispatch Room. In the Two room EDU with ante and other support rooms model there may be an admin area in the Used Goods Reception, Wash Room.

Subject	Requirements
Drainage of EWDs	Drains will be required for any EWDs installed. The drainage systems should be capable of withstanding high temperatures used for those EWDs with a thermal self-disinfection cycle (95°C) without distortion or leakage. Scottish Water should be contacted with regard to management of the proposed effluent.
Storage of PPP	Supplies of PPE should be kept close to the point of use. They should always be stored above floor level, on designated shelving in a clean dry cupboard or in an enclosed wall dispenser.
Storage of cleaning materials and process chemicals	Dedicated storage is required for cleaning materials and process chemicals. This should be above floor level, on designated shelving in a clean dry cupboard and be in accordance with the Control of Substances Harmful to Health (COSHH) regulations published 2002. All-mounted cupboards above worktop height should be avoided. Incompatible materials should be stored separately. Manual Handling Operations Regulations should be considered.
Waste disposal	There should be suitable waste containers for all types of waste generated. These containers should have hands-free lids and have a surface, which is smooth, intact, and easy to clean.
Noise level	Should be as required by the Control of Noise at Work Regulations 2005. Consideration should be given to surrounding areas where noise levels may be specified, for example where the EDU is above, below, or next to a clinical area.
Eye wash station/ first aid kit and spill kit	Required and readily available for use in an emergency.

EDU layouts

4.25. Four EDU layouts have been identified as options to enable compliance with current technical requirements for decontamination of endoscopes. The preferred EDU model for small/ medium sized units adjacent to clinical areas is the Two Room with Ante Rooms (see Appendix C) or the Two Room with Ante and other support rooms for large centralised units (see Appendix D).

Single room EDU

4.26. Its function is to:

- receive contaminated endoscopes, disassemble, test, and manually clean them
- process the endoscopes through an EWD, dry, and transfer to the clinical area for assembly and use or store in designated endoscope storage cabinet or pack disinfected endoscope

4.27. The EDU is located in the same building in which the endoscopes are used.

4.28. The key requirements are as follows.

4.29. On entering the room, staff should wash hands at the wash hand basin and put on PPE as per the COSHH assessment. Workflows from the initial stage of receiving contaminated endoscopes at the put down bench next to the test sink. The endoscope is disassembled, single use components discarded and then tested in the test sink using a wet leak tester if specified by the endoscope manufacturer's instructions for use (IFU). Endoscopes specified by their manufacturer to be dry leak tested are not placed in the test sink. The endoscope is manually cleaned in the wash sink (making use of a manual clean flushing unit if appropriate) and then rinsed in the rinse sink. The endoscope is then placed in the EWD. After processing, it is removed from the EWD and dried if required and inspected for cleanliness and dryness. The endoscope is transferred to the clinical area for assembly and immediate use or placed in a dedicated endoscope storage cabinet/ system or packed in a vacuum pack or positive pressure pack. Endoscopes failing the inspection process are returned to the dirty set down area next to the test sink for reprocessing or sent for repair or disposal as appropriate.

4.30. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free clinical waste bin
- test, wash, and rinse sinks with draining boards

- wet leak tester or dry leak tester (as specified by the endoscope manufacturer)
- manual clean flushing unit
- EWDs
- task lighting with magnifier
- endoscope storage cabinet/ system
- packing system for containing disinfected endoscopes (vacuum or positive pressure pack)
- dedicated cleaning equipment
- telephone or intercom
- computer for administration area
- first aid kit/ eye wash station

Two room EDU

Two room EDU - wash room

4.31. Its function is to receive contaminated endoscopes in the Wash Room, disassemble, test, manually clean, rinse and load into the pass-through EWD.

4.32. The Wash Room is connected via a pass-through EWD to the Inspection/ Storage/ Dispatch Room of the EDU.

4.33. The key requirements are as follows.

On entering the Wash Room of the decontamination unit staff should wash hands at the wash hand basin and put on PPE as per the COSHH assessment. Workflows from the initial stage of receiving contaminated endoscopes at the put down bench next to the test sink. The endoscope is disassembled, single use components discarded and then tested in the test sink using a wet leak tester if specified by the endoscope manufacturer's (IFU). Endoscopes specified by their manufacturer to be dry leak tested are not placed in the test sink. The endoscope is manually cleaning in the wash sink (making use of a manual clean flushing unit if appropriate) and then rinsed in the rinse sink. The endoscope is then placed in the EWD.

4.34. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free clinical waste bin
- test, wash, and rinse sinks with draining boards

- wet leak tester or dry leak tester (as endoscope manufacturer's instructions)
- manual clean flushing unit
- pass-through EWD(s)
- pass-through hatch
- dedicated cleaning equipment
- telephone or intercom
- computer for administration area
- first aid kit/ eye wash station

Two room EDU - wash room ante room

4.35. Its function is to:

- provide controlled access from the corridor to the Wash Room
- endoscopes for reprocessing are received in the ante room prior to placing in the Wash Room
- enable hand washing and PPE is put on or removed as appropriate

4.36. The ante room connects the corridor to the Wash Room.

4.37. The key requirements are as follows.

On entering the ante room, wash hands at the wash hand basin and put on PPE as per the COSHH assessment. Work flows from the initial stage of receiving endoscopes for reprocessing from the clinical area. The contaminated endoscopes enter the Wash Room via its Ante Room. On leaving the Wash Room Ante Room, remove PPE and wash hands.

4.38. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free clinical waste bin

Two room EDU - inspection/ storage/ dispatch room

4.39. Its function is to:

- unload, clean disinfected endoscopes from the EWD (dry if required), or manually washed devices from the pass through hatch, inspect for cleanliness and dryness
- then transfer to the clinical area for assembly and immediate use or place in a dedicated endoscope storage cabinet/ system or pack in a vacuum pack or positive pressure pack

4.40. The room is connected, via a pass-through washer disinfector and interlocked pass-through hatch, to the Wash Room, of the EDU.

4.41. The key requirements are as follows.

On entering the Inspection/ Storage/ Dispatch Room where there is no ante-room, staff should disinfect clean hands using alcohol gel and put on PPE. Work flows from the initial stage of unloading cleaned and disinfected endoscopes from the pass through EWD, drying if required, inspecting for cleanliness and dryness then transferring to the clinical area for assembly and immediate use or placing in a dedicated endoscope storage cabinet or pack the disinfected endoscope. On leaving the room, remove PPE and wash hands.

4.42. The following equipment is required:

- endoscope storage cabinet
- packing system for producing vacuum packs or positive pressure packs
- PPE storage
- hands free general waste bin
- task lighting with magnifier
- telephone or intercom
- computer for administration area
- first aid kit/ eye wash station

Two room EDU - inspection/ storage/ dispatch room ante room

4.43. Its function is to:

- provide controlled access from the corridor to the Inspection/ Storage/ Dispatch Room
- enable hand washing and PPE is put on or removed as appropriate

4.44. The ante room connects the corridor to the Inspection/ Storage/ Dispatch Room.

4.45. The key requirements are as follows.

On entering the ante room, wash hands at the wash hand basin and put on personal protective equipment as per the COSHH assessment. On leaving the ante room, remove PPE and wash hands.

4.46. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free general waste bin

Two room EDU with ante and other support rooms

Used goods reception

4.47. Its function is to:

- receive contaminated endoscopes in transport trolleys and retains these in the area prior to transfer to the Wash Room
- store waste prior to collection

4.48. The Used Goods Reception connects the corridor to the Wash Room.

4.49. The key requirements are as follows.

The Used Goods Reception stores contaminated endoscopes in a secure dedicated area until required for processing in the Wash Room.

4.50. The following equipment is required:

- hands free clinical waste bin
- computer for administration area

Wash room

4.51. Its function is to receive contaminated endoscopes in the room, dissemble, test, manually clean, rinse and load into the pass-through EWD.

4.52. The Wash Room is directly connected to the Used Goods Reception, the Wash Room Ante Room, and the Wash Room DSR.

4.53. The key requirements are as follows.

Work flows from the initial stage of receiving contaminated endoscopes (from the Used Goods Reception) at the put down bench next to the test sink. Each endoscope is disassembled, and single use components discarded. The endoscope is then tested in the test sink using a wet leak tester if specified by the endoscope manufacturer's (IFU). Endoscopes specified by their manufacturer to be dry leak tested are not placed in the test sink. Manual cleaning is performed in the wash sink (making use of a manual clean flushing unit if appropriate) and rinsing in the rinse sink. The endoscope is then placed in the EWD.

4.54. The following equipment is required:

- hands free clinical waste bin
- test, wash, and rinse sinks with draining boards
- wet leak tester or dry leak tester
- manual clean flushing unit
- pass-through washer disinfector(s)
- pass-through hatch

- telephone or intercom
- computer for administration area
- first aid kit/ eye wash station

Wash room ante room

4.55. Its function is to:

- provide controlled access from the corridor to the Wash Room
- enable hand washing and PPE is put on or removed as appropriate

4.56. The Wash Room Ante Room connects the corridor to the Wash Room.

4.57. The key requirements are as follows.

On entering the ante room, wash hands at the wash hand basin and put on PPE as per the COSHH assessment. On leaving the ante room, remove PPE and wash hands.

4.58. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free clinical waste bin

Wash room DSR

4.59. Its function is to provide dedicated domestic services to the Wash Room.

4.60. The Wash Room DSR connects directly to the Wash Room.

4.61. The key requirements are as follows.

The room supports the domestic cleaning activities within the Wash Room. The room stores dedicated cleaning equipment and allows for the disposal of waste cleaning materials

4.62. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free general waste bin
- stainless steel sink and drainer
- low level bucket sink
- equipment storage/ hanging facilities

- spillage kit for chemicals

Inspection room

4.63. Its function is to unload, clean disinfected devices from the EWD (dry if required) or manually washed devices from the pass through hatch and inspect for dryness and cleanliness

4.64. The Inspection room is connected, via a pass-through EWD and interlocked pass-through hatch, to the Wash Room, directly with the DSR and the Storage and Dispatch Room.

4.65. The key requirements are as follows.

Work flows from the initial stage of unloading cleaned and disinfected endoscopes from the pass through EWD. The endoscopes are then inspected and moved into the Storage and Dispatch Room.

4.66. The following equipment is required:

- hands free general waste bin
- task lighting with magnifier
- telephone or intercom
- computer for administration area
- first aid kit/ eye wash station

Inspection room DSR

4.67. Its function is to provide dedicated domestic services to the Inspection Room and the Storage and Dispatch Room.

4.68. The Inspection Room DSR connects directly to the Inspection Room.

4.69. The key requirements are as follows.

The room supports the domestic cleaning activities within the Inspection Room and the Storage and Dispatch Room. The room stores dedicated cleaning equipment and allows for the disposal of waste cleaning materials.

4.70. The following equipment is required:

- wash hand basin
- PPE storage
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free general waste bin
- stainless steel sink and drainer
- low level bucket sink

- equipment storage/ hanging facilities
- spillage kit for chemicals

Storage and dispatch room

4.71. Its function is to:

- receive clean disinfected and inspected endoscopes from the Inspection Room
- store endoscopes in an endoscope storage cabinet or pack and dispatch on trolleys as required

4.72. The Storage and Dispatch Room connects directly to the corridor and the Inspection Room.

4.73. The key requirements are as follows.

Work flows from the initial stage of receiving cleaned, disinfected, and inspected endoscopes from the Inspection Room and transferring to the clinical area for immediate use or placed in a dedicated endoscope storage cabinet/ system or process in a packing system to produce a vacuum pack or a positive pressure pack.

4.74. The following equipment is required:

- endoscope storage cabinet/ system
- packing system
- hands free general waste bin
- telephone or intercom
- computer for administration area

Storage and dispatch room ante room

4.75. Its function is to:

- provide controlled access from the corridor to the Storage and Dispatch Room
- enable hand washing and PPE is put on or removed as appropriate

4.76. The Storage and Dispatch Room Ante Room connects the corridor to the Storage and Dispatch Room.

4.77. The key requirements are as follows.

On entering the Ante room, wash hands at the wash hand basin and put on personal protective equipment as per the COSHH assessment. On leaving the Ante room, remove PPE and wash hands.

4.78. The following equipment is required:

- wash hand basin
- PPE storage
- hands free general waste bin

- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser

Domestic services room

4.79. Its function is to store domestic equipment used for cleaning Single and Two Room EDU options as described in Appendices A to C.

4.80. This room should be in the same corridor as the EDU or connect directly to the relevant area.

4.81. The key requirements are as follows.

This room supports the domestic cleaning activities within the EDU. Shelving and vertical storage is required to hold a limited amount of cleaning materials.

4.82. The following equipment is required:

- hand wash basin
- wall mounted cartridge soap dispenser
- wall mounted paper towel dispenser
- hands free general waste bin
- dedicated cleaning equipment
- low level bucket sink
- stainless steel sink with draining board
- equipment storage/ hanging facilities

Plant and chemical storage room

4.83. Its function is to contain plant and be a chemical store.

4.84. This room should be close to or connect with the Single Room EDU or the Wash Room of the other EDU models.

4.85. The key requirements are as follows.

This room may supply some of the support services required for the EDU and in addition be a chemical store. Compatibility between all chemicals and equipment in the room should be assessed and shown to be satisfactory. Consult SHPN 13 part 1: 2011 for further detail with regard to design including room finishes, mechanical and electrical and equipment/ furniture/ fittings.

4.86. The equipment to be placed in this room will be defined during the option appraisal exercise. The following equipment is required:

- a water treatment unit (RO unit and pre scavenging) and a compressor to supply air to some models of clean scope storage systems
- a spillage kit for chemicals

Project documents and quality control at design stage

4.87. The URB should have been produced as part of the final business case (FBC). Control of the resulting design that develops from the URB should be done through the Design Qualification (DQ) for the new EDU. This activity comprises of two parts, that being the method or protocol defining the qualification activities and the report defining the results/ conclusions of these activities. A risk assessment should be carried out to inform the EDU design. At an early stage in this exercise the design team should review the intended workload and maximum throughput possible covering trauma/ urgent surgery, elective/ non-urgent surgery, primary care, private sector, and clinics. This will inform the design rationale when considering the impact of production downtime. The design team should also consider if there is a requirement for contingency arrangements with other EDUs. This may occur due to a range of reasons including utilities failure, RO plant failure, upgrading of EDU, staffing problems, breakdown of EWD, steam problems, waiting times initiatives and capacity issues.

4.88. The principle of designing in duplex systems and back-up systems for critical plant/services to minimise production downtime should be considered whilst ensuring that the required quality of these services is unaffected. This should include water, RO water, steam, electricity, compressed air, HVAC, decontamination equipment and IT systems.

4.89. The design team and those responsible for the business case should be clear that an accurate specification of the production throughput is critical to ensuring an under provision or overprovision is avoided. The size of the EDU facility such as the building and its site, the engineering services and the equipment required in both capital and revenue terms may be considerable.

4.90. Increasing the size of the EDU will increase the scale of support services required. Some of these support services, for example water, steam, air ventilation plant may come from areas not shown in the model layouts in the appendices of this document. If further support rooms, not shown in the model examples in the Appendices, are required in the provision of an endoscope decontamination service, consult SHPN 13 part 1 which provides details covering design, finishes, mechanical and electrical and equipment/ furniture/ fittings. These details are presented in the form of room data sheets. If the EDU is to be built within an existing hospital complex consideration of the impact this will have should be carried out. This may include the possible impact on, for example storage, portering, transport, waste handling and supplies.

4.91. Where works are to be undertaken in existing hospitals, the design team should ensure the local Estates and Facilities Manager is represented on the team. This individual will have

significant input into the discussion of the condition and current capacities of existing services and to the evaluation of the demand load anticipated from the new EDU. As part of the project management, permit to work systems will be required. These will detail the where, when, and how in a documented protocol, the isolation and reconnection of hospital services will be managed.

The design qualification protocol

4.92. The DQ protocol should identify the project team individual(s) that are tasked with carrying out the necessary quality control checks of documentation over the project duration. This is a required element in the validation of the new EDU in line with compliance guidance GUID 5013 v3: 2024. The project documentation may comprise a range of formats of documents such as architectural drawings, Mechanical and Electrical drawings, and worksheets including an environmental matrix. The majority of this information requires to be checked across these different types of documents. This is to ensure that the information is in agreement and does not conflict between documents. For example, the information in the 1:200 scale layout EDU department drawing and the 1:50 room layouts should be agreement with the information contained in the environmental matrix. The quality control check should cite the revision of each document that was part of the review. There should be multiple quality control checks required over the duration of the project as the design developments and different revisions of the documentation are produced. All involved should be made aware of the scale of the exercise with multiple drawings covering layout, equipment schedule, finishes/ fixtures. Each of these may have multiple iterations before arriving at an agreed version.

4.93. The environmental matrix should be checked for agreement with the specifications given in this planning note SHPN 13 part 3.

4.94. The verification exercise should confirm the department layout 1:200 meets the requirements stated in the approved URB. The qualification exercise should be independent of the architect that prepared the department layout drawing.

4.95. The verification exercise should confirm the environmental matrix meets the requirements stated in the approved URB. The environmental matrix should cite the current version of the 1:200 department layout drawing. These two items should be checked as a package. There should be clarity between board and the principal contractor architect on verification of group 2 items and challenges of group 3 items. The dimensions of fixed group 3 items should be specified on the 1:50 layout drawings.

4.96. The verification exercise should confirm that for every room in the EDU there is a corresponding 1:50 layout drawing, and their content meet the requirements stated in the approved URB.

4.97. The equipment/fixtures schedule and other schedules (such as Mechanical and Electrical) on each 1:50 room layout should be checked to be in agreement with the URB and the

planning note. The number of each item should be checked, the dimensions of each item should be stated. The description should be checked for accuracy, the group rating (1, 2 or 3) is correct, and the count is correct and marries up with the room layout drawing.

4.98. Technical review that confirms the proposed design meets the requirements of this guidance namely SHPN 13 part 3 - non compliances should be identified, and an agreed documented record of the action taken.

4.99. The project team should sign off a design approval document which cites the revision number of each of the documents that comprise the design information. The agreed master list of layout drawings and other information (such as the environmental matrix) should be produced prior to any construction activity.

4.100. The agreed master list of layout drawings and other information becomes the documents used in verifying the construction (that is at the operational qualification).

4.101. It should be made clear who supplies, buys, and installs equipment. Each room 1:50 layout drawing should have a list containing equipment/ furniture and fittings to be considered. These items can be managed in a number of ways:

- supplied and installed by the main contractor
- supplied by the client and installed or fixed by the main contractor
- supplied and delivered and placed by the client

4.102. The relevant document within the qualification exercises of the Validation Master Plan (VMP) should define responsibilities (for supply and installation) and the method of verifying these have been carried out satisfactorily.

Approved and signed off master list of documentation

4.103. When planning a new build with an agreed URB - with the EDU model layout and the relevant Room Data Sheets the members of the project design team are prompted to seek and provide information. When planning an upgrade, the Room Data Sheets are applied by the project design team to the existing or modified facility layout. This is in order that the rooms can be scaled, and the associated equipment/ furniture/ fittings specified to deliver an EDU that meets their specified production throughput requirements as per their business case rationale. The Room Data Sheets provide guidance on Design, Finishes, Mechanical and Electrical and Equipment/ Furniture/ Fittings.

4.104. For every room in the department 1:200 scale layout there should be an individual room layout drawing at 1:50 scale, this includes plant rooms.

4.105. The Environmental matrix should be version controlled. The approved version should reference the approved version of the 1:200 layout drawing of the EDU.

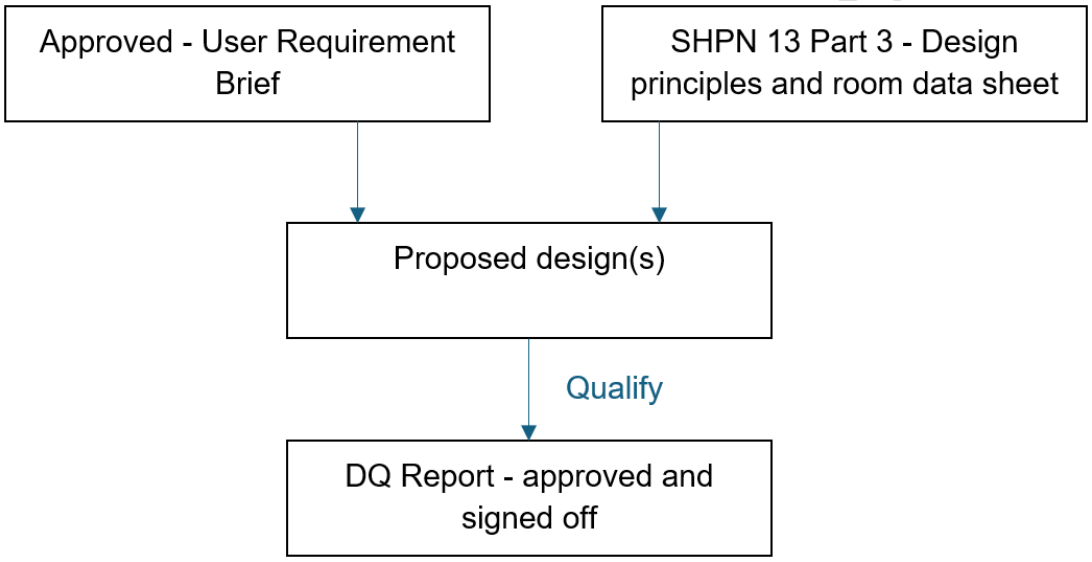
The design qualification report

4.106. The DQ report should outline that the chosen design at this point in the project has:

- been assessed as per the DQ protocol
- considered the content of the approved version controlled URB
- met the design principles of this planning note
- defined and got agreement on any derogations
- the controlled master list of documentation included and signed off
- been confirmed as being satisfactory by all stakeholders
- been signed off prior to the commencement of construction of the new build

4.107. Figure 4.1 shows the information input needed or to be considered to set a proposed design that is then qualified as per the DQ protocol resulting in the DQ report.

Figure 4.1 - Input required/ considered for proposed design then qualified as per the DQ protocol to produce the DQ report



Design change management

4.108. It is possible a design change is required after the project team has approved the design documentation. In this case standard change management practices should be followed. This should include an examination of the proposed change(s), options, any impacts and a sign-off by the project team prior to the implementation of any agreed changes.

4.109. When qualifying the design invalid reference guidance such as from Activity Data Bases (ADBs) and Health Building Note (HBN13) should not be used.

Sustainable design - SDaC

4.110. The publication Scottish Health Technical Note (SHTN) 02-01: 2023 on Sustainable Design and Construction (SDaC) covers wellbeing, circularity, and climate change. All elements outlined in the guidance should be considered. Some specific items are mentioned under staff wellbeing and climate change.

Staff wellbeing

4.111. The SDaC covers a range of items for consideration. Some specific items to consider for EDUs include:

- natural light as much as possible inside the department
- staff room facilities including space for recreation at breaks
- consideration of external space around facility for staff exercise at break times
- Greenspace considerations
- consideration of safety aspects given staff working night shifts
- good transport onto the site - and safe walking around the site
- choice of site location should consider staff safety walking to the site

Climate change

4.112. Climate change considerations include operational energy, emissions, embodied carbon, water consumption and waste. Look to identify the opportunities to remove/ reduce these factors. There should be an assessment of the decontamination equipment, the services (cold/ hot water, compressed air, air conditioning), and consumables required to run the facility and operate the compliant decontamination process.

4.113. Water treatment plant including RO units can be hot systems. There can also be high chemical use and water consumption for washer disinfectors, cart washers. Waste water quantities may also be significant.

Circular design and construction

4.114. The SDaC states a circular design and construction approach should be adopted with the aim of keeping materials in use for longer. Commit to a circular procurement hierarchy approach, as defined by Zero Waste Scotland:

- prevention
- reduce
- reuse
- recycle
- recover

4.115. Design out waste and pollution from the start. Adopt responsible design, procurement, and construction practices. Design to restore and regenerate natural systems. Design for assembly, disassembly, and recoverability. Consider expected product lifespan for all building elements and 'durable' components, including management, maintenance, and replacement. Consider opportunities for the use of reused, recycled, and recyclable products.

Refurbishment - upgrading or adaptation of existing buildings/ services

4.116. Refurbishment activities should in the first instance look to comply with the design principles outlined in this guidance. It is recognised that this may present a significant challenge.

4.117. When considering an upgrade the Room Data Sheet is applied to the existing or modified facility layout. There will be elements of the Room Data Sheet that may not be valid for example adjacencies. It is anticipated that the quality of finishes and Mechanical and Electrical specifications detailed in the Room Data Sheet could still be delivered in an upgrade. It is likely that some of the room names as specified in the Room Data Sheet would not be the same as that which are currently in use across the various health boards. Review of the content within the function and activities section in the design page of the Room Data Sheet should ensure the correct information is applied.

4.118. Before any decision is made to carry out an upgrading project, consideration should be given to the long-term strategy for the service, the need for capital investment in decontamination equipment, the space required for the new service, and the size of the existing building. Regard should also be paid to the orientation and aspect of the building and the adequacy and location of all necessary support services.

4.119. If a prima facie case emerges for upgrading following the option appraisal exercise, a thorough analysis of all functional and physical conditions of the existing building should be undertaken. This would include costs of upgrading existing hospital services if required including water mains, drains, emergency generators and boilers.

4.120. When comparing the cost of upgrading or adapting an existing building to that of a new build option, due allowance should be made for the cost of relocating people as well as building demolition and salvage costs, disruption to services, and the temporary effects on running costs of any impaired functioning of areas affected by upgrading.

4.121. A checklist of physical and other aspects of existing buildings should include:

- availability of space for alterations and additions
- type of construction
- current insulation standards

- age of the buildings, condition of fabric, for example external and internal walls, floors, roofs, doors and windows and natural light within deep core buildings all of which may be determined by a condition survey
- life expectancy and adequacy of engineering services, ease of access and facility for installation of new wiring, pipework, drainage, and ventilation systems
- the height of ceilings (high ceilings do not necessarily call for the installation of false ceilings, which are costly and often impair natural ventilation)
- changes of floor levels to avoid hazards to disabled people and in the movement of trolleys
- fire safety
- physical constraints to adaptation, such as load bearing walls and columns
- road infrastructure
- large vehicle access including fire brigade appliances
- vehicle wash area
- storage for bulk waste
- ground work survey of contamination from previous structures/ uses and planning consent for change of use or for listed building status
- Disability Discrimination Act requirements

4.122. Having decided that existing health premises are suitable for upgrading or conversion, the main requirement should be to assess how the accommodation can be adapted so as to facilitate good practice.

4.123. The main environmental factors which should be considered are the same as for a new building.

4.124. Upgrading should conform to all legislation including current fire safety, building insulation standards and other statutory regulations. The project will require building warrant and planning consent. Scottish Environment Protection Agency (SEPA) approval will also be a requirement. These statutory agencies need to be considered during the option appraisal exercise.

4.125. This summary of the main aspects of upgrading is general in character and it is recognised that each upgrading project will present its own individual problems. In many instances, compromises may have to be made between standards set out in this guidance and what it is possible to achieve. Upgrading should be functionally sound - not merely cosmetic - and appropriate for the projected needs for a number of years to come. The building life should be defined and is typically 30 to 60 years.

4.126. Any upgrading work should minimise the disruption to existing services - that is, there should be a clear segregation between building activity and the ongoing delivery of services. Refer to the publication ‘SHFN 30: 2014’ for the specification of suitable control measures. Waste handling will present additional challenges for site managers. Access for

large commercial vehicles with drop-off, load/ unload and turning may cause considerable disruption within a hospital site. Road/ footpath and surface water drainage may suffer damage as a result of construction related traffic.

Access and facilities for disabled people

4.127. It is essential to ensure that suitable access and facilities are provided for staff/ visitors who have problems of mobility or orientation. This includes those who have difficulty walking, and may use sticks, crutches, or other assistive devices, those who have a visual or hearing impairment, as well as those who use a wheelchair. Due to the nature and function of an EDU members of the general public would not have access to the facility. The following should be considered:

- the Disability Discrimination Act 1995 and amendments 2005
- The Building Regulations 1991. Approved Document M: Access and facilities for disabled people, 1999

4.128. Project teams are encouraged to refer to SHFN 14: 2000 ‘Disability access’, which gives guidance and a set of ergonomic data sheets on access, space and equipment relating to disabled people in health buildings.

4.129. Patient Safety has to be assessed alongside the needs of disabled persons working/ visiting the EDU.

Modular construction

4.130. The term modular construction is open to interpretation. And in this regard different suppliers of modular constructions may provide different products. This can range from supply of an ’empty’ module to a module that is fully fitted out with equipment, furnishings, and fittings. That said, modular construction may provide a number of benefits when considered against a traditional build.

4.131. A module that is constructed offsite at a factory and has equipment/ furniture and fittings installed in the module before leaving the factory site should allow good quality control conditions under a factory’s quality management system (QMS) with temperature control and good lighting conditions. Contrast this with a busy construction site with multiple contractors competing for the same workspace sometimes at height and under limited light levels.

4.132. A module that is fitted out at the factory may allow customer visits at various stages to verify the construction is in line with the customer’s expectations. Certain amendments if required will be easily dealt with at the factory as opposed to modifications onsite to an EDU under construction.

4.133. Another significant difference to that of a traditional build is that the User Requirements specification for their EDU should be agreed and supplied at a significantly earlier stage in a project.

4.134. Sustainable design considerations may be better addressed by modular construction in terms of the end of life recovery of materials.

4.135. There are some unique challenges presented by modular construction. It is recognised that transporting modules from the factory site to the customer's site will likely result in some cracking of the module. This should be discussed with the supplier and agree how this is to be addressed once the module arrives on site.

4.136. Experience indicates that storage of modules pending delivery or while stored in other locations can result in environment damage if insufficient protection is in place.

Engineering services

Introduction

4.137. This section describes the engineering services supplied to the EDU (refer also to the Room Data Sheet). The guidance should acquaint the engineering members of the design team with the criteria and material specification needed to meet the functional requirements. The design team brief would include detailed input from the users.

4.138. The design team should adopt a risk management approach to the design. This will require a range of technical and clinical expertise to be available to the team. Where works are to be undertaken in existing hospitals, the design team should ensure the local Estates and Facilities Manager is represented on the team. This individual will have significant input into the discussion of the condition and current capacities of existing services and to the evaluation of the demand load anticipated from the new EDU. As part of the project management, permit to work systems will be required. These will detail the where, when, and how in a documented protocol, the isolation and reconnection of hospital services will be managed.

4.139. A quality decontamination service needs continuity of delivery. The design of engineering and building services should take this into account. Points to consider include:

- backup systems
- which maintenance activities can and cannot be performed while the facility is operational
- down time for maintenance/ periodic testing/ possible repair and any subsequent cleaning activity
- failure of supply or quality of the supply (including supply and extract ventilation, electricity, water, steam, IT, and transport systems)
- response time for service, maintenance, and testing

- availability of spare parts
- unit working hours
- opportunities for planned work

4.140. The requirements for individual rooms as per the differing models given earlier in this document are given in the specific functional and design requirements section.

SHTMs

4.141. Reference should be made to the engineering sections of the relevant SHTM for example SHTM 04-01 part A: 2014, SHTM 03-01: 2022 series and the SHTM 01-06: 2023 series.

Economy and value management

4.142. Engineering services are a significant proportion of the capital cost and operational costs. Value management should be carried out at the inception stage. The design team should therefore ensure:

- life cycle economy in provision and operation, consistent with meeting the functional and mandatory requirements and maintaining clinical standards through effective risk management taking due care for the patient, staff, contractors, and the general public
- optimum benefit from the total financial resources these services are likely to absorb during their lifetime

4.143. 'Life cycle costings' should be generated as part of the cost-benefit analysis for the selection of systems and equipment within a given risk management framework.

4.144. Where various design solutions are available for a given level of risk reduction, their consequential capital and revenue costs should be compared using the discounting techniques in, for example, the Scottish Capital Investment Manual (SCIM) published by the government.

4.145. Maintainability and the cost of maintenance are key factors in both business planning and the design solution evaluation process.

4.146. In providing an energy-efficient solution, account should be taken of the local environmental policy in line with NHSScotland energy-efficiency targets (Refer to SHTN 02-01: 2021 SDaC). Users will be expected to achieve ongoing improvements in the utilisation of engineering services for a given level of activity. As a result, the design of the building management system and metering arrangements should enable areas for performance improvement in the use of resources to be identified.

4.147. Energy management should be part of the site building management system (BMS) and this should also include metering of all services where practical. Detailed guidance is contained in the SHTM 08-05: 2012 series 'Building management systems'.

4.148. The project team should be able to demonstrate consideration of the environmental benefits and economic viability of heat recovery, high efficiency lighting, and renewable energy

technologies such as wind turbines and heat pumps. None of these measures should impact adversely on the decontamination lifecycle.

Service requirements

4.149. For equipment to be available at any time and to meet throughput calculations, service requirements and provision should be based on maximum simultaneous demand; that is, no diversity is to be applied. This will have significant impact on plant size. Energy efficiency should also be considered. Service requirements for planned or foreseeable future expansion in department workload should also be considered at the design stage.

4.150. The estimated maximum demand and storage requirement for each engineering service will need to be assessed individually to take account of the size, location, operational policies, and intensity of use of the department.

Space for plant and services

4.151. Enough space should be provided for plant and services within the department. The amount of space will depend on the engineering solution chosen but will include space not only for decontamination plant and equipment but also the following:

- water treatment/ storage where required
- ventilation and air conditioning
- hot water generation
- bulk chemical distribution
- Space for plant and services should provide:
- easy and safe means of access, protected as far as possible from unauthorised entry
- space for frequent inspection and maintenance
- for eventual removal and replacement of major plant and equipment

4.152. Mechanical and electrical services should be concealed in walls and above ceilings to provide for easy cleaning and prevent build-up of contamination within clean areas.

4.153. All plant and equipment should be designed, installed, and maintained in accordance with the Construction Design and Management (CDM) Regulations. Specifically, all plant and equipment should be readily accessible for maintenance and means of maintenance and eventual replacement should be built in. Primary engineering distribution control and isolation devices should be protected against unauthorised operation for example switchgear and distribution-boards should be housed in secure cupboards and located in a safe location.

Safety

4.154. Section 6 of the Health and Safety at Work Act, as partly amended by the Consumer Protection Act, together with the Management of Health and Safety at Work Regulations,

the Workplace Regulations and the Provision and use of Work Equipment Regulations, impose statutory duties on employers and designers to minimise any risks arising from the use, cleaning, or maintenance of engineering systems.

Fire precautions

4.155. SHTM 81 Part 1: 2022 Firecode: 'Fire precautions in new hospitals' by Health Facilities Scotland (HFS) should be followed. Fire risk assessment should follow SHTM 86: 2023.

4.156. The design team will have to consider how the fire precaution requirements may affect the design (including upgrade) of the EDU. It will also require considering its effect on the existing surrounding occupied areas in so far as the alarms and means of escape is concerned.

Noise and speech privacy

4.157. Excessive noise and vibration from engineering services, whether generated internally or externally and transmitted to individual areas, or noise from other sources can adversely affect operational efficiency of the department and cause discomfort (which could include patients).

4.158. In addition to designing for control of noise levels there may be a need to ensure speech privacy so that confidential conversations are unintelligible in adjoining rooms.

Engineering commissioning

4.159. The engineering services should be commissioned in accordance with the validation system identified in the current version of each SHTM.

4.160. A frequent cause of failure of projects to meet their design intent is ineffective commissioning. When construction projects are behind schedule, commissioning is sometimes squeezed into an inadequate timescale. This should be avoided as the lifetime running cost and occupant satisfaction can be adversely affected, possibly with serious consequences and large rectification costs.

4.161. Commissioning of engineering systems should not be left entirely in the hands of the installing contractor. The ideal arrangement is the use of independent specialist commissioning, however, where the scale of the project does not justify this, independent verification of commissioning and testing should be carried out. The person with professional responsibility for signing off the commissioning and testing of each engineering service should be clearly identified. Consult your AE(D) for advice on commissioning of decontamination equipment.

4.162. Full commissioning and operation documentation should be provided on completion of the project and users should be formally trained in the operation of the engineering services within the facility. Responsibility for delivery of this training should be clearly defined prior to commissioning activities.

Equipment validation

4.163. Decontamination equipment should be validated in line with SHTM 01-06: 2023 series. The quality of product from an EDU is highly dependent on satisfactory validation of the equipment. The advice of an AE(D) should be sought.

Mechanical services

Heating

4.164. The controlled environments should be heated by the mechanical ventilation system. There should be no hot water radiators in the decontamination area of the EDU as these can form dust traps. The heat emitted by equipment in a decontamination facility can be significant and this should be taken into account in the design.

Temperature controls

4.165. Heating systems should be time-controlled to provide the required temperature during the working day and a reduced temperature of approximately 12 to 15ºC outside of working hours. An override system should be in place where there is a change to standard working hours.

Ventilation

4.166. The design rationale for ventilation of EDU models is one based on staff protection and comfort. However, in all new build EDUs and upgrades to existing EDUs where installation of such ventilation is possible, a ventilation supply and extract system should be chosen such as to maintain relatively clean areas at positive pressure with respect to relatively dirty areas to minimize risks of cross contamination. As the ventilation system does not provide the primary source of protection for devices being reprocessed, all other measures designed to minimize device contamination must be strictly adhered to, for example automated cleaning processes and work procedures.

4.167. Ventilation requirements includes the statutory requirements from COSHH and the Health and Safety at Work Act.

4.168. The ventilation system should remove heat, vapours, aerosols, and gases at source. Refer to SHTM 01-06: 2023 series for requirements of decontamination equipment.

4.169. Ventilation supply plant should include a prefilter and a secondary filter. Filters should be readily accessible for replacement, with a gauge indicating clearly to the lay user, when they require to be changed. Filters should only be changed outwith operational times and sufficient time should be allowed post fit for the air quality in the area to recover to satisfactory levels before reprocessing devices.

4.170. Extract discharge arrangements for extract systems should be protected against back-pressure from adverse wind effects and consider staff/ public safety.

4.171. Supply and extract ventilation systems should include controls and indicated control panels in the plant room/ space to confirm satisfactory operational status of each system. Alarms should be repeated wherever necessary to ensure they are dealt with timeously. Indication and alarm status of the ventilation system should be provided in the area where devices are washed and also where inspected if a separate area.

Ventilation - single room EDU

4.172. The air-handling system should extract potentially infectious aerosols and maintain room temperature and relative humidity to an acceptable comfort level taking account of the Temperature/ Relative Humidity (T/RH) effects from room equipment. This system should provide, at least, the minimum fresh air requirements of 8 litres/ second/ person.

4.173. The supply air should enter the room through a ceiling diffuser. The diffuser could be fitted in the ceiling at either side of the room. The air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard British Standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 7 AC/h with no recirculation of the supply air.

4.174. The air extract could be through a grille fitted in the ceiling or the wall close to the cleaning activity in the sinks for example at 600mm above the worktop between the test, wash, and rinse sinks. The air extract should be at 10 AC/h. The room pressure should be not positive with respect to adjoining areas.

4.175. It is clear that in this model there is potential for contamination, including that from the ‘dirty stages’ of the cleaning process, to settle out in the clean areas of the decontamination process, such as in the inspection area. The environmental cleaning regime in place should take account of this.

Ventilation - two room EDU

4.176. The air-handling system should maintain room temperature and relative humidity to an acceptable comfort level taking account of the T/RH effects from room equipment and provide minimum fresh air requirements of 8 litres/ second/ person. The Inspection, Storage and Dispatch Room should be positive pressure with respect to adjoining areas.

4.177. The supply air should enter the room through a ceiling diffuser. The air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 10 AC/h.

4.178. The air extract of 7 AC/h should be sufficient to maintain the room temperature and relative humidity at comfort levels taking account of the equipment in use in the room. Where an ante room is used air extract would be from both the Inspection/ Storage/ Dispatch Room and its ante room with a wall mounted extract grille connecting the Inspection/ Storage/ Dispatch Room to its ante room.

Wash room of two room EDU

4.179. The air-handling system should extract potentially infectious aerosols, maintain room temperature and relative humidity to an acceptable comfort level taking account of the T/RH effects from room equipment and provide the minimum fresh air requirements. The Wash Room should be at negative pressure with respect to adjoining areas.

4.180. The supply air should enter the room through a ceiling diffuser. The supply air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 7 AC/h. There should be no recirculation of the supply air. Where an ante room is installed the supply air should be fed into both the Wash Room and its ante room with a wall mounted extract grille connecting the Wash Room and its ante room.

4.181. The air extract should be through a grille fitted in the ceiling or the wall of the Wash Room close to the cleaning activity in the sinks such as at 600mm above the worktop between the test, wash, and rinse sinks. The air extract should be at 10 AC/h.

Ventilation - two room EDU with ante and other support rooms - used goods reception

4.182. The air-handling system should extract potentially infectious aerosols, maintain room temperature and relative humidity to an acceptable comfort level taking account of the T/RH effects from room equipment and provide the minimum fresh air requirements. The supply air should enter the room through a ceiling diffuser. The supply air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 7 AC/h. There should be no recirculation of the supply air. The air extract should be through a grille fitted in the ceiling. The air extract should be at 10 AC/h. The Used Good Reception Room should be at negative pressure with respect to adjoining areas.

Two room EDU with ante and other support rooms - wash room

4.183. The air-handling system should extract potentially infectious aerosols, maintain room temperature and relative humidity to an acceptable comfort level taking account of the T/RH effects from room equipment and provide the minimum fresh air requirements. The supply air should enter the room through ceiling diffusers. The supply air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 7 AC/h. There should be no recirculation of the supply air. The air extract should be through grilles fitted in the ceiling close to the cleaning activity in the sinks. The air extract should be at 10 AC/h. The Wash Room should be at positive pressure with respect to the Used Goods Reception and negative pressure with respect to all other areas.

Two room EDU with ante and other support rooms- inspection room

4.184. The air-handling system should maintain room temperature and relative humidity to an acceptable comfort level taking account of the T/RH effects from room equipment and provide minimum fresh air requirements of 8 litres/ second/ person.

4.185. The supply air should enter the room through ceiling diffusers. The air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 10 AC/h.

4.186. The air extract of 7 AC/h should be sufficient to maintain the room temperature/ relative humidity at comfort levels taking account of the equipment in use in the room. The Inspection Room should be at positive pressure with respect to all adjoining areas.

Two room EDU with ante and other support rooms - storage and dispatch room

4.187. The air-handling system should maintain room temperature and relative humidity to an acceptable comfort level taking account of the T/RH effects from room equipment and provide minimum fresh air requirements of 8 litres/ second/ person.

4.188. The supply air should enter the room through ceiling diffusers. The air should be filtered using a filter of minimum ISO ePM2.5, 80% as filter standard BS EN ISO 16890-1: 2016. The air supply should be a minimum of 10 AC/h.

4.189. The air extract of 7 AC/h should be sufficient to maintain the room temperature and relative humidity at comfort levels taking account of the equipment in use in the room. The Storage and Dispatch Room should be at negative pressure with respect to the Inspection Room and at positive pressure with respect to all other areas.

Hot and cold water services

4.190. Guidance on the design and installation of hot and cold water supply and distribution systems is contained in SHTM 04-01: 2014 Water safety for healthcare premises part A: Design, installation, and testing. All installations must comply with the Water Regulations and Scottish Water Bye Laws. As a result, Scottish Water may require to be informed of some water systems being installed. If the premises use private water supplies, then the installation must comply with the Private Water Supplies (Scotland) Regulations.

4.191. The manufacturer of the EWD shall specify the requirements for water supplied to the EWD. Consult the endoscope manufacturer's reprocessing instructions to confirm the intended water quality used to reprocess the scope is fit for purpose with regard to patient safety and scope functionality. See SHTM 01-06: 2023 series regarding the water treatment equipment and the water used for final (post disinfection) rinsing of endoscopes. Consult an AE(D) regarding this matter.

Compressed air

4.192. Where a separate compressed air supply is required for equipment's pneumatic controls, it may be supplied from the site's pneumatic control system or duplicate compressors. Consideration should be given to the drying of air supplies and space requirements.

Decontamination Equipment

4.193. Guidance on choice, procurement, installation, and validation of decontamination equipment is given in SHTM 01-06: 2023 series. Advice should be sought from an AE(D).

Electrical services

Electrical installation

4.194. Electrical installation should comply with SHTM 06-01 parts A and B: 2015 Electrical services supply and distribution design considerations and operational management. SHTM 06-01: 'Electrical services supply and distribution' replaced SHTM 2007: 'Electrical services supply and distribution' and SHTM 2011: 'Emergency electrical services', and absorbed SHTM 2014: 'Abatement of electrical interference'.

4.195. The point of entry for the electrical supply will be a switchboard housing the main isolators and distribution equipment. This space will also be the distribution centre for subsidiary electrical services. Supplies should be metered in such a way as to make the EDU consumption identifiable, and whenever possible, equipment should be mounted at a height that gives easy access from a standing position. Switchgear should be lockable in the 'off' position.

4.196. The electrical installation in occupied areas should be concealed using thermoplastic-insulated cables and screwed conduit or trunking to provide mechanical protection (in certain circumstances, mineral insulated, metal sheathed may be used depending on requirements). External installations should use thermoplastic-insulated cables in galvanised screwed steel conduit with waterproof fittings.

Electrical interference

4.197. Care should be taken to avoid mains-borne interference, electrical radio frequency and telephone interference affecting computers and other electronic equipment used in the facility for example swipe card systems for secure entry.

4.198. Electrical products, systems and installations should not cause, or be unduly affected by electromagnetic interference in compliance with Electromagnetic Compatibility Regulations.

4.199. Guidance on the abatement of electrical interference is given in SHTM 06-01: 2015.

Lighting

4.200. Fluorescent luminaries should comply with BS EN 55015: 2019+A11: 2020 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment.

4.201. The lighting solution should comply with the Health and Safety (Display Screen Equipment (DSE)) Regulations where appropriate.

4.202. Luminaires should be located to enable ready access for lamp changing and maintenance. Energy efficient luminaires should be used unless their use can be shown to be inappropriate.

4.203. Safety lighting should be provided on primary escapes routes in line with SHTM 06-01: 2015 'Emergency electrical services'.

4.204. The design team should ensure that emergency lighting conforms to the emergency procedures and site contingency plan.

Socket - outlets and power connections

4.205. Consideration should be given to the provision of devices to protect the integrity of electronic data held on processing equipment.

4.206. Sufficient 13-amp switched and shuttered socket-outlets, connected to ring circuits should be provided to supply equipment, which supplies the decontamination process, when at maximum use that is there should be no diversity allowed in relation to process equipment, which may be in use simultaneously.

4.207. Appliances requiring a three-phase supply or those rated in excess of 13-amp single phase should be permanently connected to separate fused sub-circuits. The sub-circuits should be fed from the distribution board and terminate at a local isolator. The design team should agree on the location, type (flush or surface mounted), form of indication, IP rating, construction, type of cable outlet, facilities for locking of isolator in the off position and labelling of such isolators.

4.208. Heating appliances and automatic equipment should have indicator lights to show when they are energised. Indicators should be incorporated in the control panel of the apparatus, in the control switch, or in the socket-outlet from which the apparatus derives its supply.

4.209. The electrical supply connections to electro-medical equipment should comply with the relevant SHTMs.

4.210. Socket-outlets should be connected to essential circuits in accordance with the advice in SHTM 06-01: 2015.

4.211. Isolation switches should be provided adjacent to all engineering plant and equipment for use by maintenance staff. The location, type and facilities provided on the isolation of

switches should be agreed with the Senior Authorised Person (Low Voltage) (AP(LV)) to ensure that the fixed installation enables NHS Board policies on low voltage operations to be maintained in the EDU. Such communication should be in writing and allow sufficient time for adequate consideration given the AP(LV)'s other duties.

Emergency electrical supplies

4.212. Requirements for connection of individual circuits and items of equipment to Uninterruptible Power Supply (UPS) and/ or standby generation systems should be discussed with users and with equipment suppliers and be compliant with SHTM 06-01: 2015. The UPS should be provided with a bypass for failure or maintenance purposes. Designers should undertake a risk assessment with the planning team to identify the operational impact when an electrical supply is not available.

4.213. All critical infrastructure including security, communication, clock, and alarm systems should be supplied from 'essential circuits.'

Internal/ external communications

4.214. Central telephone facilities for internal and external calls should be extended to serve this department. Facilities for communication between separate rooms should be provided.

Electronic data gathering

4.215. Cable routes for data links should be provided between rooms as required.

Internal drainage

4.216. The main objective is to provide an internal drainage system which:

- safely and effectively carries waste fluids away to the water authority sewer, uses minimum pipe-work work, remains water and airtight and is sufficiently ventilated to retain the integrity of water seals
- has a design of internal drainage that complies with SHTM 04-01 Part A: 2015 regulations
- have drains from washer-disinfectors that comply with local water regulations. Guidance is given in SHTM 01-06: 2023
- has a gradient of branch drains that is uniform and adequate to convey maximum discharge to the stack without blockage

5. Construction and procurement

Control of design

5.1. Construction activities should not commence until a full set of documentation has been prepared, agreed, and signed off by the board. A master list should be controlled and available throughout the project. The board should have identified their responsible person for the master list including change management during construction. The full set of documentation includes: the Endoscope Decontamination Unit (EDU) department layout drawing(s) at 1:200 scale accounting for all levels, a site drawing showing infrastructure, for every room in the department individual room layout drawings at 1:50 scale (there may be more than one for each room) and environmental matrix. The 1:50 individual room layouts should contain equipment schedules with equipment/ furniture and fittings specified. Other mechanical and electrical drawings will require to be approved and be part of the master list, for example ventilation layouts.

Working groups in operation during construction

5.2. There may be a range of working groups, some technical, some delivery in operation during construction. An awareness of the significant time commitment required should have been identified at the business case stages. EDU managers managing an existing facility while involved in the new build project will require substantial additional support to be able to actively participate in these working groups while still running a service.

Control of procurement

5.3. Board procurement should procure as per the specification given in the equipment schedules of the individual rooms 1:50s layouts drawings as cited in the controlled master list. Items to be procured by others should be made clear in the equipment schedule. There are examples of where lack of scrutiny during procurement has led to project delays/ increased costs. These include:

- an equipment supplier providing a quotation which may include options that are in fact requirements
- services to equipment not being provided during the construction such as hot and cold water supply and extract ventilation

5.4. At the early stage of design work, equipment may be identified for purchase but at the time of placing the order the equipment sought is not available or has a long lead time. Design controls/ change management needs to be in place if alternative equipment/ components are required to be procured.

Construction plan

5.5. General roles, responsibilities and activities should be described and assigned within the construction plan along with a schedule, a quality plan, and a clean build protocol. All contractors' and sub-contractors' activities should be coordinated for the duration of the entire project. Responsibility for this coordination should be defined as a part of the construction plan.

5.6. Schedule construction activities should be coordinated using a schedule that documents timing, sequence, and key milestones for the project. The plan should include the major items of decontamination equipment. Each (of these) should detail the services required such as compressed air, cold water, hot water, extract ventilation and location of drains. The plan should detail when water pipework comes online. Temporary storage space should also be identified for delivery of the potentially significant volume of furniture/ fittings associated with the decontamination equipment. The concrete slab should not be poured until the location of the drains for all the decontamination equipment to be installed (or for future additional machines) has been specified on approved drawings on the master list.

5.7. Planning the go live of water systems should be clearly identified in the program. Achieving the satisfactory quality of water can take time and should be adequately allowed for in the program. For example, several disinfection exercises may be required over several weeks to arrive at acceptable microbiological levels in the water. Delays at this point may result in delays to contractors carrying out commissioning of decontamination equipment such as the endoscope washer disinfectors (EWDs) and other equipment requiring a water supply such as the Reverse Osmosis (RO) plant (see Scottish Health Technical Memorandum (SHTM) 04-01 part A: 2014).

Quality plan

5.8. A quality plan should be developed in consultation with relevant stakeholders and should consider procedures for:

- identifying changes that require an agreement
- identifying and documenting deviations
- assessing the impact of the consequences of these changes and deviations
- approval, by appropriate designated staff, of changes, deviations, and corrective actions
- documenting the control of construction activities and information
- responsibility
- management of documentation
- clean build protocol

5.9. A clean build protocol should be considered for the construction project. Application across all construction and assembly related activities both on and off the construction site, should be considered. Examples of requirements for a clean build protocol include:

- the construction site should be protected from the external environment at the earliest practical opportunity
- areas should be provided for the set down of materials, including sufficient space for the inspection of incoming materials
- critical components, such as final filters, should be protected from contamination and impact until fixed in their final position
- materials that are delivered to site in a clean condition, such as Heating Ventilation and Air Conditioning (HVAC) ducting, should be kept clean

5.10. Considerations should be given to include training and instruction for all personnel attending the construction site, including visitors. This should outline safe working procedures and assist in ensuring good workmanship, correct conduct on site and adherence to any clean build protocol implemented on site.

Construction verification during construction

5.11. A systematic set of verifications should be carried out throughout the construction to ensure that each part of the construction process is compliant with the agreed design documentation.

5.12. Some points to note during construction:

- cable trays should not be overloaded with cables and allow for spare capacity in place
- cable trays should be equipotential bonded
- cable ties should be metal and not plastic
- permanent quality labels should be in place for valves, cables, control panels and fixtures as safety isolators
- ceiling access hatches where allowed should be of suitable finish and clear access provided for the services being accessed, that is there should be no obstructions such as from cable trays, baskets, or ladders

Modular build

5.13. A module that is constructed offsite at a factory and has equipment/furniture and fittings installed in the module before leaving the factory site should allow good quality control conditions under a factory's quality management system with temperature control and good lighting conditions.

5.14. A module that is fitted out at the factory may allow customer visits at various stages to verify the construction is in line with the customer's expectations. Certain amendments if required

may be more easily dealt with at the factory as opposed to modifications onsite to an EDU under construction.

5.15. There are some unique challenges presented by modular construction. It is recognised that transporting modules from the factory site to the customer's site will likely result in some cracking of the module(s). This should be discussed with the supplier and agree how this is to be addressed once the module(s) arrives on site.

5.16. Experience indicates that storage of modules pending delivery or while stored in other locations can result in environment damage if insufficient protection is in place.

6. Verifying the construction, installation qualification and operational qualification

Decontamination equipment installation and operational qualification

6.1. The design information including the 1:50 relevant room layouts should have detailed the type and number of each type of decontamination equipment. The Installation Qualifications (IQ) and Operational Qualifications (OQ) of the decontamination equipment may be carried out prior to or at the same time of the IQ and OQ checks of the new decontamination facility. The equipment validation [IQ and OQ] stage is outlined in Health Facilities Scotland (HFS) publication Scottish Health Technical Memorandum (SHTM) 01-06 part A: 2023. These equipment qualifications are for fixed processing equipment. These qualifications should include the confirmation that the services (such as water, compressed air, extract ventilation, drains) provided to these machines are satisfactory. Further, the building fabric around these machines should be confirmed as finished to the required quality during the equipment installation. The subsequent construction verification exercise should include inspection of the building fabric finish quality around these machines.

Water quality confirmation impacting on the build program

6.2. The water supply used as that provided by Reverse Osmosis (RO) plant should be validated prior to connection of the feed water to decontamination equipment such as Endoscope Washer Disinfectors (EWDs). Confirmation of satisfactory microbiological water quality can take several weeks (or months if multiple disinfection exercises are required) and should be allowed for in the build program. Commissioning of certain decontamination equipment (such as washer disinfectors) cannot commence until the water supply quality is confirmed.

Construction verification

6.3. A systematic set of verifications should be carried out at the end of the construction stage to ensure that it compliant with the agreed design documentation.

The facility installation qualification

6.4. Using the current approved master list of documentation each room within the Endoscope Decontamination Unit (EDU) should be visually inspected to confirm:

- it is compliant with the content of its 1:50 layout drawing
- the quality of the fabric finish is satisfactory

6.5. Items within the EDU site but external to the building should also be confirmed as being located as per the site data sheet.

6.6. Any variances found in the layout drawings should be logged and an action plan set to revise the drawings. Once revised and confirmed as satisfactory the master list of documentation should be updated.

6.7. Any issues found with the quality of the fabric finish should be addressed and an action plan set to achieve the required quality. Once completed the fabric finish should be confirmed in the facility IQ report as being satisfactory.

The facility operational qualification

6.8. Using the current approved environmental matrix each room should be checked to confirm it meets the specification details in the matrix. It should be verified that there are as-built layout drawings at 1:50 scale for every room and for the department layout at 1:200 scale. Other as built drawings for the services should also be verified. Confirm that all necessary operating/ maintenance instructions have been received for any relevant facility fixtures/ fittings/ systems.

6.9. At the conclusion of the construction process a set of as-built drawings (if the IQ found discrepancies), operating instructions and construction verification results should be provided in a timely manner.

6.10. In order to prepare for start-up provision of the following information should be considered:

- checks and inspections to be completed prior to bringing the installation and systems into operation
- procedures to start, stop and restart the installation under normal and failure mode situations
- acceptable ranges of the performance parameters
- off peak and turn-down procedure
- procedures to follow when alert or action limits being reached
- information on how to operate airlocks and pass-through hatches
- calibration, operation, and maintenance information for on the monitoring system
- procedure for verification and testing after maintenance activities

6.11. Visual verification of the quality/ integrity of finish of fabric is required. A snagging process should identify any areas requiring attention.

6.12. Clean down of the facility is arranged and documented by the principal contractor.

6.13. Initial testing of air handling system to determine impact of turn-down on pressure differential cascade (these findings will inform the testing under Performance Qualification (PQ) conditions).

Handover - what it is and is not

6.14. The handover of the facility should be defined and agreed between the principal contractor and the board and documented. During the design qualification it should be clear what equipment is to be installed by the principal contractor and the equipment to be installed by board assigned contractors such as suppliers of EWDs. As the quality of room fabric finish can impact room performance it should be clear which parties are responsible for ensuring the required quality is delivered.

6.15. Handover by the principal contractor to the board at the end of the construction and prior to the facility PQ is not acceptance by board that the facility is fit for purpose (and satisfactory). Acceptable results reported at the PQ of facility conducted/ arranged by the board provide evidence of a satisfactory build. The principal contractor should have been made aware of this at the start of the project to avoid disputes at the end of the project. Contractors that install decontamination equipment such as endoscope washer disinfectors (EWDs) are not under principal contractor control.

Functional verification

6.16. Upon completion of the setting to work phase a set of functional tests should be executed to confirm satisfactory technical function of the rooms. The following tests are required out as part of functional verification:

- door interlock function and timing
- supply air volume flow rate/ airflow at each supply grill
- air-handling systems pressure drops
- room pressure differentials
- temperature and humidity test
- noise and light levels
- failure modes tests (fan interlocks, stand-by systems)
- energy consumption and efficiency evaluation - operational and turn-down

7. Verifying performance on start-up, the performance qualification

The performance qualification protocol

7.1. The Performance Qualification (PQ) protocol agreed by the Endoscope Decontamination Unit (EDU)'s quality management team should identify that the following records/ documents are available:

- Installation Qualification (IQ) data and reports signed as approved
- Operational Qualification (OQ) data and reports signed as approved
- PQ data
- Performance verification

Decontamination equipment

7.2. The performance qualifications of the decontamination equipment should be compliant with requirements in the Scottish Health Technical Memorandum (SHTM) 01-06: 2023 series. Any item of decontamination equipment not in the scope of the SHTM should be validated to the latest relevant standard.

Facility

7.3. Upon completion of setting to work and functional verification phases, a set of performance tests should be executed to confirm satisfactory performance. The following tests are required as part of performance verification:

- air temperature/ relativity humidity controlled within in this planning note limits
- pressure differentials controlled within limits specified in this planning note

7.4. After satisfactory OQ and any subsequent clean down activity, verification tests should be of sufficient duration to demonstrate consistent performance. Real production or simulated production may be used provided it is a true reflection of testing under the operational occupancy status for the EDU. For example, the air temperature/ relative humidity (T/RH) and the pressure differentials should be demonstrated over three working days (that is in the operational occupancy state) to be within limits.

The performance qualification report

7.5. The PQ report should confirm the following:

- the design qualification report of the facility was completed, satisfactory and signed as approved by the board

- the installation and operational qualifications reports of the facility were completed, satisfactory and signed as approved by the board
- the performance qualification requirements detailed in the protocol for equipment and the facility were completed and were satisfactory, reported in the PQ report and confirmed by the EDU's quality management team
- any change management activities throughout the project should be listed and the final list agreed as satisfactory
- if there any outstanding actions a corrective action plan should be included in the report

Warranties

7.6. These should only become active after a satisfactory performance qualification report is published.

Training

7.7. Management should ensure that the personnel operating and maintaining the installation are competent for their assigned duties and have received appropriate training for the specific installation in preparation for handover. Training should include relevant practices for energy management and maintenance. The responsibility for providing training should be defined. Training should be carried out as specified and documented.

Maintenance instructions

7.8. Maintenance activities and their frequency should be defined and implemented as per the manufacturer's instructions. Impact on the installation and processes should be considered when planning and executing all maintenance activities. A record of any maintenance carried out upon the installation during start-up should be maintained. A record of all training given should be maintained. Training content, identification of personnel providing and receiving the training and training date and duration should form part of the record.

8. Routine production and maintenance

Operational policies

8.1. The following operational policies should be followed.

Leak testing, cleaning, and disinfection

8.2. A pre-clean of the endoscope should be carried out in the clinical area prior to transfer to the Endoscope Decontamination Unit (EDU). This involves removal of gross contamination by wiping outer surface and flushing of all channels. All devices returned to the EDU should be treated as potentially contaminated and be subjected to standard infection control precautions. A leak test should be carried out prior to pre-cleaning. Cleaning should completely remove all soiling. Thorough pre-cleaning followed by automated cleaning and chemical disinfection minimises the infection risk to staff and patients. Cleaning and disinfection should be carried out in a validated endoscope washer disinfector (EWD) in line with the requirements of Scottish Health Technical Memorandum (SHTM) 01-06: 2023. EWDs should be of the pass-through type where possible as per the preferred two room models. At the end of the process, clean, disinfected, and dry (by EWD or other method) endoscopes should be inspected for cleanliness/ dryness and tested and/ or inspected for functionality but should not be compromised by unnecessary further handling. For operational reasons endoscopes may require to be dried in the storage cabinets that have a drying function. In these cases, inspection of the endoscope for cleanliness is carried out prior to placing it into the storage cabinet. Manufacturer's instructions for reprocessing should be consulted to ensure they are compatible with the operational policies defined above.

Staff protection

8.3. The type and nature of the Personal Protective Equipment (PPE) for example protective clothing, eye protection and face mask for the dirty processes of the EDU should be specified based on a Control of Substances Harmful to Health (COSHH) and Infection control risk assessment for the area. Visitors for example maintenance staff should also wear appropriate PPE within the EDU.

Education and training

8.4. All staff working within the EDU should have initial and regular ongoing training and competency assessment. The documented training scheme requires training records for each individual to be kept, identifying that they have the required competency to carry out their assigned duties. A skills register should be maintained.

Traceability

8.5. A system allowing the tracking and tracing of medical devices passing through the EDU (and any storage cabinet/ system) should be in place. For each item of decontamination equipment, a log should be kept for each cycle detailing the devices processed, personnel involved and the parameters of the cycle. Each process event can be recorded either manually or on an Information Technology (IT) system along with the cycle number (EWD) and the person responsible for carrying out each stage of the process. Tracking of devices to the patients on whom they are used is a requirement (NHS Management Executive Letter (MEL) (1999)65)).

Domestic services

8.6. High standards of cleanliness are essential throughout the EDU. Dedicated and appropriate cleaning equipment and materials should be available for the EDU. Cleaning should be managed to minimise the risk of transferring contamination from a dirty area to a clean area. With a Two Room EDU this can be achieved, by having separate Domestic Service Rooms (DSRs) for the wash room and the inspection/ storage/ dispatch room with dedicated cleaning equipment/ consumables. Or alternatively, separate clearly identified cleaning equipment, for each area, would be stored in a single DSR located outwith the EDU rooms. With the Single Room EDU, dedicated cleaning equipment would be used such that cleaning commences at the clean zone and works back towards the dirty zone of the decontamination area. The DSR should be designed and fitted out to enable storage of cleaning equipment in a clean, dry, and tidy manner, and cleaning products in accordance with the requirement of the COSHH Regulations. A cleaning schedule should be produced which specifies materials and methods to be used, the frequency of cleaning and the persons responsible for carrying it out. The endoscope operator may also have assigned cleaning duties. The cleaning schedule should be approved by the person with designated responsibility, for example a microbiologist or infection control nurse and should be monitored by the person responsible for the EDU. Reference should be made to the Scottish Health Facility Note (SHFN) 01-02: 2016 NHSScotland National Cleaning Services Specification published by Health Facilities Scotland (HFS). Environmental cleaning Floor cleaning equipment should consist of a mop and two-bucket system with free rinsing neutral detergent in hand hot water. A high-efficiency particulate air (HEPA) filtered exhaust vacuum cleaner should be used. Rotary scrubbers should not be used unless all devices are first removed from the area and all horizontal work surfaces are cleaned after the floors. Work surfaces should be cleaned with a non-linting cloth and a solution of neutral detergent and hand hot water as per detergent manufacturer's instructions. Walls, windows, and ceilings are cleaned with a non-linting mop or cloth and a solution of neutral detergent and hand hot water.

Waste disposal

8.7. The arrangements for handling and storage of waste awaiting collection should be formally documented and be in line with current legislation. Guidance on waste management is

provided in Scottish Hospital Technical Note (SHTN) 3: 'Management and Disposal of Clinical Waste' and the HFS 'Guide to Carriage of Dangerous Goods Regulations' with respect to soiled devices - both documents are available on the NSS website. Use identified bag holders with appropriate waste bags and with hands-free operated lids. All sharps should be disposed of at point of use and not transferred to the decontamination area. Waste should not be stored in a clean zone where it may compromise the decontamination process. In the case of a Single Room EDU the waste should be neither stored nor carried through the clean zone of the room. The cost of waste disposal should be included in the option appraisal.

Materials procurement and storage

8.8. Only materials used in the EDU and those items that are to be processed should be stored or passed through the EDU. Items should be stored in a way that allows appropriate cleaning of the area. Time, access, facilities, and training should be allowed for appropriate cleaning of the EDU. Storage of raw materials should not compromise the decontamination process in the EDU. The COSHH regulations should be considered in both design and operation. Processed endoscopes should be stored in a separate dedicated location.

Packaging and transportation

8.9. Cleaned and disinfected endoscopes should be transported in a manner which protects them from sources of water and contamination. Containment systems are available to protect the device from contamination and damage during transportation. Used devices should be transported safely from the clinical area where used to the EDU. They should be transported in solid walled, leak proof and lidded containers. For internal movement solid walled, leak proof and plastic covered container may be considered. When transported through public access areas the containers should be secure. Container labels should indicate that the contents are contaminated and give details of the sender and the intended recipient. There should be suitable facilities for cleaning all surfaces of the transit containers and trolleys between use. A documented cleaning procedure should be used and records of cleaning kept. At the design stage the space requirements for cleaning and storage of transport containers between use should be considered.

Maintenance

8.10. There should be a maintenance procedure(s) that document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements should apply to equipment used in production, the control of the work environment, monitoring, and measurement. Records of such maintenance should be maintained.

8.11. Maintenance and testing of decontamination equipment and building fabric needs to be allowed to take place and not put off due to production pressure. Support should be given from senior management at the health board to allow essential maintenance. There should be adequate provision of estates staff to enable this maintenance to be completed in a timely manner. There should also be a procedure to describe what to do in the event of unplanned maintenance work arising from example water passing through the ceiling or the floor being flooded.

9. Post occupancy evaluation

9.1. The project plan for the build should identify that a post project evaluation will be conducted and completed in a timely fashion. The project plan should identify the individual(s) who will carry out this work and where the evaluation is to be communicated (Post Occupancy Evaluation (POE).

9.2. The POE is described in the Scottish capital investment manual Project Monitoring and Service Benefits Evaluation 2017. The evaluation has a project monitoring stage and a service benefits stage (see Figure 9.1).

Figure 9.1 - Assessing project monitoring stages and service benefits evaluation

What will be assessed:	When it will be carried out		How it will be done (approach)
	Milestone Date	Report submission	
Project Monitoring stage:			
Project Costs			
Project Programme			
Project Scope Changes			
Health & Safety Performance			
Design & Technical Aspects			
Risk Management Issues			
Service Benefits Evaluation stage:			
Expected benefits			
Stakeholder expectations			
Impact of service change			
Service activity & performance			

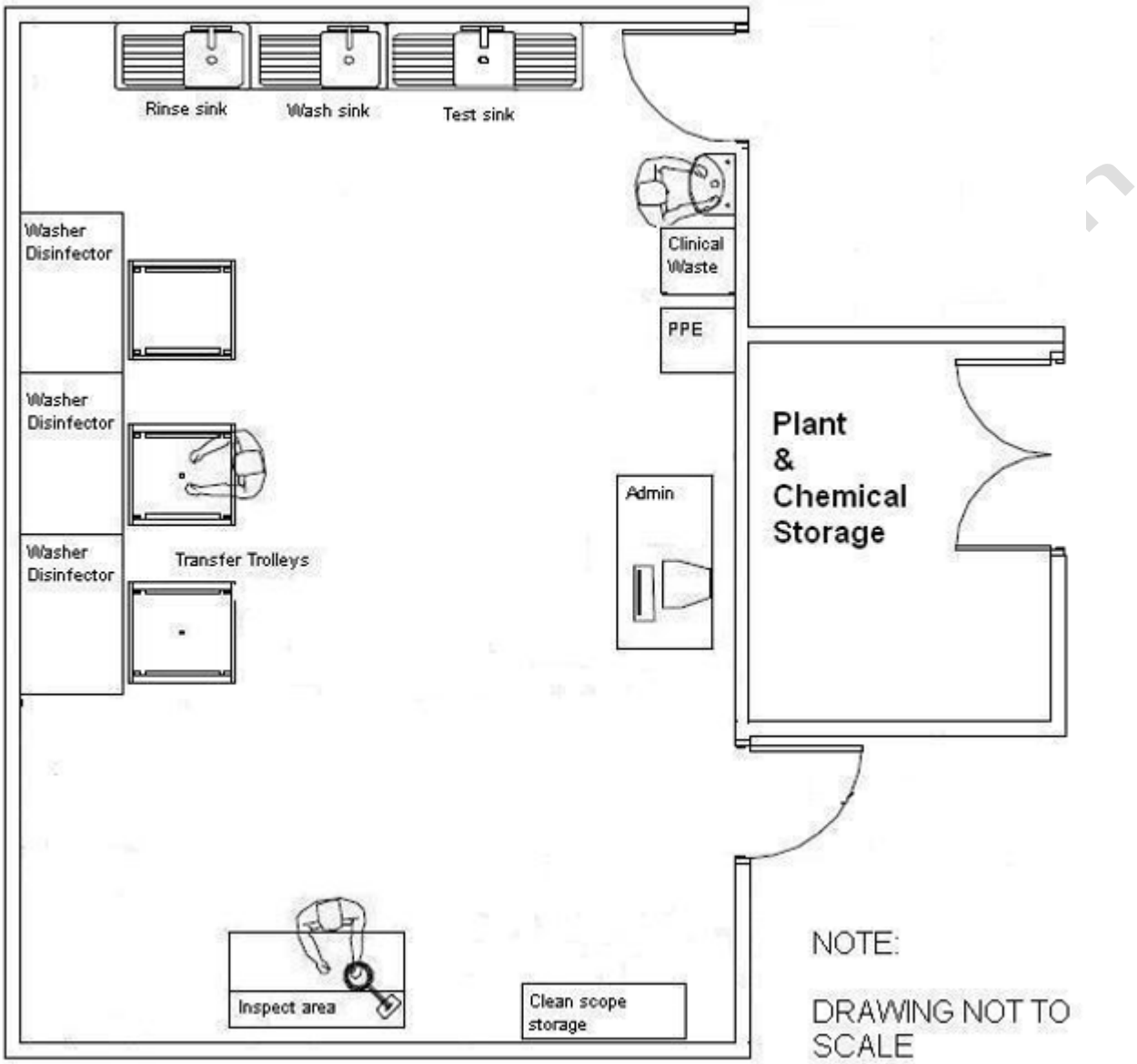
9.3. The Project Scope Changes element under the project monitoring stage in Figure 9.1 should have been summarised in the Change management activities reported in the Performance Qualification (PQ) report (see section 7). The design and technical aspects

should also have been confirmed as satisfactory in the approved and board signed PQ report.

9.4. The stakeholder expectations should have been clear in the User Requirement Brief (URB) at the start of the project and this would also be referred to in the PQ report.

Appendix A Single room EDU layout

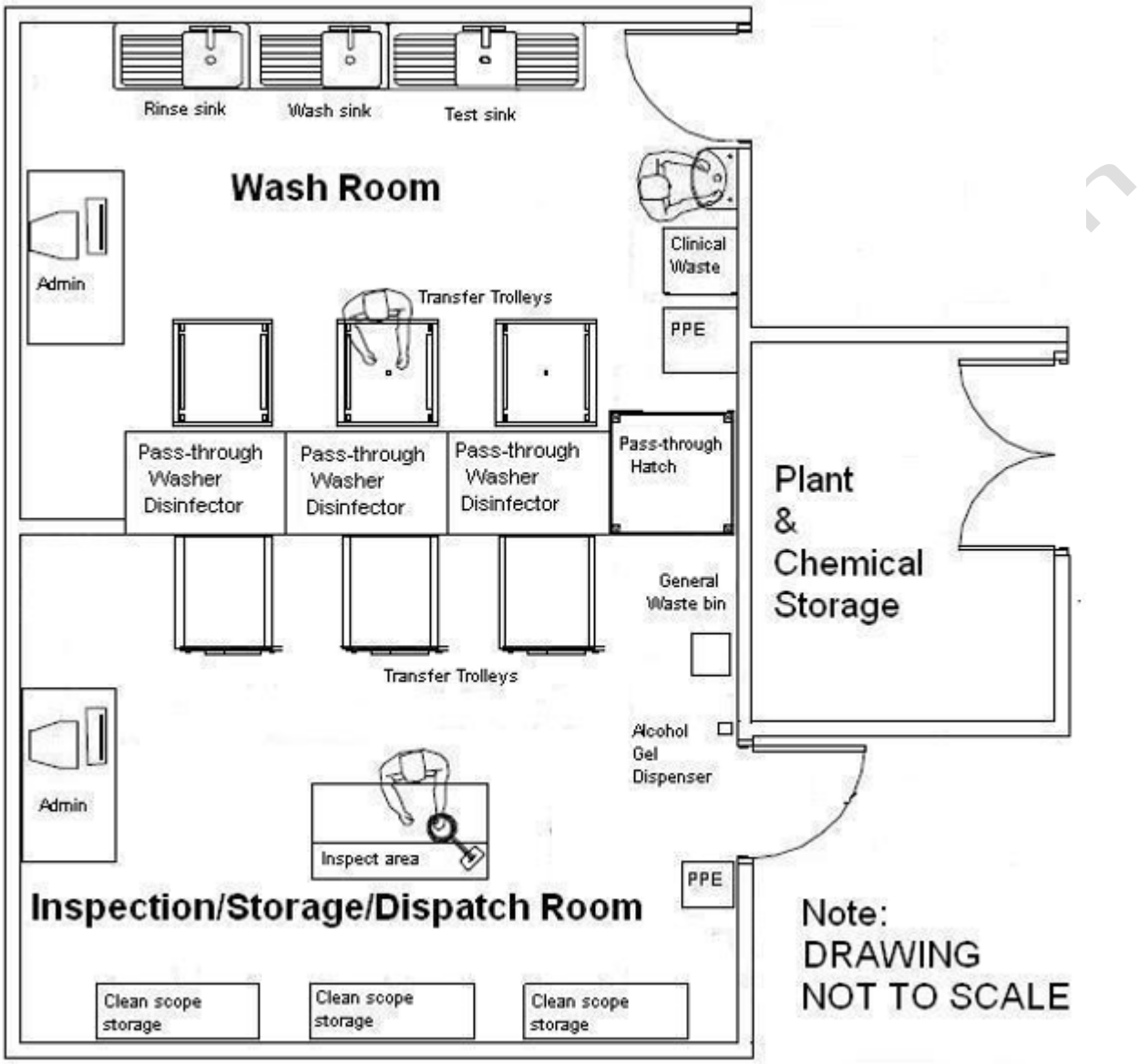
Figure A.1 - Single room EDU



A.1 The option appraisal will determine the type and number of each item of equipment. This will include the equipment required for the Plant and Chemical Storage Room. Other areas or rooms not shown are required to support this model, for example domestic services and trolley parking.

Appendix B Two room EDU layout

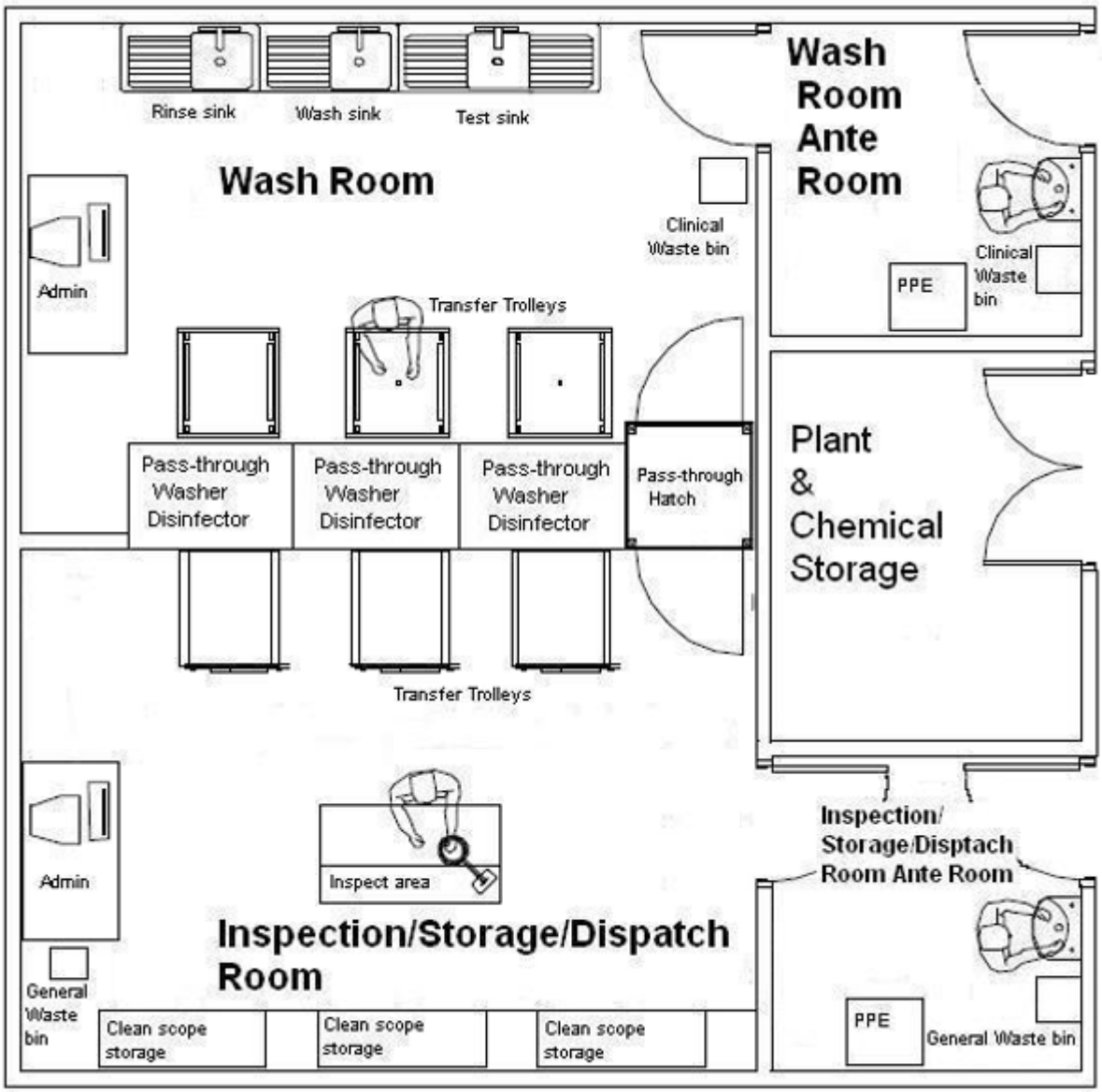
Figure B.1 - Two room EDU



B.1 The option appraisal will determine the type and number of each item of equipment. This will include the equipment required for the Plant and Chemical Storage Room. Other areas or rooms not shown are required to support this model, for example domestic services and trolley parking.

Appendix C Two room EDU with ante rooms layout

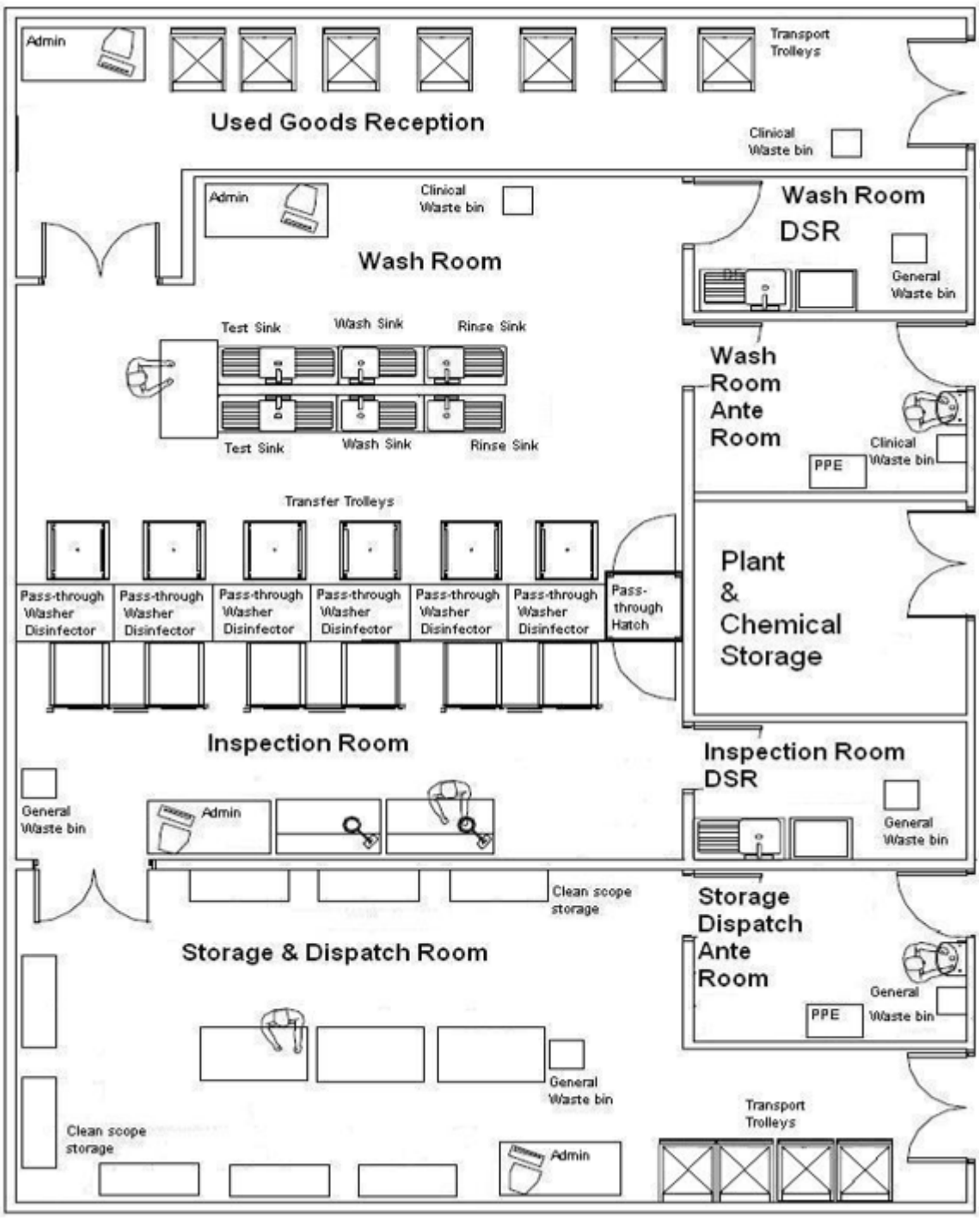
Figure C.1 - Two room EDU with ante rooms



C.1 The option appraisal will determine the type and number of each item of equipment. This will include the equipment required for the Plant and Chemical Storage Room. Other areas or rooms not shown are required to support this model, for example domestic services and trolley parking.

Appendix D Two rooms EDU with ante and other support rooms layout

Figure D.1 - Two room EDU with ante and other support rooms



D.1 The option appraisal will determine the type and number of each item of equipment. This will include the equipment required for the Plant and Chemical Storage Room.

Abbreviations

AC/h: Air Changes per hour

AE(D): Authorising Engineer (Decontamination)

AE(MGPS): Authorising Engineer (Medical Gas Pressure Systems)

AEDET: Achieving Excellence Design Evaluation Toolkit

AP(LV): Authorised Person (Low Voltage)

BMS: Building Management System

BS: British Standard

CDM: Construction Design and Management

CDU: Central Decontamination Unit

CEL: Chief Executive Letter

CIG: Capital Investment Group

COSHH: Control of Substances Harmful to Health

DL: Department Letter

DS: Design Statement

DSE: Display Screen Equipment

DQ: Design Qualification

DSR: Domestic Service Room

EDU: Endoscope Decontamination Unit

EO: Ethylene Oxide

ERCP: Endoscopic Retrograde Cholangiopancreatography

EWD: Endoscope Washer Disinfector

FBC: Final Business Case

HAI-SCRIBE: Healthcare Associated Infection Systems for Controlling Risk in the Built Environment

HDL: Health Department Letter

HEPA: High-Efficiency Particulate Air

HFS: Health Facilities Scotland

HVAC: Heating Ventilation and Air Conditioning

IA: Initial Agreement

IFU: Instructions For Use

IMS: Information Management System

IP: Index of Protection

IPCT: Infection, Prevention and Control Team

IQ: Installation Qualification

IT: Information Technology

KSAR: Key Stage Assurance Review

MEL: Management Executive Letter

MHRA: Medicines and Healthcare products Regulatory Agency

NDAP: National Design Assessment Panel

NSS: National Services Scotland

OBC: Outline Business Case

OQ: Operational Qualification

POE: Post Occupancy Evaluation

PPE: Personal Protective Equipment

PQ: Performance Qualification

PSCP: Principal Supply Chain Partner

PVC: Poly Vinyl Chloride

QMS: Quality Management System

RMD: Reusable Medical Device

RO: Reverse Osmosis

SBC: Standard Business Case

SCIM: Scottish Capital Investment Manual

SDaC: Sustainable Design and Construction

SEPA: Scottish Environment Protection Agency

SHFN: Scottish Health Facility Note

SHPN: NHSScotland Health Planning Note

SHTM: Scottish Health Technical Memorandum

SHTN: Scottish Health Technical Note

SOP: Standard Operating Procedure

T/RH: Temperature/ Relative Humidity

TOE: Transoesophageal Echocardiograph

UPS: Uninterruptible Power Supply

URB: User Requirement Brief

VMP: Validation Master Plan

Definitions

Accessory for a medical device means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/ their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s). [SOURCE: Regulation (EU) 2017/745 article 2 - (2)].

Active ingredient: chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Adventitious contamination: The unplanned introduction of environmental micro-organisms or non-viable particles/ fibres onto a medical device or product.

Air change rate: rate of air exchange expressed as number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the cleanroom. [SOURCE: BS EN ISO 14644-16:2019].

Automatic controller: device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Bioburden: population of viable microorganisms on or in a product and/ or sterile barrier system. [SOURCE: EN ISO 11737-1: 2018 section 3 definitions].

Carrier: A device that carries, conveys, or transports the load through the department via a trolley/ carriage or on a rail/track into/through a decontamination process.

Clean: visually free of soil and below specified levels of analytes. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Cleaning: removal of contaminants to the extent necessary for further processing or for intended use. Note: Cleaning consists of the removal, usually with detergent and water, of adherent soil (for example blood, protein substances and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated process that prepares the items for safe handling and/or further processing. [SOURCE: EN ISO 17664: 2017 section 3 definitions].

Cleaning agent: physical or chemical entity, or combination of entities, having activity to render an item clean. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Cycle complete: message from the automatic controller that the operating cycle has ended successfully. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Decontamination: A combination of processes, including cleaning, disinfection and/or sterilization, used to render a reusable item safe for further use.

Decontamination: refer to definitions for “processing” and “reprocessing.”

Diffuser: device placed on inlet air supply terminal to improve distribution of incoming air with room air Note 1 to entry: A mesh grille or a perforated screen is not considered to be a diffuser. [SOURCE: BS EN ISO 14644-16 section 3 definitions].

Disinfection: process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose. [SOURCE: EN ISO 17664: 2017 section 3 definitions].

Disinfection: A process used to reduce the number of viable micro-organisms but which may not necessarily inactivate some viruses and bacterial spores.

Design Team: A multi disciplined team of relevant experts including those involved in decontamination, engineering, building and design and service users. These individuals will require to be ‘approved suppliers’ as stated in the quality management system BS EN 13485. They have the responsibility for approving the Validation Master Plan for delivery of the EDU.

Duplex systems: Two identical systems that are capable of operating independently with the intention of allowing continuity of the service while one of the systems is out of use due to a breakdown or undergoing routine maintenance. Note, systems have been sold as ‘duplex’ but still share common elements for example control panels or storage tanks.

Endotoxin: lipopolysaccharide component of the cell wall of Gram-negative bacteria that is heat stable and elicits a variety of inflammatory responses in animals and humans. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Heat-labile: That which is likely to be damaged or destroyed by the normal heat disinfection process.

Installation Qualification (IQ): is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification. [SOURCE: EN 285: 2015].

Instructions for use (IFU): means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken. [SOURCE: Regulation (EU) 2017/745 article 2 - (14)].

Invasive device: means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. [SOURCE: Regulation (EU) 2017/745 article 2 - (6)].

Labelling: label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. [SOURCE: EN ISO 13485: 2016 section 3 definitions].

Life-cycle: all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: EN ISO 13485: 2016 section 3 definitions] product, equipment, or materials to be processed together within an operating cycle. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Load: Collectively, all the goods, equipment and materials that are put into a sterilizer or washer-disinfector at any one time for the purpose of processing it.

lumen device: item that consists of tube(s) or pipe(s). [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; and control of conception: and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC).

Manual cleaning: Manual cleaning -removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process. [SOURCE: EN ISO 17664: 2017 section 3 definitions].

Medical device: means any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception
- products specifically intended for the cleaning, disinfection, or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [SOURCE: Regulation (EU) 2017/745 article 2 - (1)]

Microbial contamination: presence of unintended bacteria, fungi, protozoa, or viruses. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Microbe-carrying particle: particle on which a microorganism is carried, normally dispersed into room air by personnel as a skin cell, or fragment of skin cell, on which a skin microbe(s) is carried. [SOURCE: BS EN ISO 14644-16: 2019].

Microbial contamination: Deposition of viable or potentially viable elements of bacteria, fungi, or viruses onto or within articles previously rendered free of them.

Operational Qualification (OQ): is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures. [SOURCE: EN 285: 2015].

Particulate: Minute portions of matter which may cause contamination.

Performance Qualification (PQ): is defined as the process of obtaining and documenting PQ evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.

Periodic testing: is a series of tests carried out at daily, weekly, quarterly, and yearly intervals.

Process chemical: formulation of chemical compounds intended for use in a washer-disinfector. Note: Process chemicals include for example detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners. [SOURCE: EN ISO 15883-1: 2014 section 3 definitions].

Processing: activity to prepare a new or used healthcare product for its intended use. Note processing includes cleaning, disinfection, and sterilization (if necessary and applicable). A healthcare product refers to a medical device. [SOURCE: EN ISO 17664: 2017 (published 25 October 2017) section 3 definitions].

Processor: organization and/or individual with the responsibility for carrying out actions necessary to prepare a new or reusable healthcare product for its intended use. Note a healthcare product refers to a medical device. [SOURCE: EN ISO 17664:2017 section 3 definitions].

Process challenge device PCD: item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. [SOURCE: EN ISO 11138-1: 2017 section 3 definitions].

Product family: group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Protective packaging: configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use. [SOURCE: EN 11607-1: 2017].

Quality Management System (QMS): In this planning note the QMS is taken to be that as defined in BS EN ISO 13485:2003.

Reference load: specified load created to represent combinations of items that provide defined challenge(s) to a process. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Relative humidity: measure of water vapour in the air expressed as a percentage of the maximum for a given temperature. Note 1 to entry: It is expressed as a percent. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Reprocessing: means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device. [SOURCE: Regulation (EU) 2017/745 article 2 - (39)].

Reusable medical device (RMD): medical device designated or intended by the manufacturer as suitable for processing and reuse. Note: This is not a medical device that is designated or intended by the manufacturer for single-use only. [SOURCE: EN ISO 17664: 2017 section 3 definitions].

Room Data Sheets: In this planning note the Room Data Sheets provide detailed specifications and lists to consider on:

- design
- finish
- mechanical and electrical
- equipment/ furniture/ fittings

Seal integrity: <packaging> characteristics of a seal to minimize the risk of ingress of microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Service life: number of processing cycles and/or life-time that a medical device can be subjected to and remain suitable and safe for its intended use. [SOURCE: EN ISO 17664: 2017 section 3 definitions].

Single-use medical device: medical device designated or intended by the manufacturer for one-time use only. Note: A single-use medical device is not intended to be further processed and used again. [SOURCE: EN ISO 17664: 2017 section 3 definitions].

Single-use device: means a device that is intended to be used on one individual during a single procedure. [SOURCE: Regulation (EU) 2017/745 article 2 - (8)].

Single patient use: means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use. [SOURCE: Ref Page 14 - Medicines and Healthcare products Regulatory Agency (MHRA) Single-use medical devices: implications and consequences of reuse December 2013].

Source strength: rate describing the number of particles or colony-forming units emitted from an object per time unit. Note 1 to entry: A source can be a person, equipment, or an object. [SOURCE: BS EN ISO 14644-16: 2019 section 3 definitions].

Type tests: is a series of tests conducted by the manufacturer to establish the working data for decontamination equipment. For example, type test in EN 285: 2015 is a series of checks and tests for a particular design of sterilizer and type test in EN 15883-1: 2014 is a test programme to verify conformity of a washer-disinfector type to this standard and establish data for reference in subsequent tests.

Tray: A container, usually with a flat base and upturned edges, used for containing an assembly of surgical instruments for packing to be used in an aseptic procedure.

Unique Device Identifier (UDI): means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. [SOURCE: Regulation (EU) 2017/745 article 2 - (15)].

Usable chamber space: specified geometry within the chamber that is available to accept the load. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

User Requirement Brief (URB): An approved document which clearly specifies the users requirement for the EDU. It is developed and approved during the Business Case and provides input to the Design Qualification.

Upgrade: a modification to the fabric or structure of the existing decontamination facility which may impact on product quality and or service provision. Examples would include:

- the replacement or introduction of additional major decontamination equipment such as washer disinfectors or sterilizers
- replacement of air ventilation systems serving production areas

Validation Master Plan (VMP): An approved documented process which specifies the approach to be taken in the build/upgrade of the EDU. The VMP will detail the four distinct qualification exercises required. These are:

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Validation: is the documented procedure required for obtaining, recording, and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification.

Viable micro-organisms: Micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

Washing: removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary [SOURCE: EN ISO 15883-1: 2014 section 3 definitions].

Washer-disinfector WD: equipment designed to clean and disinfect product. [SOURCE: EN ISO 11139: 2018 section 3 definitions].

Works tests: series of tests performed during or after manufacture to demonstrate compliance of each equipment with the requirements of the test specified [SOURCE: EN 285: 2015].

Washer-disinfector: Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, and pharmaceutical practice.

Configuration: distribution and orientation of a load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Cycle: complete set of stages of a process that is carried out, in a specified sequence. Note 1 to entry: Loading and unloading are not part of the operating cycle. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current version of these references.

Government publications

1. Scottish Capital Investment Manual 2024 whole system infrastructure planning
2. NHS Health Department Letter (HDL) (2007) 4 Decontamination - Migration to Single Use Pre-Sterilized individually wrapped small orthopaedic implants
3. NHS HDL (2006) 45 Decontamination - Treatment of patients in the independent healthcare sector
4. NHS HDL (2006) 40 Decontamination - Updated guidance on compliance in primary care
5. NHS HDL (2003) 42 Decontamination - NHSScotland Sterile Services Provision Review Group (Glennie Group)
6. NHS HDL (2002) 67 Decontamination - NHSScotland Sterile Services Provision Review Group
7. NHS HDL (2001) 66 Healthcare Associated Infection: Review of Decontamination Services and Provision across NHSScotland
8. NHS HDL (2001) 10 Decontamination of Medical Devices
9. NHS MEL (1999) NHS in Scotland Infection Control: Decontamination of Medical Devices
10. NHS CEL 19 (2010) A Policy on Design Quality for NHSScotland
11. DL (2023)03 NHSScotland Assure: Key Stage Assurance Reviews (KSAR) - Commissioning and Handover, Feb 2023 - Alan Morrison.
12. DL (2024)02 NHSScotland: Whole System Infrastructure Planning, Feb 2024

Acts and regulations

13. Medicines and Medical Devices Act 2021
14. The Medical Devices (Amendment) (Great Britain) Regulations 2023 SI 2023 no.627
15. (The) Medical Devices Regulations 2002, SI 2002 No 3017, HMSO.
16. Regulation (EU) 2017 – 745 on medical devices, 2017.
17. (The) Building (Scotland) Act 2003, TSO.

18. (The) Building (Forms) (Scotland) Amendment Regulations 2006, SSI 163 2006, TSO
19. Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 SI 2000 No 2531. HMSO, 2000.
20. Clean Air Act 1993. HMSO 1993.
21. Confined Spaces Regulations 1997. SI 1997 No 1713. HMSO, 1997.
22. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004. SI 2004 No 568.
23. Consumer Protection Act 1987, HMSO.
24. Construction (Design and Management) [CONDAM] Regulations, TSO, 2007.
25. Control of Noise at Work Regulations 2005 SI No. 1643.
26. Control of Substances Hazardous to Health Regulations 2002, SI 1999 No 2677, HMSO.
27. Controlled Waste Regulations 1992. SI 1992 No 588.
28. Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) 2002. SI 2002 No 2776
29. Disability Discrimination Act 1995 and amendments 2005, HMSO.
30. Electricity at Work Regulations 1989. SI 1989 No 635. HMSO, 1989.
31. Electricity Safety, Quality and Continuity Regulations 2002. SI 2002 No 2665. HMSO, 2002.
32. Electrical Equipment (Safety) Regulations 1994. SI 1994 No 3260. HMSO, 1994.
33. Electromagnetic Compatibility Regulations 1992, SI 1992 No 2372, HMSO, 1992.
34. Employers Liability (Compulsory Insurance) Regulations 1998. SI 1998 No 2839. HMSO, 1998.
35. Environment Protection Act 1990, HMSO.
36. Furniture and Furnishings (Fire) (Safety) Regulations 1988. SI 1998 No 1324. HMSO, 1988.
37. Health & Safety at Work Act 1974, HMSO.
38. Health and Safety (Display Screen Equipment) Regulations 1992, SI 1992 No 2792, HMSO, 1992.
39. Health and Safety (Safety Signs and Signals) Regulations 1996. SI 1996 No 341. HMSO, 1996.
40. Low Voltage Electrical Regulations 1997. HMSO, 1997.

41. (The) Management of Health and Safety at Work Regulations 1999, SI 1999 No. 2051, HMSO.

42. Manual Handling Operations Regulations 1992. SI 1992 No 2793. HMSO, 1992.

43. Personal Protective Equipment Regulations 2002. SI 2002 No 1144. HMSO, 2002

44. Plugs and Sockets (Safety) Regulations 1994. SI 1994 No 1768. HMSO, 1994.

45. Pollution Prevention and Control (Scotland) Regulations 2000. SI 2000 No 323. TSO

46. Pressure Equipment Regulations 1999. SI 1999 No 2001. HMSO, 1999.

47. Pressure Systems Safety Regulations 2000. SI 2000 No 128.

48. (The) Provision and Use of Work Equipment Regulations 1998, SI 1998 No 2306, HMSO.

49. Producer Responsibility Obligations (Packaging Waste) Regulations 2005. SI 2005 No 3468. HMSO, 2005

50. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR 95). SI 1995 No 3163. HMSO, 1995

51. (The) Regulatory Reform (Fire Safety) Order 2005. SI 2005 No 1541. HMSO, 2005.

52. (The) Special Waste Regulations 1996, SI 1996 No 972, HMSO.

53. Supply of Machinery (Safety) Regulations 1992. SI 1992 No 3073. HMSO, 1992.

54. (The) Water Supply (Water Fittings) Regulations 1999, SI 1999 No. 1148, The Stationery Office.

55. Water Supply (Water Quality) (Scotland) Amendment Regulations 2001, TSO.

56. Working Time Regulations 1998. SI 1998 No 1833. HMSO, 1998.

57. (The) Workplace (Health, Safety and Welfare) Regulations 1992, SI 1992 No 3004, HMSO.

Standards

58. BS EN ISO 17664-1: 2021. Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices, BSI.

59. BS EN ISO 16890-1: 2016 Air filters for general ventilation Part 1: Technical specifications, requirements and classification system based upon particulate matter efficiency (ePM) (ISO 16890-1:2016)

60. BS EN 1822-1: 2019 High efficiency air filters (EPA, HEPA and ULPA) Part 1: Classification, performance testing, marking

61. BS EN ISO 15223-1: 2021 Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements

62. BS EN ISO 20417: 2021 Medical devices. Information to be supplied by the manufacturer

63. BS EN 12056-2: 2000 Gravity drainage systems inside buildings. Sanitary pipework, layout, and calculation. BSI, 2000.

64. BS EN ISO 13485: 20032016+A11: 2021 Medical devices. Quality management systems. Requirements for regulatory purposes. BSI, 2021.

65. BS EN 14182:2002 Packaging. Terminology. Basic terms and definitions

66. PD CEN ISO TR 14969:2005 Medical devices. Quality management systems. Guidance on the application of ISO 13485:2003. BSI, 2003.

67. BS EN ISO 14971:2019+A11: 2021 Medical devices. Application of risk management to medical devices

68. BS EN ISO 15883-1:2009 + A1:2014 Washer-disinfectors. General requirements, terms and definitions and tests. BSI 2014.

69. BS EN ISO 15883-4:2018 Washer-disinfectors. BSI, 2018.

70. BS EN ISO 15883-5:2021 Washer-disinfectors. Performance requirements and test method criteria for demonstrating cleaning efficacy. BSI

71. BS EN ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices

72. BS EN IEC 55015:2019+A11:2020 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment.

73. BS EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. BSI, 2010.

74. BS EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. BSI.

Health Facilities Scotland Guidance

Compliance series

75. GUID 5013 v3: 2024 NHSScotland Requirements for compliant Endoscope Decontamination Units

Scottish Health Planning Notes

76. SHPN 40: Common activity spaces. Health Facilities Scotland (HFS) 2008.

Scottish Health Technical Memoranda

77. SHTM 00 Best practice guidance for healthcare engineering Policies and principles, v2 HFS, 2013
78. SHTM 01-06 series. Decontamination of flexible thermolabile endoscopes and TOE ultrasound probes in an EDU, HFS, 2023.
79. SHTM 56: Partitions. HFS, 2006.
80. SHTM 57: Internal glazing. HFS, 2006.
81. SHTM 58: Internal doorsets. HFS, 2006
82. SHTM 59: Ironmongery. HFS, 2006.
83. SHTM 60: Ceilings. HFS, 2006.
84. SHTM 61: Floors: HFS, 2009.
85. SHTM 64: Sanitary assemblies, HFS, 2009
86. SHTM 69: Protection, HFS, 2006
87. SHTM 06-01: Electrical services supply and distribution part A: Design considerations: 2015 part B: Operational Management 2015
88. SHTM 08-01: Specialist services Acoustics v1: 2015
89. SHTM 08-05: Specialist services Building Management System 2012
90. SHTM 02-01 Medical gas pipeline systems part A: Design, installation, validation, and verification: v1 2012 and Part B v2: Operational management 2015
91. SHTM 2023: Access and accommodation for engineering services. HFS, 2001.
92. SHTM 04-01 Water safety for healthcare premises part A: Design, installation, and testing: 2014. Other Parts published 2011 to 2015.
93. SHTM 03-01 (Interim Version – Additional guidance related to COVID 19 to be added in an update in 2022) Specialised ventilation for healthcare premises Part A v3 2022: The concept, design, specification, installation, and acceptance testing of healthcare ventilation systems
94. SHTM 03-01 Specialised ventilation for healthcare premises (Interim Version - Additional guidance related to COVID 19 to be added in an update in 2022) Part B v2: 2022: The management, operation, maintenance, and routine testing of existing healthcare ventilation systems
95. SHTM 86 v6 NHSScotland Firecode Fire Risk Assessment published Aug 2023

Scottish Health Facilities Notes/ Scottish Health Technical Notes

96. SHFN 14: Disability access. HFS, 2000.

97. SHFN 30: Infection control in the built environment. V4 part A Manual - Information for Design Teams, Construction Teams, Estates and Facilities, and Infection Prevention & Control Teams: 2014 HFS.

98. SHTN 03-01 NHSScotland Waste Management Guidance v7 HFS 2023

99. SHTN 02-01 NHSScotland Sustainable Design and Construction Guide (SDaC) 2023

Other

100. GUID 5006 v1 Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices, HFS, 2013.

101. Framework to Support Staff Development in the Decontamination of Re-usable Medical Devices v2, NHS Education for Scotland (NES) 2022.