

Scottish Health Planning Note 13

Part 3 Decontamination Facilities: Endoscope Decontamination Units



September 2010



Contents

page

1.	Executive summary	7
1.1	Purpose	7
1.2	Overview of topics	7
1.3	Advice and expertise	8
2.	Introduction	10
2.1	Background	
2.2	Option appraisal	
2.3	Capital Investment	13
3.	General service considerations	14
3.1	Introduction	14
3.2	Standards, regulations and guidance	15
3.3	Service strategy considerations	
3.4	Service objectives	17
3.5	Service requirements	17
3.6	Sizing a department (see also paragraph 4.3)	18
3.7	Location of the EDU	18
3.8	Operational policies	19
	3.8 Testing, cleaning and disinfection	19
	3.9 Staff protection	20
	3.10 Education and training	
	3.11 Traceability	20
	3.12 Domestic Services	20
	3.13 Waste disposal	21
	3.14 Materials procurement and storage	
	3.15 Packaging and transportation	21
		~~
4. 4.1	General functional and design requirements	
	Introduction	
4.2	EDU Room Data Sheet	
4.3 4.4	Sizing the facility (also see paragraph 3.6)	
4.4 4.5	EDU layout Single Room	
4.5	Two Room (with or without Ante Rooms)	
4.0	Two Room with Ante and other Support Rooms	
4.7	Environmental cleaning.	
ч.0	4.9 Floor cleaning	
		51

	4.10	Work surfaces cleaning	.31
	4.11	Wall, window and ceiling cleaning	.31
5.	Spec	ific functional and design requirements	.32
5.1	Single	e Room EDU	.32
	5.1	Function	.32
	5.2	Location	. 32
	5.3	Key requirements	. 32
	5.4	Equipment	.32
5.5	Two F	Room EDU - Wash Room	.33
	5.5	Function	.33
	5.6	Location	.33
	5.7	Key requirements	.33
	5.8	Equipment	.33
5.9	Two F	Room EDU – Wash Room Ante Room	.34
	5.9	Function	34
	5.10	Location	34
	5.11	Key requirements	34
	5.12	Equipment	34
5.13	B Two F	Room EDU – Inspection/Storage/Dispatch Room	.34
	5.13	Function	
	5.14	Location	34
	5.15	Key requirements	. 35
	5.16	Equipment	
5.17	' Two F	Room EDU – Inspection/Storage/Dispatch Room Ante Room	.35
	5.17	Function	
	5.18	Location	. 35
	5.19	Key requirements	35
	5.20	Equipment	
5.21		Room EDU with Ante and other Support Rooms – Used Goods	
		ption	36
	5.21	Function	.36
	5.22	Location	36
	5.23	Key Requirements	36
	5.24	Equipment	
5.25	5 Two F	Room EDU with Ante and other Support Rooms – Wash Room	. 36
	5.25	Function	
	5.26	Location	36
	5.27	Key requirements	
	5.28	Equipment	
5.29		Room EDU with Ante and other Support Rooms – Wash Room Ant	
	5.29	Function	
	5.30	Location	
	-		

[©] Health Facilities Scotland, a Division of NHS National Services Scotland

	5.31	Key requirements	37
	5.32	Equipment	37
5.33	Two F	Room EDU with Ante and other Support Rooms	
	– Was	sh Room DSR	38
	5.33	Function	38
	5.34	Location	38
	5.35	Key requirements	38
	5.36	Equipment	38
5.37		Room EDU with Ante and other Support Rooms	
	– Insp	pection room	38
	5.37	Function	38
	5.38	Location	39
	5.39	Key requirements	39
	5.40	Equipment	39
5.41		Room EDU with Ante and other Support Rooms – Inspection Roor	
	5.41	Function	39
	5.42	Location	
	5.43	Key requirements	
	5.44	Equipment	39
5.45		Room EDU with Ante and other Support Rooms – Storage and	
		tch Room	
	5.45	Function	
	5.46	Location	
	5.47	Key requirements	
	5.48	Equipment	40
5.49		Room EDU with Ante and other Support Rooms – Storage and	
		tch Room Ante Room	
			40
	5.50	Location	
	5.51	Key requirements	
	5.52	Equipment	
5.53		estic Services Room	
	5.53	Function	
	5.54	Location	
	5.55	Key requirements	
	5.56	Equipment	
5.57	Plant	and Chemical Storage Room	
	5.57	Function	
	5.58	Location	
	5.59	Key requirements	
	5.60	Equipment	42
6.	Gene	ral guidance	43

6.1	Introduction		
6.2	Econo	omy	.43
6.3	Upgra	de	.43
7.	Engin	eering Services	.44
7.1	Introd	uction	.44
7.2	Mode	Specifications and Technical manuals.	.44
7.3	Econo	omy and Value Management	.45
7.4	Servic	e requirements	.45
7.5		e for plant and services	
7.6	Acces	s to control and isolation devices	.46
7.7	Safety	/	.46
7.8		recautions	
7.9	Noise	and speech privacy	.47
7.10	Engin	eering commissioning	.47
		ment validation	
7.12	Mecha	anical services	.48
	7.12	Heating	.48
	7.13	Temperature controls	.48
7.14	Ventila	ation	
	7.15	Ventilation - Single Room EDU	.49
	7.16	Ventilation - Two Room EDU	
	7.17	Inspection/Storage/Dispatch room of Two Room EDU	
	7.18	Wash Room of Two Room EDU	.50
	7.19	Ventilation - Two Room EDU with Ante and other Support	
		Rooms - Used Goods Reception	.50
	7.20	Two Room EDU with Ante and other Support Rooms – Wash Room	.51
	7.21	Two Room EDU with Ante and other Support Rooms- Inspection	
		Room	.51
	7.22	Two Room EDU with Ante and other Support Rooms- Storage an Dispatch Room.	
7 23	Hot ar	nd cold water services	
		ressed air	
		ntamination Equipment	
		ical services	
7.20	7.26	Electrical installation	
	7.27	Electrical Interference	
	7.28	Lighting	
	7.29	Socket - outlets and power connections	
	7.30	Emergency electrical supplies	
	7.31	Internal/external communications	
	7.32	Electronic data gathering	
7.33		al drainage	



References5	56
-------------	-----------

Appendices	63
Appendix 1: Single Room EDU model – Decontamination Room	64
Appendix 2: Two Room EDU model	65
Appendix 3: Two Room EDU model with Ante Rooms	66
Appendix 4: Two Room EDU with Ante and other Support Rooms	67

cknowledgements68

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 Division of NHS National Services Scotland, shall have no responsibility for any errors in or omissions therefrom, or any use made of, or reliance placed upon, any of the contents of this document.

1. Executive summary

Purpose

1.1 This section of Scottish Health Planning Note (SHPN) 13 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. This guidance supersedes the decontamination guidance given in SHPN 52:'Accommodation for day care – Endoscopy unit.'

Overview of topics

1.2 The document outlines the objectives of an Endoscope Decontamination Unit, and service requirements in terms of the provision and operation of the facility.

Failure to adequately decontaminate flexible endoscopes between use may increase the risk of transmission of infection between patients and/or compromise the quality of clinical samples, e.g. biopsy samples.

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 are decontaminated (*including non lumen nasendoscopes used in examination clinics*). The four models are:

For centralised services:

• Two room endoscope decontamination unit with ante and other support rooms.

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.

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 (model layout shown in Appendix 3);
- for centralised services, the two room endoscope decontamination unit with ante and other support rooms (model layout shown in Appendix 4).

The option appraisal exercise should determine which model is appropriate.



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, steam problems, waiting times initiatives and capacity issues.

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, air conditioning (HVAC), decontamination equipment and IT systems.

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 underprovision or overprovision is avoided. The size of the EDU facility i.e. the building and its site, the engineering services and the equipment required in both capital and revenue terms may be considerable.

Increasing the size of the EDU will increase the scale of support services required. Some of these support services, e.g. 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, e.g. storage, portering, transport, waste handling and supplies.

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.

Advice and expertise

1.3 Planning and design of an EDU should include input from relevant experts in the areas of, for example, decontamination, engineering, building and design, infection control, procurement, IT and also users of the service and suppliers of the required specialised equipment.



Note: This Planning Note 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' endoscope washer disinfectors 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.

2. Introduction

Background

2.1 This Scottish Health Planning Note (SHPN) provides information to assist individuals and organisations make informed decisions on the provision of endoscope decontamination services.

The Sterile Services Provision Review Group in 2003 established that there was a lack of guidance on the provision of endoscopy decontamination facilities. As the Glennie Technical requirements did not cover the decontamination of thermolabile endoscopes, the Decontamination Team at Health Protection Scotland and the Decontamination Technical Advisory Panel (DTAP) were commissioned to prepare guidance on behalf of the Glennie Group. 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 document was referenced in HDL (2005)01 Decontamination – Compliance in Primary Care.

Endoscopes and their accessories are classified as medical devices (see Note below) under the Medical Devices Directive (93/42/EEC). Included within the essential requirements are the undernoted:

- devices and manufacturing processes must be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties;
- devices must 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.

Note: Medical Device: Any instrument, apparatus, appliance 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 or compensation for and injury or handicap; investigation, replacement of part of the anatomy or 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. Abbreviated from the Medical Device Regulations 2002.

Failure to adequately decontaminate flexible endoscopes between use may increase the risk of transmission of infection between patients and/or compromise the quality of clinical samples, e.g. biopsy samples.

An EDU is a unit set up to reprocess only flexible, thermolabile, endoscopes and their accessories, where appropriate. The facilities and equipment



available within EDUs are not suitable for the reprocessing of endoscopes and their accessories used in procedures involving contact with high CJD transmission risk tissues e.g., neuroendoscopes. Whereas in CDUs thermal processes are used to achieve sterilization, the terminal decontamination process stage in EDUs is high level disinfection using a liquid chemical disinfectant. Specialist endoscope washer disinfectors are used.

Option appraisal

- 2.2 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.

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

Note: Local authority planners and building control agencies may, depending on the planned location, consider the EDU as a 'Factory'. In these cases location zoning will have significant influence over planning approval applications. Upgrades of existing facilities may require use of other accommodation whilst refurbishment works are in progress.

This SHPN contains information on the building and operating principles for four main models of endoscope decontamination units where the only viable option is high level disinfection for all thermolabile endoscopes:

- Two room endoscope decontamination unit with ante and other support rooms;
- Two room endoscope decontamination unit with ante rooms;
- Two room endoscope decontamination unit;
- Single room endoscope decontamination unit.

Where the option appraisal exercise has identified that a large centralised decontamination unit is a viable option, the two room endoscope decontamination unit with ante and other support rooms model would be the preferred choice.

Version 1: September 2010 Page 11 of 68 © Health Facilities Scotland, a Division of NHS National Services Scotland The preferred model for a new build of small / medium sized units adjacent to clinical units is the two room decontamination unit with ante rooms. The ante rooms are intended to provide controlled access of personnel, provide a separate area for hand washing and donning personal protective equipment (PPE) and to provide a measure of future proofing the facility in the event of the need for additional technical requirements.

This model is also applicable for the upgrade of existing facilities. However, where unavoidable constraints exist, a single room EDU model may have to be considered. The single-room model is the highest risk option with regard to adventitious contamination from the wet processes of hand washing and manual cleaning and from undertaking clean and dirty processing in the same room. In this model therefore tight procedural control is required to minimize the risk of recontamination of devices.

An endoscope decontamination unit may be set up as any of the four models described in this document. It should be noted that:

- the management and staff responsible for decontamination may have other duties e.g., clinical duties;
- an EDU may serve a single clinical speciality or several (e.g., linked to an operating theatre suite) in the same building.

An essential requirement for endoscope decontamination facilities is an effective separation of clean and dirty processes.

The nature of the cleaning and disinfection process means that, when completed, a disinfected device is not usually packaged and protected against recontamination. The endoscope washer disinfector should therefore be close to the point of use or measures should be taken to transport the decontaminated endoscope in a manner that does not compromise its status. An endoscope storage cabinet/system may be employed to store endoscopes under validated conditions.

It should be noted that there is likely to be a need for external technical support with regard to, for example:

- Authorising Engineer (Decontamination) [AE(D)] services;
- Authorising Engineer (Medical Gas Pipeline Systems), AE (MGPS);
- assessment of decontamination requirements;
- process mapping;
- procurement of medical devices;
- procurement of decontamination equipment;
- maintenance and testing of decontamination equipment;
- decontamination policy;
- staff training;



- infection control;
- planning and design support;
- electrical services;
- heating/ventilation/air conditioning design;
- health and safety;
- IT and communications.

Appropriate expertise may be available from NHS Boards and/or Health Facilities Scotland Decontamination Services. Sustainable design should be employed to attain a satisfactory environmental performance for the EDU. BRE environmental assessment method (BREEAM) assessors should be consulted at the design stage of the project.

Capital Investment

2.3 This SHPN provides information to assist individuals and organisations make informed decisions on the provision of decontamination services from an EDU. The Scottish Capital Investment Manual (SCIM) has been prepared by the Scottish Government Health Directorate. This investment manual creates a framework within which NHS Boards can plan, develop, procure and manage their infrastructure projects effectively and efficiently. The guidance within the manual is mandatory (as stated in letter CEL 19(2009)) and must be followed by all NHSScotland bodies. The SCIM is now only available online.

3. General service considerations

Introduction

- 3.1 For effective decontamination, minimum acceptable standards need to be achieved at all stages of the decontamination life cycle. The following issues must be considered:
 - management of the decontamination processes;
 - workflow of decontamination process stages;
 - activity at each process stage;
 - facilities and equipment required for each stage, including stocks of medical devices;
 - procurement logistics- supply and storage of consumables;
 - validation, testing and maintenance of equipment, and where appropriate support services;
 - operational policies and procedures;
 - management of waste;
 - training requirements for personnel decontaminating devices, management of the decontamination process, and testing/maintenance of the decontamination equipment.

A number of principles have been identified which help to achieve the highest standards for decontaminating medical devices. These are:

- effective decontamination, infection control and health and safety policies should be in place covering all aspects of the life cycle;
- appropriate, dedicated facilities should be provided for decontamination;
- devices should be decontaminated i.e., test channel patency and leak test, manual pre-clean, wash and disinfect using validated automated processes, which ensure reproducibility, store in an appropriate environment to avoid recontamination and transport in a fashion that prevents recontamination;
- equipment for validated processes should be fit for its intended purpose and requires planned preventative maintenance, periodic testing and correct use;
- validated processes require that automated equipment be fitted with chart recorders or data loggers to enable monitoring of the critical variables of each cycle, independent of the sensors used to control the machine;
- there should be physical segregation of those elements of the decontamination process dealing with contaminated devices and those dealing with cleaned/disinfected devices, to minimise the risk of recontamination of clean devices. Physical segregation implies that disassembly and pre-cleaning of devices are carried out in a separate room



from post disinfection inspection and packaging. The automated cleaning and disinfection part of the process takes place in a pass-through machine between the two rooms. The two room endoscope decontamination models described above reduce the risk that contamination arising from dirty stages of the decontamination process will re-contaminate clean devices, and the risk of unwashed devices moving on for reuse. The single room model relies on strict process flow and procedural control. Taking account of all these factors the one room model will be at significantly higher risk of recontamination of cleaned and disinfected devices compared to the two room models. It should be noted that strict procedural controls are required to ensure unprocessed devices are not mixed up with cleaned devices;

- for each endoscope reprocessed, details are required to be kept of all stages of the decontamination process through to which patient the endoscope was used on. Records are also required for each equipment cycle detailing the devices processed, the parameters of the cycle, the chemicals used and personnel involved;
- reprocessing instructions for all endoscopes should be formally reviewed, prior to purchase, to ensure that they are compatible with the available decontamination processes;
- single-use devices must not be reprocessed or re-used;
- a system for managing stock levels should be in use;
- a cleanable transport system for moving devices to and from the EDU(see 3.15).

Standards, regulations and guidance

3.2 It is important to be aware that a raft of European and International standards, and best practice guidance documents e.g. Scottish Health Technical Memoranda exist covering the decontamination of reusable medical devices etc. Decontamination is a continually evolving area and therefore planning work should recognise that future upgrades might be necessary. Refer to the References Section for a list of documents.

Note: In addition to contamination during clinical use, there are a number of potential sources of contamination of a device following cleaning and disinfection. These include: raw materials and their storage; products used during processing; personnel; equipment and the reprocessing environment. It is therefore critical that the risk of contamination is minimised at all stages of the decontamination lifecycle.

Contamination can be minimised by controlling the building and engineering services that directly affect the decontamination processes, personnel and reprocessing environment. The following will assist in this effort:

- dedicated, compliant decontamination facilities;
- control of access to the decontamination area;



- trained staff with a full understanding of their major role in the decontamination process and infection control procedures;
- identification and monitoring of services supplying the decontamination unit.

One individual should have defined responsibility and overall control of all parts of the decontamination life cycle, including acquisition and disposal of devices, and would fulfil the role of 'User' as specified in SHTM 2030.

Note: Acquisition may be centralised rather than a local function.

A decontamination policy which specifies the requirements for documented policies, procedures, work instructions and records for all key elements of the decontamination process should be in place and approved by senior management.

Service strategy considerations

3.3 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 must be considered including costs, benefits, risks, uncertainties and value for money.

When planning and designing an EDU there must 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.

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

- 3.4 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 i.e. 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 must 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

3.5 The service can be described under the following headings, which are used to provide an overview of the requirements of the EDU function.

Environment

- segregation of processes;
- control of contamination through environment, automated processes, personnel and materials.



Equipment

- fit for purpose;
- validated, routinely tested and regularly maintained in accordance with SHTM 2030, BS EN 15883, Medicines and Healthcare Products Regulatory Agency (MHRA) guidance and other relevant European and International standards.

Management

- documentation as required to meet technical requirements including policies, procedures and records for all key elements of the decontamination process;
- staff training programme, which is documented, recorded, monitored and reviewed;
- records to allow traceability through the decontamination process to the patient and vice versa;
- Health and Safety requirements.

Sizing a department (see also paragraph 4.3)

3.6 The capacity requirements on the EDU will depend on the local needs. This will require detailed assessment of:

- the clinical activity, sessions per day, patients per session, number and type of procedures per patient and devices required for each type of procedure;
- the number of hours of decontamination activities.

Both current and likely future demands should be considered.

This information should be included in the operational policy. Throughput calculations for decontamination equipment capacity need to be established. In addition to meeting the capacity requirements, the segregation of clean and dirty processes will influence the size of the facility. Consult paragraphs 4.2 - 4.3 for sizing the equipment, fixtures and fittings once throughput calculations have been carried out.

Location of the EDU

3.7 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 e.g. power, water, 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.

Operational policies

Testing, cleaning and disinfection

3.8 A pre-clean of the endoscope is carried out in the clinical area prior to transfer to the 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 is 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 in line with the requirements of SHTM 2030 and BS EN ISO 15883-1, 4. Washer disinfectors 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 HEPA filtered storage cabinets. 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

3.9 The type and nature of the personal protective equipment (PPE) e.g. protective clothing, eye protection and face mask for the dirty processes of the EDU will be specified based on a 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

3.10 All staff working within the EDU need 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

3.11 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 IT system along with the cycle number (endoscope washer disinfector (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 MEL(1999)65).

Domestic Services

3.12 High standards of cleanliness are essential throughout the EDU. Dedicated and appropriate cleaning equipment and materials must 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 (DSR) for the wash room and the inspection/storage/dispatch room. 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 e.g. microbiologist or infection control nurse, and should be monitored by the person responsible for the EDU. Reference should be made to the NHSScotland National Cleaning Services Specification 2009 published by HFS. (http://www.hfs.scot.nhs.uk/online-services/publications/facilities/)

Waste disposal

3.13 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 Health Facilities Scotland 'Guide to Carriage of Dangerous Goods Regulations' with respect to soiled devices. Both documents are available on the Health Facilities Scotland web site www.hfs.scot.nhs.uk. Use identified bag holders with appropriate waste bags and with hands-free operated lids. All sharps must 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

3.14 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 must be allowed for appropriate cleaning of the EDU. Storage of raw materials should not compromise the decontamination process in the EDU. The Control of Substances Hazardous to Health (COSHH) regulations should be considered in both design and operation. Processed items should be stored in a separate dedicated location.

Packaging and transportation

3.15 Cleaned and disinfected endoscopes must 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, some also contain the device during the cleaning and disinfection process.

> Used devices must 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 must 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.

4. General functional and design requirements

Introduction

4.1 The design rationale should be to deliver a satisfactory decontamination process for medical devices that has no adverse effect on the clinical environment, patients, staff or on other medical devices.

Consideration should be given to the following:

- capacity planning for current and projected service requirements;
- all decontamination should take place in a designated controlled area separate from the clinical area;
- design of the decontamination area should allow adequate space to avoid congestion, and allow segregation of clean and dirty activities and processed and unprocessed devices;
- the passage of all materials and personnel should be controlled. Access to the decontamination area should be restricted to staff who have received appropriate training and be secured to prevent public access;
- clean endoscopes should be stored in dedicated, endoscope storage cabinet/systems. Such storage cabinets/systems require testing and planned maintenance;
- maintenance repair and testing (where appropriate) of building, facilities and equipment, pest control and provision and condition of services e.g. power, water, communication, alarm systems and drainage;
- room finishes in line with the room data sheet (see 4.2);
- the staff changing facilities should be maintained in a clean and tidy condition;
- cloakrooms, staff rest areas and toilets must be separate from the decontamination area;
- environmental impact of the design/use of the EDU, carbon footprint, waste products, recycling etc.



EDU Room Data Sheet

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 a washer disinfector or pass through hatch, penetrating the wall, must be sealed. Edges where the wall meets the ceiling should be coved. Examples of suitable wall finish include: elastomeric vinyl compound, epoxy coating, PVC with welded joints and acrylic paint. If plasterboard is used it must be moisture resistant and all exposed edges sealed. Suitable wall protection from trolley movement should be considered, i.e. mid height crash rail, durable materials on lower part of walls, protective corners and coved skirting.
Flooring	 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 must be non-slip. In Two Room EDUs the wash room flooring must 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 SHTM 60:'Ceilings') and that all tiles/hatches are sealed during installation and after any subsequent maintenance activity.

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 IP54, i.e. 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 BS 7671- it should not cause overload in the supplying system. An enhanced power supply may be required for endoscope washer disinfectors. 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 2022. This would include the connections. Only Medical grade air is suitable for processing endoscopes. Consult an AE (MGPS).
Air conditioning, Heating /Ventilation (see also paragraph 7.12 to paragraph 7.22)	Mechanical ventilation required for all models of EDUs. Note: Certain manufacturers of drying 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 drying 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. Guidance for all room models- maintain an average room temperature between 16 to 21°C and average relative humidity of 40 to 70%RH. Two Room Endoscope decontamination unit with Ante Rooms (as appendix 3) <i>Wash Room</i> 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. <i>Inspection/Storage/Dispatch Room</i> Supply 10 AC/h to the 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.



Cont'd -	
Air conditioning,	Two room endoscope decontamination unit with ante and other support rooms (as Appendix 4)
Heating	
/Ventilation	Used Goods Reception
(see also paragraph 7.12 to paragraph 7.22)	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. <i>Wash Room</i>
	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. Recirculation 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. <i>Wash Room DSR</i>
	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.
	Two Room EDU (as Appendix 2)
	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 (as Appendix 1)
	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.

	Г
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 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 must 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). Note: In the Two Room model (Appendix 2) there is no wash hand basin installed in the Inspection/Storage/Dispatch Room in order that water aerosolisation is minimised and operational misuse (i.e.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.
Endoscope Storage cabinet / system	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 HEPA filtered air drying system. The air movement in/out of the cabinet should not interfere with the room air ventilation.

Administration 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.
	Note: In the Two room endoscope decontamination unit with ante and other support rooms model there may be an admin area in the Used Goods Reception, Wash Room, Inspection Room and the Storage and Dispatch Room.
Drainage requirements for endoscope washer	Drains will be required for any endoscope washer disinfectors installed. The drainage systems must 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.
disinfectors	
Storage of PPE	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 COSHH regulations. Wall-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, e.g., where the EDU is above, below or next to a clinical area (see 7.9).
Eye wash station/ First Aid Kit and spill kit	Required and readily available for use in an emergency.

Sizing the facility (also see paragraph 3.6)

4.3 Recognising that an EDU may in some cases need to be fitted within existing space constraints, and given that there are a range of possible configurations, it is not appropriate to specify room dimensions. It must be borne in mind however, that these facilities are in constant use, with staff spending a significant portion of their working day within the facility. It is important that adequate space is provided for the required processes to be carried out both conveniently and safely.

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) will be determined by selecting the individual components as required from Table A. (and allowing for access/maintenance) to accommodate the throughput.

Area/item or equipment	Length (m)
Door	0.9
Wash hand basin (could be in ante room)	0.6
Dirty set down area	1.4
Test sink with draining board	1.0
Wash sink with draining board	1.0
Detergent pump (under wash sink)	n/a
Pre rinse set down area	1.4
Rinse sink with draining board	1.0
Post rinse set down area	1.4
Endoscope Washer Disinfector (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
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
PPE storage (could be on a wall)	0.5
Waste storage (could be under bench)	0.5
Table A	

Note: Other areas or rooms are required to support the first three models, e.g. DSR(s) and trolley parking. The requirements for the Plant and Chemical Storage room would be assessed during the option appraisal process.

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 must not be to the detriment of providing a continuous forward process flow from dirty to clean e.g. 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.

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.

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

A dedicated Domestic Services room (see paragraph 3.12), 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 1 to 3. 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.

Note: In the Two Room with Ante and other support rooms model (Appendix 4) a separate DSR will be directly connected to the areas where clean and dirty endoscopes are processed.

EDU layout

4.4 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 (Appendix 3) or the Two Room with Ante and other support rooms for large centralised units (Appendix 4).

Single Room

4.5 Prior to transfer from the clinical area to the EDU, the external, and when appropriate, lumens of the endoscope will have undergone preliminary removal of gross contamination by clinical staff immediately after use. On arrival in the EDU, the scope is dismantled and a leak test carried out at the test sink. Manual cleaning is carried out in the wash sink and then rinsed in the rinse sink. The scope is then processed through the EWD. On removal from the EWD the scope is inspected, and dried if required, transferred to the clinical area for immediate use or stored in the scope storage area. Endoscopes found to be soiled after processing through the EWD inspection are returned for reprocessing.

Two Room (with or without Ante Rooms)

4.6 Prior to transfer from the clinical area to the wash room, the external, and when appropriate, lumens of the endoscope will have undergone preliminary removal of gross contamination by clinical staff immediately after use. On arrival in the EDU, the scope is dismantled and a leak test carried out at the test sink. Manual cleaning is carried out in the wash sink and is then rinsed in the rinse sink. The scope is then processed through the pass-through EWD. The scope is then removed from the EWD in the Inspection/Storage/Dispatch Room, inspected, and dried if required, transferred to the clinical area for immediate use or stored in the scope storage area. Endoscopes found to be soiled after processing through the EWD inspection are returned for reprocessing.

Two Room with Ante and other Support Rooms

4.7 Prior to surgeries from the clinical area to the used good reception area, the external, and when appropriate, lumens of the endoscope will have undergone preliminary removal of gross contamination by clinical staff immediately after use. The trolleys containing the soiled endoscopes are then transferred to the wash room. On arrival in the Wash Room, the scope is dismantled and a leak test carried out at the test sink. Manual cleaning of the scope is carried out in the wash sink and it is then rinsed in the rinse sink. The scope is then processed through the pass-through EWD. The scope is then removed from the EWD in the Inspection Room, inspected and dried if required, transferred to the clinical area for immediate use or stored in the scope Storage and Dispatch Room. Endoscopes found to be soiled after processing through the EWD inspection are returned for reprocessing.

Environmental cleaning

4.8 For Two Room EDU options, separate cleaning equipment should be used for environmental cleaning of clean and dirty areas. Where this is not practical, the clean areas must be cleaned first, followed by the dirty areas and the equipment thoroughly cleaned before re-use. For the Single Room model, single dedicated cleaning equipment is used. A microbiologist should be consulted to approve the cleaning regime.

Floor cleaning

4.9 The equipment will consist of a mop and two-bucket system with free rinsing neutral detergent in hand hot water. A 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 cleaning

4.10 Work surfaces are cleaned with a non linting cloth and a solution of neutral detergent and hand hot water as per detergent manufacturer's instructions.

Wall, window and ceiling cleaning

4.11 Walls, windows and ceilings are cleaned with a non linting mop or cloth and a solution of neutral detergent and hand hot water as per detergent manufacturer's instructions.

Specific functional and design requirements 5.

Single Room EDU

Function

5.1 Receive contaminated endoscopes, disassemble, test and manually clean. Process the scope through a EWD, dry, and transfer to the clinical area for assembly and use or store in designated endoscope storage cabinet/system.

Location

5.2 In the same building in which the endoscopes are used.

Key requirements

On entering the decontamination room, staff should wash hands at the wash 5.3 hand basin and put on PPE as per the COSHH assessment.

> Work flows from the initial stage of receiving contaminated endoscopes at the put down bench next to the test sink. The scope is disassembled, single use components discarded and then tested in the test sink. The scope is manually cleaned in the wash sink and then rinsed in the rinse sink. The scope 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 scope is transferred to the clinical area for assembly and immediate use or placed in a dedicated endoscope storage cabinet/system. Devices 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.

Equipment

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;
- leak test equipment;
- endoscope washer disinfector(s);
- task lighting with magnifier;
- endoscope storage cabinet/system;
- dedicated cleaning equipment;

5.4

- telephone or intercom;
- computer for administration area;
- First Aid Kit/Eye Wash station.

Two Room EDU - Wash Room

Function

5.5 Receive contaminated endoscopes in the Wash Room, disassemble, test, manually clean, rinse and load into the pass-through endoscope washer disinfector.

Location

5.6 Connected via a pass-through endoscope washer disinfector to the Inspection/ Storage/Dispatch Room of the endoscope decontamination unit.

Key requirements

5.7 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.

Work flows from the initial stage of receiving contaminated endoscopes at the put down bench next to the test sink. The scope is disassembled, single use components discarded and then tested in the test sink. The scope is manually cleaning in the wash sink and then rinsed in the rinse sink. The scope is then placed in the EWD.

Equipment

- 5.8 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;
 - leak test equipment;
 - pass-through endoscope washer disinfector(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

Function

5.9 The Wash Room Ante Room provides 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. Hand washing is performed in this area. PPE is put on or removed as appropriate in the ante room.

Location

5.10 Connects the corridor to the Wash Room.

Key requirements

5.11 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.

Equipment

- 5.12 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

Function

5.13 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.

Location

5.14 Connected, via a pass-through washer disinfector and interlocked pass-through hatch, to the Wash Room, of the EDU.

Key requirements

5.15 On entering the Inspection/Storage/Dispatch Room where there is no anteroom, 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 / system.

On leaving the room, remove PPE and wash hands.

Equipment

- 5.16 The following equipment is required:
 - dedicated ventilated scope storage cabinet/system;
 - 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

Function

5.17 The Inspection/Storage/Dispatch Room Ante Room provides controlled access from the corridor to the Inspection/Storage/Dispatch Room. Hand washing is performed in this area. PPE is put on or removed as appropriate in this area.

Location

5.18 Connects the corridor to the Inspection/Storage/Dispatch Room.

Key requirements

5.19 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.

Equipment

5.20 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

Function

5.21 The Used Goods Reception receives contaminated endoscopes in transport trolleys and retains these in the area prior to transfer to the Wash Room. Waste is stored prior to collection.

Location

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

Key Requirements

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

Equipment

- 5.24 The following equipment is required:
 - hands free clinical waste bin;
 - computer for administration area.

Two Room EDU with Ante and other Support Rooms – Wash Room

Function

5.25 Receive contaminated endoscopes in the room, dissemble, test, manually clean, rinse and load into the pass-through endoscope washer disinfector.

Location

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

Key requirements

5.27 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 scope is disassembled and single use components discarded. The scope is then tested in the test sink. Manual cleaning is performed in the wash sink then rinsed in the rinse sink. The scope is then placed in the EWD.

Equipment

- 5.28 The following equipment is required:
 - hands free clinical waste bin;
 - test, wash and rinse sinks with draining boards;
 - leak test equipment;
 - pass-through washer disinfector(s);
 - pass-through hatch;
 - telephone or intercom;
 - computer for administration area;
 - First Aid Kit/Eye Wash station.

Two Room EDU with Ante and other Support Rooms – Wash Room Ante Room

Function

5.29 The Wash Room Ante Room provides controlled access from the corridor to the Wash Room. Hand washing is performed in this area. PPE is put on or removed as appropriate in the ante room.

Location

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

Key requirements

5.31 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.

Equipment

- 5.32 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 with Ante and other Support Rooms – Wash Room DSR

Function

5.33 The Wash Room DSR provides dedicated domestic services to the Wash Room.

Location

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

Key requirements

5.35 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.

Equipment

- 5.36 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.

Two Room EDU with Ante and other Support Rooms – Inspection room

Function

5.37 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.

Location

5.38 Connected, via a pass-through endoscope washer disinfector and interlocked pass-through hatch, to the Wash Room, directly with the DSR and the Storage and Dispatch Room.

Key requirements

5.39 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.

Equipment

- 5.40 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.

Two Room EDU with Ante and other Support Rooms – Inspection Room DSR

Function

5.41 The Inspection Room DSR provides dedicated domestic services to the Inspection Room and the Storage and Dispatch Room.

Location

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

Key requirements

5.43 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.

Equipment

- 5.44 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.

Two Room EDU with Ante and other Support Rooms – Storage and Dispatch Room

Function

5.45 Receive clean disinfected and inspected endoscopes from the Inspection Room. These endoscopes are stored in a dedicated endoscope storage cabinet/system and dispatched on trolleys as required.

Location

5.46 Direct connection to the corridor and the Inspection Room.

Key requirements

5.47 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.

Equipment

- 5.48 The following equipment is required:
 - endoscope storage cabinet/system;
 - hands free general waste bin;
 - telephone or intercom;
 - computer for administration area.

Two Room EDU with Ante and other Support Rooms – Storage and Dispatch Room Ante Room

Function

5.49 The Storage and Dispatch Room Ante Room provides controlled access from the corridor to the Storage and Dispatch Room. Hand washing is performed in this area. PPE is put on or removed as appropriate in this area.

Location

5.50 Connects the corridor to the Storage and Dispatch Room.

Key requirements

5.51 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.

Equipment

- 5.52 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

Function

5.53 This room is used to store domestic equipment used for cleaning Single and Two Room EDU options as described in Appendices 1 to 3.

Location

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

Key requirements

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

Equipment

- 5.56 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

Function

5.57 This room may be used to hold plant and be a chemical store (refer to paragraph 7.5).

Location

5.58 This room should be close to or connect with the Single Room EDU or the Wash Room of the other EDU models. (see Appendices).

Key requirements

5.59 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 must be assessed and shown to be satisfactory. Consult SHPN 13 Part 1 for further detail with regard to design including room finishes, mechanical and electrical and equipment/furniture/fittings.

Equipment

5.60 The equipment to be placed in this room will be defined during the option appraisal exercise. It may include 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 should be included.

6. General guidance

Introduction

6.1 This Section presents guidance relating to the function and design aspects of endoscope decontamination units in healthcare buildings, where new builds or upgrade projects are planned.

Economy

6.2 Consideration should be given to matters concerning, space provision, maintenance, energy consumption and staffing levels. Planning should aim for efficient use of all resources.

Upgrade

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

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.

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 SHFN 30 for further details regarding protection of sensitive areas during construction work. http://www.hfs.scot.nhs.uk/online-services/publications

7. Engineering Services

Introduction

7.1 This Section describes the engineering services supplied to the EDU (refer also to paragraph 4.2, 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.

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.

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

- back up 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.

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.

Model Specifications and Technical manuals.

7.2 The NHS Model Engineering Specifications are sufficiently flexible to reflect local needs. Where required, reference should be made to the engineering

sections of Scottish Health Technical Memoranda (SHTM) SHTM 2025 and SHTM 2030.

Economy and Value Management

- 7.3 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.

'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.

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' published by the Scottish Government Health Directorate.

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

In providing an energy-efficient solution, account should be taken of the local environmental policy in line with NHSScotland energy-efficiency targets. 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.

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 SHTM 2005: 'Building management systems'.

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

7.4 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.

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

7.5 Enough space should be provided for plant and services within the department (refer to paragraph 4.3). 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.

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.

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.

Access to control and isolation devices

- 7.6 Primary engineering distribution control and isolation devices should be:
 - protected against unauthorised operation e.g., switchgear and distributionboards should be housed in secure cupboards and located in a safe location.

Safety

7.7 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

7.8 As Scottish Health Technical Memorandum (SHTM) 81: Firecode: 'Fire precautions in new hospitals' by Health Facilities Scotland. A fire risk assessment is still required where an EDU is built within a new hospital in order to comply with the Fire Precautions (Workplace) Regulations. Other SHTMs in the Firecode series give technical guidance on various building, engineering and equipment issues. Where the EDU is built outwith a hospital complex and as part of a health building with only day case patients then SHTM 86 as opposed to SHTM 81 may apply.

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 to consider its effect on the existing surrounding occupied areas in so far as the alarms and means of escape is concerned.

Noise and speech privacy

7.9 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).

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

7.10 The engineering services should be commissioned in accordance with the validation system identified in the current version of each Scottish Health Technical Memorandum.

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.

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.

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

7.11 Decontamination equipment should be validated in line with SHTM 2030 or European/International Standards as appropriate. 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

7.12 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 (See paragraph 4.2 – Air conditioning).

Temperature controls

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

Ventilation

7.14 The ventilation standards applicable to central decontamination units, where controlled clean room environments exist, are not practicable in endoscope decontamination units. The design rationale for ventilation of these 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, e.g., automated cleaning processes and work procedures.

Ventilation requirements are specified in SHTM 2025. It identifies the statutory requirements from COSHH and the Health & Safety at Work Act.



The ventilation system should remove heat, vapours, aerosols and gases at source (refer to paragraph 4.2 – Ventilation). Consideration should be given to the impact of hot products from washer disinfectors. Washer disinfectors may require dedicated extract systems. Refer to SHTM 2030 Part 1.

Ventilation supply plant should include a prefilter and a secondary filter as per BS EN 779. 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.

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

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

Note: There is a statutory requirement to mechanically ventilate all enclosed workspaces.

7.15 This should require an air-handling system that should extract potentially infectious aerosols and maintain room temperature (T) and relative humidity (RH) to an acceptable comfort level taking account of the T/RH effects from room equipment. This system should provide, at least, the minimum fresh air requirements of 8 litres/second/person (ref: SHTM 2025 Part 2, paragraph 3.15).

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 Class EU3. The air supply should be a minimum of 7 air changes per hour with no recirculation of the supply air.

The air extract could be through a grille fitted in the ceiling or the wall close to the cleaning activity in the sinks e.g. at 600mm above the worktop between the test, wash and rinse sinks. The air extract should be at 10 air changes per hour. The room pressure should be not positive with respect to adjoining areas.

Note: 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, e.g. in the inspection area. The environmental cleaning regime in place should take account of this.

Version 1: September 2010 Page 49 of 68 © Health Facilities Scotland, a Division of NHS National Services Scotland

Ventilation - Two Room EDU

7.16 There is a statutory requirement to mechanically ventilate all enclosed workspaces.

Inspection/Storage/Dispatch room of Two Room EDU

7.17 This would require an air-handling system that would:

Maintain room temperature (T) and relative humidity (RH) 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.

The supply air should enter the room through a ceiling diffuser. The air should be filtered using a filter of minimum Class EU3. The air supply should be a minimum of 10 air changes per hour.

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. 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.

Wash Room of Two Room EDU

7.18 This should require an air-handling system that 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.

The supply air should enter the room through a ceiling diffuser. The supply air should be filtered using a filter of minimum Class EU3. The air supply should be a minimum of 7 air changes per hour. 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.

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 e.g., at 600mm above the worktop between the test, wash and rinse sinks. The air extract should be at 10 air changes per hour.

Ventilation - Two Room EDU with Ante and other Support Rooms - Used Goods Reception

7.19 This should require an air-handling system that 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 Class EU3. The air supply should be a minimum of 7 air changes per hour. 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 air changes per hour. 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

7.20 This should require an air-handling system that 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 Class EU3. The air supply should be a minimum of 7 air changes per hour. 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 air changes per hour. 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

7.21 This should require an air-handling system that would:

Maintain room temperature (T) and relative humidity (RH) 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 supply air should enter the room through ceiling diffusers. The air should be filtered using a filter of minimum Class EU3. The air supply should be a minimum of 10 air changes per hour.

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

7.22 This should require an air-handling system that should:

Maintain room temperature (T) and relative humidity (RH) 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 supply air should enter the room through ceiling diffusers. The air should be filtered using a filter of minimum Class EU3. The air supply should be a minimum of 10 air changes per hour.



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 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

7.23 Guidance on the design and installation of hot and cold water supply and distribution systems is contained in SHTM 2027. 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. Pipework materials should be in accordance with Scottish Hospital Technical Note (SHTN) 2 Domestic Hot and Cold Water Services in Scottish Healthcare Premises. If the premises use private water supplies then the installation must comply with the Private Water Supplies (Scotland) Regulations.

> The requirements for the control of legionella bacteria in hot and cold water systems are given in SHTM 2040.

The manufacturer of the EWD shall specify the requirements for water supplied to the EWD. Consult the scope 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 BS EN ISO 15883-1 and BS EN ISO 15883-4 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

7.24 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. Further guidance is given in Scottish Health Technical Memorandum SHTM 2030: 'Washer-Disinfectors.'

Decontamination Equipment

7.25 Guidance on choice, procurement, installation and validation of washer disinfectors is given in SHTM 2030. Advice should be sought from an AE(D).

Electrical services

Electrical installation

7.26 Electrical installation should comply with BS 7671 – 'Requirements for electrical installations'; IEE wiring Regulations.

> 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 (refer also to paragraph 4.2 – Electrical power).

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

7.27 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, e.g. swipe card systems for secure entry.

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

Guidance on the abatement of electrical interference is given in SHTM 2014.

Lighting

7.28 Fluorescent luminaries should comply with BS EN 55015.

The lighting solution should comply with the Health and Safety (Display Screen Equipment) Regulations where appropriate (refer also to paragraph 4.2 – Lighting).

Luminaires should be manufactured and tested in accordance with the requirements of BS 4533. Their location should afford ready access for lamp changing and maintenance. Energy efficient luminaires should be used unless their use can be shown to be inappropriate.

Safety lighting should be provided on primary escapes routes in line with SHTM 2011: 'Emergency electrical services' and BS 5266.

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

Socket - outlets and power connections

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

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 i.e., there should be no



diversity allowed in relation to process equipment, which may be in use simultaneously.

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.

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.

The electrical supply connections to electro-medical equipment should comply with BS 5724 and the relevant SHTMs.

Socket-outlets should be connected to essential circuits in accordance with the advice in SHTM 2011: 'Emergency electrical services'.

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 Senior Authorised Person (Low Voltage) 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

7.30 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. 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.

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

Internal/external communications

7.31 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

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

Internal Drainage

7.33 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 (refer also to paragraph 4.2 – Drainage requirements for endoscope washer disinfectors);
- has a design of internal drainage that complies with BS EN 12056 and the current building regulations. Guidance is given in SHTM 2023;
- have drains from washer-disinfectors that comply with local water regulations. Guidance is given in SHTM 2030;
- has a gradient of branch drains that is uniform and adequate to convey maximum discharge to the stack without blockage.



References

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

Government publications

NHS HDL(2006) 45 Decontamination – Treatment of patients in the independent healthcare sector, SEHD.

NHS HDL(2006) 40 Decontamination – Updated guidance on compliance in primary care, SEHD.

NHS Scotland HDL (2005)01 Decontamination – Compliance in Primary Care, SEHD.

NHS HDL(2003) 42 Decontamination – NHS Scotland Sterile Services Provision Review Group (Glennie Group), SEHD.

NHS HDL(2002) 67 Decontamination – NHS Scotland Sterile Services Provision Review Group, SEHD.

NHS HDL(2001) 66 Healthcare Associated Infection: Review of Decontamination Services and Provision across NHS Scotland, SEHD.

NHS HDL(2001) 10 Decontamination of Medical Devices, SEHD.

Sterile Services Provision Review Group – 1st Report 2001, SEHD.

NHS MEL(1999)65 Variant Creutzfelt-Jakob Disease (vCJD): Minimising the risk of transmission, SEHD.

NHS MEL(1999) NHS in Scotland Infection Control: Decontamination of Medical Devices, SEHD.

Acts and Regulations

(The) Building (Scotland) Act 2003, The Stationery Office (TSO).

(The) Building (Forms) (Scotland) Amendment Regulations 2006, SSI 163 2006, TSO

Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 SI 2000 No 2531, TSO.

Clean Air Act 1993, TSO.

Confined Spaces Regulations 1997. SI 1997 No 1713, TSO.



The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004. SI 2004 No 568, TSO.

Consumer Protection Act 1987, TSO.

Construction (Design and Management) [CONDAM] Regulations, TSO, 2007.

Control of Noise at Work Regulations 2005, TSO.

Control of Substances Hazardous to Health Regulations 2002, SI 1999 No 2677, TSO.

Controlled Waste Regulations 1992. SI 1992 No 588, TSO.

Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) 2002. SI 2002 No 2776, TSO.

Disability Discrimination Act 1995, TSO.

Electricity at Work Regulations 1989. SI 1989 No 635, TSO.

Electricity Safety, Quality and Continuity Regulations 2002. SI 2002 No 2665, TSO.

Electrical Equipment (Safety) Regulations 1994. SI 1994 No 3260, TSO,

Electromagnetic Compatibility Regulations 1992, SI 1992 No 2372, TSO.

Employers Liability (Compulsory Insurance) Regulations 1998. SI 1998 No 2839, TSO.

Environment Protection Act 1990, TSO.

Environmental Protection (Duty of Care) Regulations 1991. SI 1991 No 2839, TSO.

Factories Act 1961, TSO.

(The) Fire Precautions (workplace) Regulations 1999, TSO.

Furniture and Furnishings (Fire) (Safety) Regulations 1988. SI 1988 No 1324, TSO.

Gas Appliances (Safety) Regulations 1995. SI 1995 No 1629, TSO.

Gas Safety (Installation and Use) Regulations 1998. SI 1998 No 2451, TSO.

Health & Safety at Work etc Act 1974, TSO.

Health and Safety (Display Screen Equipment) Regulations 1992, SI 1992 No 2792, TSO.



Health and Safety (Safety Signs and Signals) Regulations 1996. SI 1996 No 341, TSO.

Low Voltage Electrical Regulations 1997, TSO.

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

Manual Handling Operations Regulations 1992. SI 1992 No 2793, TSO.

(The) Medical Devices Regulations 2002, SI 2002 No 3017, TSO.

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

Pressure Equipment Regulations 1999. SI 1999 No 2001, TSO.

Personal Protective Equipment Regulations 2002. SI 2002 No 1144, TSO.

Plugs and Sockets etc (Safety) Regulations 1994. SI 1994 No 1768, TSO.

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

Pressure Systems Safety Regulations 2000. SI 2000 No 128, TSO

(The) Private Water Supplies (Scotland) Regulations 2006, TSO.

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

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

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

Simple Pressure Vessels (Safety) Regulations 1991. SI 1991 No 2749, TSO.

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

Scottish Water Bye Laws 2004, TSO.

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

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

Working Time Regulations 1998. SI 1998 No 1833, TSO.

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



European/International Standards

BS 4533

101: 1990, EN 60598-1:1989 Luminaires. Specification for general requirements and tests. BSI.

102.22: 1990, EN 60598-2-22:1990 Luminaires. Particular requirements. Specification for luminaire for emergency lighting. BSI.

102.55: 1986 Luminaires. Particular requirements. Specification for luminaires for hospitals and healthcare buildings. BSI.

103.2: 1986 Luminaires. Performance requirements. Specification for photometric characteristics of luminaires for hospitals and health care buildings. BSI.

BS 5266-7: 1999, BS EN 1838:1999, Lighting applications. Emergency lighting. BSI.

BS 5283:1986 Glossary of terms relating to disinfectants. BSI.

BS 5724-1: 1989, BS EN 60601-1: 1990 Medical electrical equipment. General requirements for safety. BSI.

PD 6609:2007 Environmental cleanliness in enclosed spaces. Guide to in situ high efficiency filter leak testing. BSI.

BS 6651: 1999 Code of practice for protection of structures against lightning. BSI.

BS 7671: 2008 Requirements for electrical installations. IEE Wiring Regulations. Seventeenth edition. BSI.

BS 8300: 2001 Design of buildings and their approaches to meet the needs of disabled people. Code of practice. BSI.

BS EN 779: 2002 Particulate air filters for general ventilation. Determination of the filtration performance. BSI.

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

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

BS EN ISO 15883-1:2006 Washer-disinfectors. General requirements, terms and definitions and tests. BSI.

BS EN ISO 15883-4:2008 Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

Version 1: September 2010 Page 59 of 68 © Health Facilities Scotland, a Division of NHS National Services Scotland



CEN ISO / TS 15883-5:2005 Washer-disinfectors. Part 5 Test soils and methods for demonstrating cleaning efficacy

BS EN 55015: 2001 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment. BSI.

BS EN 61010-1:2001, IEC 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements. BSI.

BS EN 61010-2-041:1997, IEC 61010-2-041:1995 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes. BSI.

BS EN 61010-2-042:1997, IEC 61010-2-042:1997 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes. BSI.

BS EN 61010-2-045:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields. BSI.

Department of Health guidance

NHS Estates (2003) Model Engineering Specification C32 – Automated Endoscope Reprocessors for Flexible Endoendoscopes

Health Facilities Scotland guidance

Scottish Health Technical Memoranda (SHTMs)

SHTM 55: Windows, Health Facilities Scotland, 2006.

SHTM 56: Partitions, Health Facilities Scotland, 2006.

SHTM 57: Internal glazing, Health Facilities Scotland, 2006.

SHTM 58: Internal doorsets, Health Facilities Scotland, 2006.

SHTM 59: Ironmongery, Health Facilities Scotland, 2006.

SHTM 60: Ceilings, Health Facilities Scotland, 2009.

SHTM 61: Floors, Health Facilities Scotland, 2009.

SHTM 64: Sanitary assemblies, Health Facilities Scotland, 2009.

SHTM 69: Protection, Health Facilities Scotland, 2006.



SHTM 81: Fire protection in new hospitals, Health Facilities Scotland, 2009.

SHTM 86: Fire risk assessment: Healthcare premises, Health Facilities Scotland 2007.

SHTM 2010: Sterilization, Health Facilities Scotland, 2001.

SHTM 2011: Emergency electrical services, Health Facilities Scotland, 2001.

SHTM 2014: Abatement of electrical interference, Health Facilities Scotland, 2001.

SHTM 2022: Medical Gas Pipe-workline Systems, Health Facilities Scotland, 2001.

SHTM 2023: Access and Accommodation for Engineering Services, Health Facilities Scotland, 2001.

SHTM 2025: Ventilation in Healthcare Premises, Health Facilities Scotland, 2001.

SHTM 2027: Hot and cold water supply, storage and mains services, Health Facilities Scotland, 2001.

SHTM 2030: Washer Disinfectors, Health Facilities Scotland, 2001.

SHTM 2031: Clean steam for sterilization, Health Facilities Scotland, 2001.

SHTM 2040: The control of legionellae in healthcare premises - a code of practice, Health Facilities Scotland, 1999.

Scottish Health Facilities Notes (SHFN)/Scottish Health Planning Notes (SHPN)/Scottish Health Technical Notes (SHTN)

SHPN 52 Accommodation for day care – Part 2 - Endoscopy unit. Health Facilities Scotland, 2002

SHFN 30: Infection Control in the Built Environment, Health Facilities Scotland, 2007.

SHTN 2 Domestic hot and cold water systems for Scottish healthcare premises, Health Facilities Scotland, 1999.

SHTN 3 Management and disposal of clinical waste, Health Facilities Scotland, 2002.

The above documents are available on the Health Facilities website at www.hfs.scot.nhs.uk/



Other publications

Health Protection Scotland. Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management, Dec 2004. <u>www.hps.scot.nhs.uk/</u>

Local Decontamination Units: Guidance on the Requirements for Equipment, Facilities and Management, 2005. Health Protection Scotland. www.hps.scot.nhs.uk/

Model Infection Control Policies, 2010. Health Protection Scotland. <u>www.hps.scot.nhs.uk/</u>

Guide to the Carriage of Dangerous Goods Regulations with respect to soiled devices, 2007. Health Facilities Scotland. <u>www.hfs.scot.nhs.uk/</u>

Appendices

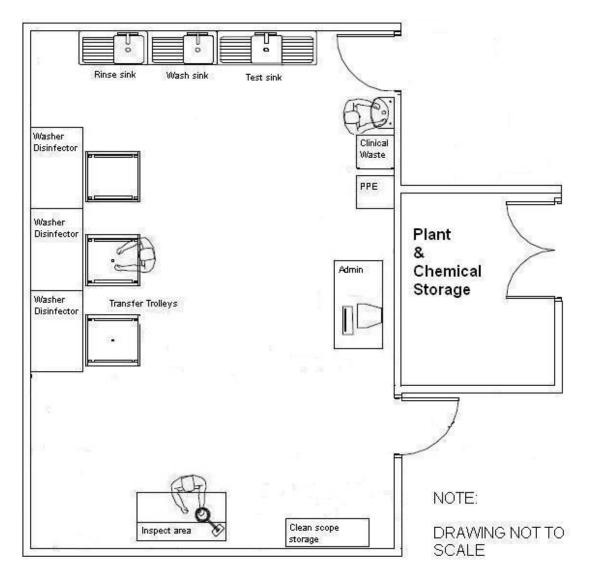
Appendix 1: Single Room EDU model – Decontamination Room

Appendix 2: Two Room EDU model

Appendix 3: Two Room EDU model with Ante rooms

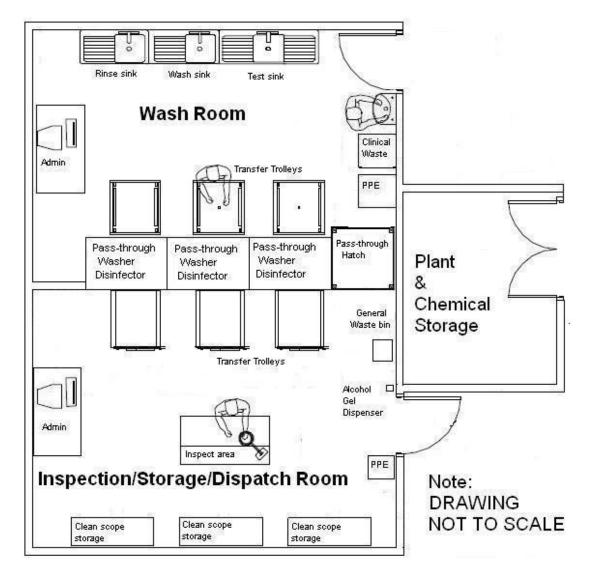
Appendix 4: Two Room EDU with Ante and other Support Rooms

Appendix 1: Single Room EDU model – Decontamination Room



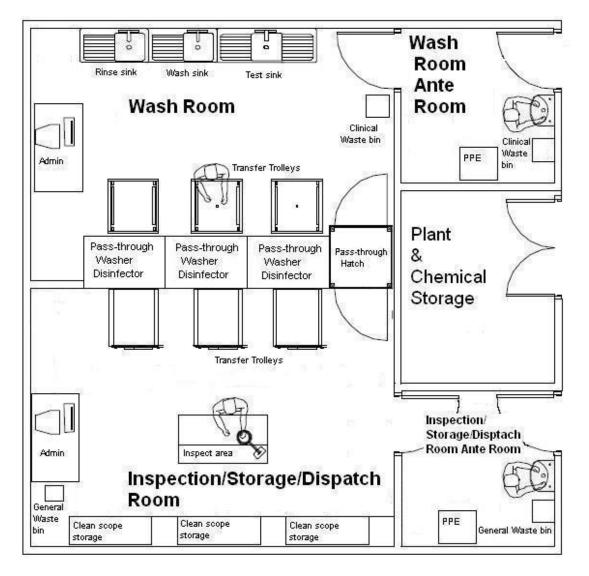
The option appraisal will determine the type and number of each item of equipment. This will include the equipment required for the Plant and Chemical Storage Room. Other areas or rooms not shown are required to support this model, e.g. domestic services and trolley parking.

Appendix 2: Two Room EDU model



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, e.g. domestic services and trolley parking.

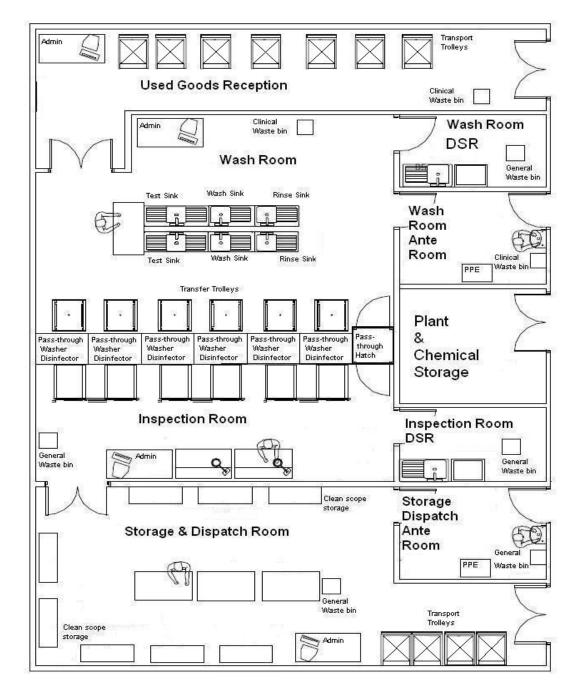




NOTE: DRAWING NOT TO SCALE

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, e.g. domestic services and trolley parking.

Appendix 4: Two Room EDU with Ante and other Support Rooms



NOTE: DRAWING NOT TO SCALE

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.



Acknowledgements

This document builds on the work of a number of organisations and individuals. It was produced at the request of the NHSScotland Sterile Services Provision Review (Glennie) Group with considerable input from Health Protection Scotland and representatives of NHSScotland Boards.

Health Facilities Scotland (HFS) gratefully acknowledges all contributions to this publication. We would particularly like to thank the members of the Working Group who generously donated their time to offer their expert advice and consultation on drafts.

Thanks are also due to all those who commented on the draft during the consultation period.