NHS National Services Scotland

Scottish Health Planning Note 13

Part 2

Decontamination Facilities: Local Decontamination Units

Health Facilities Scotland
Engineering and Environment

June 2008

Contents

1. Executive summary

Purpose

1.1 This section of Scottish Health Planning Note (SHPN) 13 provides guidance to help planners, estates and facilities managers, local decontamination unit (LDU) managers, capital planning and design teams to plan and design a LDU.

Overview of topics

1.2 The document discusses the objectives of an LDU and service requirements in terms of the provision and operation of the facility.

This SHPN contains information on the building and operating principles for three main models of LDUs:

- Two room local decontamination unit with ante rooms;
- Two room local decontamination unit;
- Single room local decontamination unit.

The preferred option for a new build or upgrade is the Two Room LDU with Ante Rooms.

Note: The ventilation standards applicable to central decontamination units, where controlled clean room environments exist, are not practicable in LDUs.

The design rationale for ventilation of these three LDU models is one based on staff protection and comfort. However, in all new build LDUs and upgrades to existing LDUs 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 minimise 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 minimise device contamination must be strictly adhered to e.g. automated cleaning processes and work procedures.

Guidance on interim arrangements where decontamination takes place in the treatment room is not given, as this option is not in compliance with the 'Glennie' Technical Requirements.

Note: Capacity planning has not been addressed in detail in this version of the document. A future version will contain full details of the requirements for capacity planning. Throughput calculations taking account of current and any future needs will be required in order that the size of the facility can be determined.

Advice and expertise

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

Acknowledgements

1.4 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 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.

2. Introduction

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

2.2 The Sterile Services Provision Review Group report, The 'Glennie Report', was published under cover of HDL(2001)66 in August 2001. This report set out a framework for change, specifically related to the technical and operational standards required for the decontamination of re-usable medical devices*. The Technical Requirements for re-processing of devices were based on the potential risk for transmission of CJD at three risk levels (high, medium & low), for the particular tissue with which a device is in contact during use.

Re-usable medical devices and their accessories are classified as medical devices 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.

2.3 In accordance with the Glennie Framework, all re-usable devices used in procedures which involve contact with high and medium CJD transmission risk tissues must be re-processed in a central decontamination unit (CDU), where compliance with the Glennie Technical Requirements, necessary for this level of risk, can be economically achieved.

2.4 The facilities and equipment available within a Local Decontaminant Unit (LDU) are only appropriate for re-processing devices used in procedures which involve contact with low CJD transmission risk tissues. The provision of an LDU should only be considered following a detailed option appraisal that considers all aspects and risks, including, funding, space and services provision, nature of clinical activity, and ability to meet the Glennie Technical Requirements**.**

* **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.

2.5 This SHPN contains information on the building and operating principles for three main models of local decontamination units, where the only viable option is to carry out decontamination locally. These are:

- Two room local decontamination unit with ante rooms;
- Two room local decontamination unit;
- Single room local decontamination unit.

2.6 The preferred model for a new build is the two-room local 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 Protection Equipment (PPE) and to provide a measure of future proofing the facility in the event of the need for additional technical requirements.

2.7 The two room LDU with the ante room model is also applicable for the upgrade of existing facilities. However, where unavoidable constraints exist, the other local decontamination models may have to be considered. The single room LDU 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 processes in the same room. In this model, therefore, tight procedural control is required to minimise the risk of re-contamination of devices.

2.8 A LDU is characterised by the following operational features:

- reprocesses devices used in procedures contacting tissues considered low risk for the transmission of CJD;
- sterilizes singly wrapped or unwrapped items dependent on the type of sterilizer available;
- the unit is equipped to process only relatively low volumes of devices with efficient use of decontamination equipment;
- processed items are generally not transported outside the building in which the LDU is located (other than for domiciliary visits by staff from the clinical unit of which the LDU is part, where the devices are sterilized wrapped, in an appropriate sterilizer and remain under the control of the clinical staff);
- under the control of one or more clinicians who use the re-processed devices;
- staff responsible for decontamination may have duties other than decontamination;
- a LDU may serve several clinical disciplines e.g. general medicine; dentistry and podiatry located in the same building or it may just serve one treatment room/speciality;
- does not supply to a third party.

2.9 The ability of a LDU to supply more than one clinic is dependent on its location in relation to the clinical areas, its design and the type of decontamination equipment being used. It should be noted that within primary care there might be a need for external technical support with regard to, for example:

- Authorised Person (Sterilizers) [AP(S)] services;
- assessment of decontamination requirements;
- procurement of medical devices;
- procurement of decontamination equipment;
- maintenance and testing of decontamination equipment;
- decontamination policy;
- staff training;
- infection control;
- planning & design support;
- electrical services;
- heating/ventilation/air conditioning design;
- health and safety.

Appropriate expertise may be available from NHS Boards and/or Health Protection Scotland.

3. General service considerations

Introduction

The decontamination life cycle encompasses each stage of the decontamination process.

Figure 1: The decontamination cycle

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;
- validation, testing and maintenance of equipment, and where appropriate support services;
- operational policies and procedures;
- training requirements for personnel decontaminating devices and for those managing the decontamination process.

3.2 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., washed, disinfected and sterilized using validated automated processes, which ensure reproducibility, unless the manufacturer's instructions state otherwise i.e. manual washing only;
- 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 re-contamination of clean devices. Physical segregation implies that disassembly and cleaning of used devices are carried out in a separate room from inspection, packing and sterilization. The two-room local decontamination models 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 sterilization or re-use. 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 re-contamination of cleaned 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 sterilized devices, particularly those that are unwrapped;
- 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 i.e. batch traceability;
- reprocessing instructions for all reusable devices 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 transport system for moving devices to and from the LDU (see paragraphs 3.32 to 3.36).

Standards, regulations and guidance

3.3 It is important to be aware that, a number of British, European and International standards and best practice guidance documents e.g., Scottish Health Technical Memoranda, exist which cover the decontamination of reusable

medical devices etc. Decontamination is a continually evolving area and therefore planning work should recognize 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 and prior to sterilization. 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.

3.4 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.

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 Scottish Health Technical Memorandum (SHTM) 2010: 'Sterilization' and SHTM 2030: 'Washer Disinfectors'.

3.5 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

3.6 The provision and maintenance of a compliant LDU is a significant, high cost and ongoing responsibility. The provision of a LDU should therefore only be considered as a last resort following a detailed option appraisal into alternative arrangements. All aspects must be considered including costs, benefits, risks, uncertainties and value for money, associated with the following options:

- use of single-use devices only;
- use of a CDU;
- a combination of use of single-use devices and re-usable devices reprocessed through a CDU;
- provision of a compliant LDU by upgrade of an existing facility;
- provision of a compliant LDU by a new build;
- a combination of use of single use devices and provision of a compliant LDU.

3.7 When planning and designing a LDU there must be a clear understanding of the requirements. This includes the undernoted 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;
- re-usable medical device inventory requirements;
- potential future demand.

3.8 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 sterile and sterilized 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.

Service objectives

3.9 Before embarking on a design and development project for a LDU 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 through the LDU 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 eg sterile or sterilized;
- 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 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 LDU provides a high quality and cost-effective service;
- providing adequate labelling for safe use. It must be clearly evident which devices are sterile and which have been sterilized but cannot be considered sterile at point of use;
- ensuring automated equipment is validated, maintained and tested and the process is controlled and monitored;
- maintenance records (including equipment breakdown details) to demonstrate compliance.

Service requirements

3.10 The service can be described under the following headings, which are used to provide an overview of the requirements of the LDU 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 2010: 'Sterilisation' and 2030: 'Washer Disinfectors', Medicines and Healthcare Products Regulatory Agency (MHRA) guidance and relevant British, 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.

Sizing a department (see paragraphs 4.3 – 4.9)

3.11 The capacity requirements on the LDU 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, 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 – 4.9 for sizing the equipment, fixtures and fittings once throughput calculations have been carried out.

Location of the LDU

3.12 When choosing the location of the LDU the following should be considered.

- availability of space;
- distance from clinical units;
- revenue and capital costs;
- turnaround time;
- re-usable medical device inventory;
- quality and capacity of engineering services e.g., power, water, sewerage;
- personnel issues;
- planning permission;
- service development strategy;
- fire precaution requirements;
- structural survey;
- potential for water leakage.

Operational policies

As a general guideline, the Operational Policy should include the following; information-document control, background, summary, regulatory requirements, aim of the service, clinical opening hours, decontamination service hours of operation, staffing and management and governance (roles/responsibilities), training and supervision, functions of the designed solution, risk assessment, equality and diversity statement and references.

Cleaning and disinfection

3.13 All devices returned to the LDU should be treated as contaminated and be subject to standard infection control precautions.

3.14 Cleaning should completely remove all soiling. Thorough cleaning followed by thermal disinfection minimises the infection risk to staff when handling devices prior to sterilization and reduces the microbial challenge for the sterilization process.

3.15 Cleaning and disinfection should be carried out in a washer disinfector validated, tested and maintained in line with the requirements of SHTM 2030:

'Washer Disinfectors'. Washer disinfectors should be of the pass-through type where the two rooms or two rooms with ante room models are in use. Ultrasonic cleaners for pre-cleaning, if required, should conform to the requirements of the same document.

3.16 Only items specified by the manufacturer as requiring manual washing should be manually cleaned. These items should be phased out and devices capable of automated washer disinfector reprocessing introduced and/or single use devices introduced.

3.17 At the end of the process, clean, disinfected and dry devices should be inspected for cleanliness, dryness and tested and/or inspected for functionality but should not be compromised by unnecessary further handling.

Sterilization

3.18 Where the devices require to be sterilized this should be carried out in a sterilizer validated in accordance with the requirements of SHTM 2010: 'Sterilisation' and European International standards as applicable.

3.19 The choice, purchase, installation, testing and maintenance of all types (N, B & S) of sterilizers should conform to the requirements of SHTM 2010: 'Sterilisation' and BS EN 13060 as applicable. Consult an AP(S).

3.20 Devices should only be wrapped when a Type B or some Type S sterilizers are to be used. Where different types of sterilizer are in use within the LDU, appropriate staff training and clear identification of sterilizer types are essential, to prevent device loads being processed through the wrong sterilizer, resulting in failure of the sterilization process.

Staff protection

3.21 The type and nature of the personal protective equipment (PPE) e.g. protective clothing, eye protection, face mask, for the dirty processes of the LDU will be determined based on a COSHH risk assessment of the area. Visitors e.g. maintenance staff should also wear appropriate PPE within the LDU.

Education and training

3.22 All staff working within the LDU 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

3.23 A system allowing the tracking and tracing of medical devices passing through the LDU should be in place.

3.24 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 (ultrasonic cleaner, washer disinfector (WD) and sterilizer) and the person responsible for carrying out each stage of the process. Recording by exception and batch records may be used (i.e. the devices rejected after unsatisfactory process stages are recorded and details of the cycles used for 'rework'.)

3.25 Tracking of devices to the patients on whom they are used is currently only a Glennie Technical Requirement for devices used in procedures involving tissues considered to be medium or high risk for transmission of CJD. Such instrumentation should not be processed through a LDU where the equipment and facilities are only suitable for reprocessing devices used for procedures where there is contact only with low CJD transmission risk tissues.

Domestic Services

3.26 High standards of cleanliness are essential throughout the LDU. Dedicated and appropriate cleaning equipment and materials must be available for the LDU. Cleaning should be managed to minimise the risk of transferring contamination from a dirty area to a clean area. With the two rooms LDU this can be achieved by having separate domestic service rooms (DSR) for the wash and sterilization room. Alternatively, separate clearly identified cleaning equipment, for each area would be stored in a single DSR. With the one room LDU, 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.

3.27 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.

3.28 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 LDU.

Waste disposal

3.29 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 Health Facilities Scotland's 'Guide to the 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/publications 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. The cost of waste disposal should be included in the

option appraisal, in relation to both operating an LDU and using single use devices.

Materials procurement and storage

3.30 Only materials used in the LDU and those items that are to be processed should be stored or passed through the LDU. Items should be stored in a way that allows appropriate cleaning of the area.

3.31 Time, access, facilities and training must be allowed for appropriate cleaning of the LDU. Storage of raw materials should not compromise the decontamination process in the LDU and 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.

Transportation

3.32 Devices required to be sterile at point of use can only be transported if they were sterilized wrapped in a sterilizer designed to process wrapped items. Unwrapped sterilized devices should be bagged to protect them from gross contamination and marked “Sterilized only” and should be clearly distinguishable and stored separately from sterile devices.

3.33 Sterile wrapped devices and sterilized bagged devices must be transported in separate, dry, clean, containers to protect them from sources of water and contamination. Containment of the device protects the device itself, and its packaging, from damage.

3.34 Used devices must be transported safely from the clinical area where used to the LDU. They should be transported in solid walled, leak proof and lidded containers. 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.

3.35 There should be suitable facilities for cleaning of the transit containers between use. A documented cleaning procedure must be used and records of cleaning kept.

3.36 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, and 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;
- there should be separate dedicated storage areas outwith the LDU for sterile and sterilized goods. Storage areas should be fitted with appropriate shelving, be cleanable, dry, well lit and secure;
- maintenance repair and testing (where appropriate) of building, facilities and equipment, pest control and provision of services e.g. power, water, sewerage;
- room finishes in line with the room data sheet (see paragraph 4.2);
- the staff changing facilities should be maintained in a clean and tidy condition;
- cloakrooms and toilets must be separate from the decontamination area.

LDU Room data sheet

4.2

Area	Description
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: spray elastomeric vinyl compound, epoxy coating, PVC with welded joints and oil-based paint.
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. For single room LDU, flooring must be non-slip. In two room LDUs, 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 LDU 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: spray elastomeric vinyl compound, epoxy coating, PVC with welded joints and oil-based 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 are 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. The LDU 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	Enclosed in intact, easy to clean, fluid impermeable casings and rated at IP54. Light level 500 lux at workbench level.
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 washer disinfectors. Sufficient appropriately placed power points should be provided at a minimum of 150mm above bench level and IP55 rated.

Area	Description
Compressed air	If an automated lubrication system is required for dental hand pieces, compressed dental air may be required. Consult equipment manufacturer for details.
Medical grade air	Consult equipment manufacturer for details. If required, the air should be compliant with SHTM 2022: 'Medical gas pipeline systems'. This would include the connections.
Air conditioning Heating/ Ventilation (also refer to paragraphs 7.26-7.37)	Mechanical ventilation required for all models of LDUs. Ensure supply and extract grills or pressure relief dampers are kept free of obstructions. **Two Room LDU with Ante Rooms** *Wash Room* Supply a total of 7 air changes per hour (ACH) to the Wash Room and its ante room (based on each individual area). Extract 10 ACH (based on the combined Wash Room and its ante room area) directly from the Wash Room. Re-circulation of the supply is not permitted. Wash Room to be negative pressure with respect to adjoining areas. *Sterilization Room* Supply 10 ACH to the Sterilization Room (based on the combined Sterilization Room and its ante room area). Extract a total of 7 ACH from the Sterilization Room and its ante room (based on each individual area). Sterilization Room to be positive pressure with respect to adjoining areas. **Two Room LDU** *Wash Room* Supply 7 ACH to the Wash Room and extract 10 ACH from the Wash Room. Re-circulation of the supply air into the Wash Room is not permitted. Wash Room to be negative pressure with respect to adjoining areas. *Sterilization Room* Supply 10 ACH to the Sterilization Room and extract 7 ACH from the Sterilization Room. Sterilization Room to be positive pressure with respect to adjoining areas. **Single Room LDU** Supply 7 ACH and extract 10 ACH. No recirculation of the supply air is permitted. Room to be **not** positive pressure with respect to adjoining areas. Guidance – Maintain an average room temperature between 16^0C to 21^0C and average relative humidity of 40 to 70%RH.
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.

Area	Description
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 are unavoidable in the work unit surface they require to be sealed, 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 for the application.
Manual wash and rinsing sinks	Dedicated rectangular stainless steel sinks with draining boards are required, 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. 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.
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 hand wash solution dispenser should be wall-mounted near the wash hand basin. The hand wash 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. ***Note:*** *In the Two Room model, there is no wash hand basin installed in the Sterilization 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 Sterilization Room. Staff hands should be socially clean prior to entrance to the room.*
Administration Area	This area is used to manage the decontamination documentation. A computer may be used. In the single room LDU a single administration area is required. In the Two Room LDUs an administration area is required in both the Wash Room and the Sterilization Room.
Drainage requirements for washer disinfectors	Drains will be required for any washer disinfectors installed. The drainage systems must be capable of withstanding high temperatures (95^{o}C) without distortion or leakage. Scottish Water should be contacted with regard to management of the proposed effluent. Where a LDU is served by a septic tank the following points should be considered: a) The tank volume needs to be sized to ensure the primary settlement process takes place with the increased discharge volumes associated with an automated washer disinfector; b) If the wastewater is at an elevated temperature entering the tank, ensure that there is no inhibition of the decomposition process; c) The level of chemical contaminants leaving the septic tank into the soak away or subsurface drainage system is within Scottish Environment Protection Agency (SEPA) guidelines.

Area	Description
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.
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	No set level. Consideration should be given to surrounding areas where noise levels may be specified, e.g., where the LDU is above, below or next to a clinical area (see paragraph 7.21).
Eye wash station and spill kit	Required and readily available for use in an emergency.

Sizing the facility

4.3 Recognising that a LDU will in many 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.

4.4 The size of the LDU whether a one room, two room or two room with ante rooms model will be determined by selecting the individual components as required from Table A. and allowing for access/maintenance to accommodate the throughput. Note other areas or rooms are required to support these models e.g. DSR(s), device storage areas and trolley parking.

Area / Item or equipment	Length (m)
Door	0.9
Wash hand basin (could be in Ante Room)	0.6
Dirty set down area	0.6
Wash sink with draining board	1.0
Ultrasonic cleaner	0.5
Pre rinse set down area	0.5
Rinse sink with draining board	1.0
Post rinse set down area	0.5
Washer Disinfector (could be under bench)	0.6
Interlocked pass-through hatch (for 2 room model)	0.5
Post wash set down inspection area	0.5
Hand piece automated lubrication	0.3
Pre-Sterilization packaging	0.5
Heat sealer	0.5
Pre Sterilization set down area	0.5
Sterilizer	0.6
Post-Sterilization cooling dispatch area	0.6
Water treatment unit (could be under bench or on a wall)	0.6
Administration area (2 required for two room LDU)	1.0
PPE storage (could be on a wall)	0.5
Waste storage (could be under bench)	0.5

Table A

4.5 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, e.g. using an under bench washer disinfector, 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. Where appropriate, making use of self-seal pouches may obviate the need for a heat sealer and free up work space.

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

4.7 Sterile and sterilized devices should be stored in separate designated areas outwith the LDU. Both storage areas should ensure that packaged devices are stored in a manner that does not interfere with the integrity of the packaging.

4.8 Storage requirements outwith the LDU for the transport containers should be considered.

4.9 A dedicated domestic services room(s) see paragraph 3.26, outwith the LDU, or a dedicated space within a general DSR, should be provided to support the cleaning activities in the LDU. 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.

LDU Layout

4.10 Three LDU layouts have been identified as options to enable compliance with current technical requirements for decontamination of re-usable medical devices in a primary care setting. The preferred LDU model is the two rooms with ante rooms.

Single room local decontamination

4.11 Devices for reprocessing are transferred, via the corridor, to the decontamination room, placed in the dirty set-down area, sorted, disassembled (if appropriate), pre-cleaned in an ultrasonic cleaner if required and placed in the washer disinfector (WD) (or manually washed depending on manufacturer's instructions). Next the devices are reassembled, inspected for cleanliness, dryness, damage and functionality. Where required by manufacturer's instructions dental hand pieces are lubricated. Devices failing the inspection process are returned to the dirty set down area for reprocessing or sent for repair or disposal as appropriate. Devices passing inspection are then either:

- wrapped prior to sterilization in a sterilizer designed for processing wrapped items, inspected and then transferred for immediate use or stored in the designated storage area;
- sterilized in a sterilizer for unwrapped items then either used immediately or bagged to protect from gross contamination for later use in procedures not requiring the item to be sterile at point of use, and stored in the designated storage area.

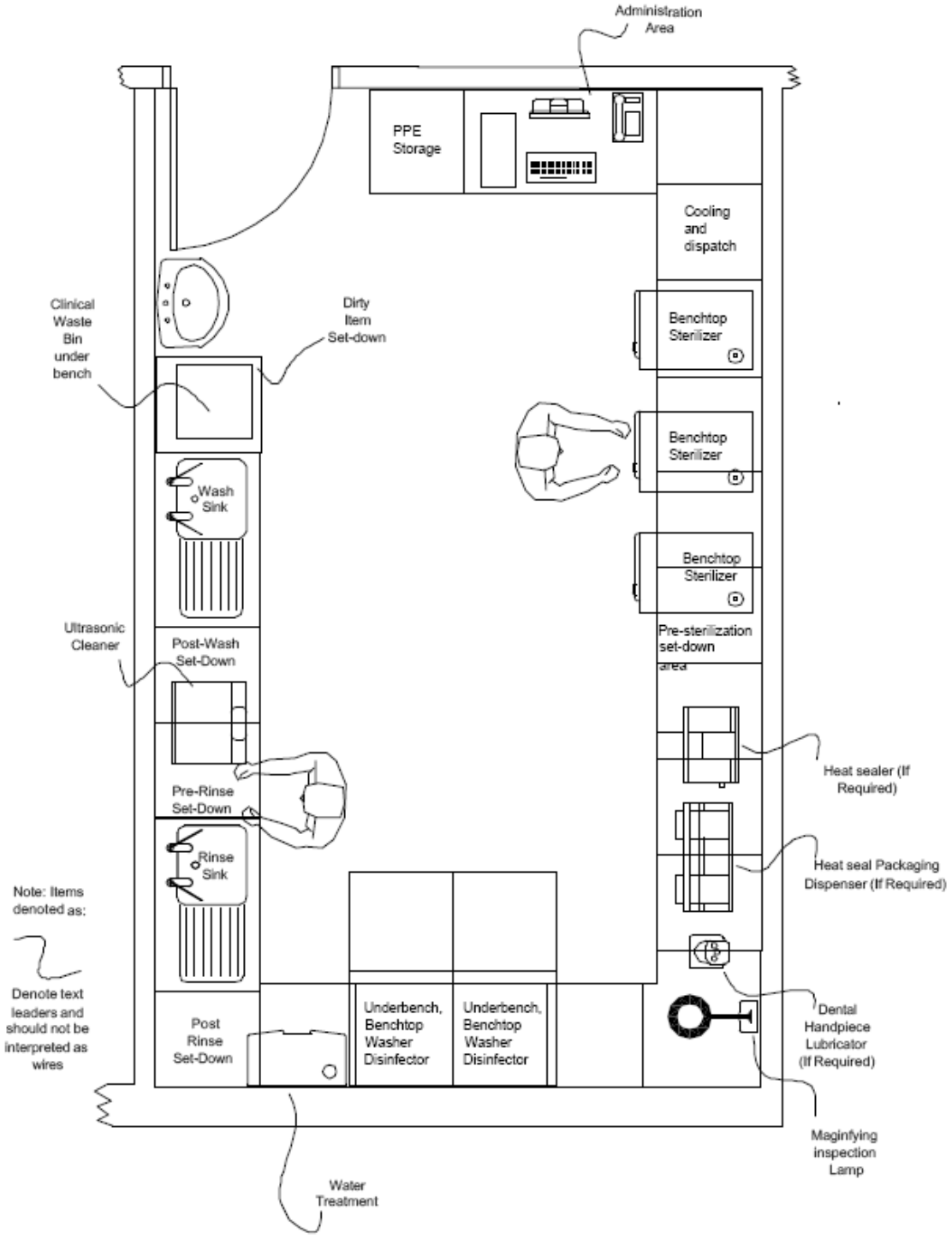
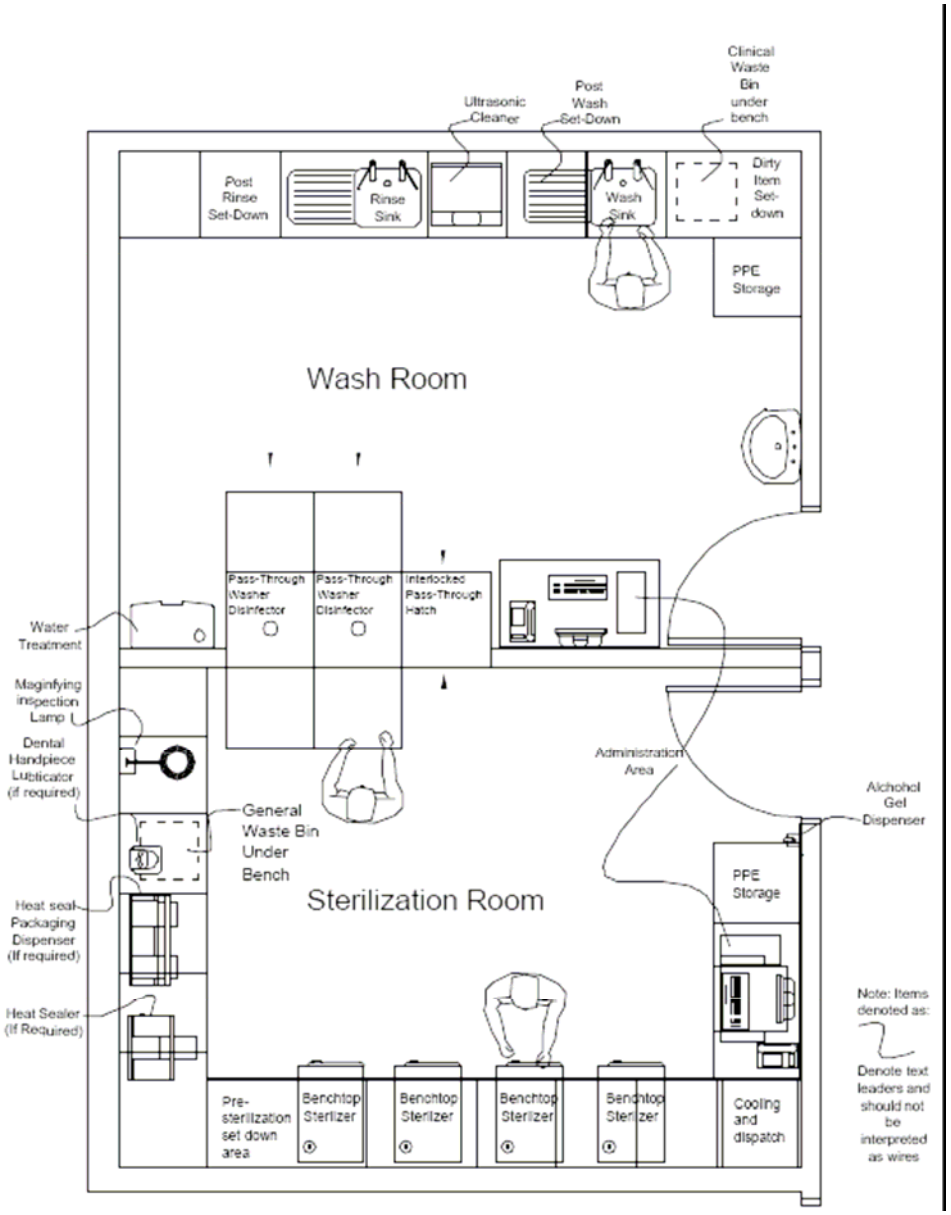


Figure 2: Single Room Local Decontamination Unit – Drawing NOT TO SCALE.

The option appraisal will determine the type and number of each type of equipment. Other areas or rooms not shown are required to support this model, e.g. device storage, domestic services and trolley parking.



Figures 3: Two Room Local Decontamination Unit (without ante rooms)

Drawing NOT TO SCALE

The option appraisal will determine the type and number of each type of equipment. Other areas or rooms not shown are required to support this model, e.g. device storage, domestic services and trolley parking.

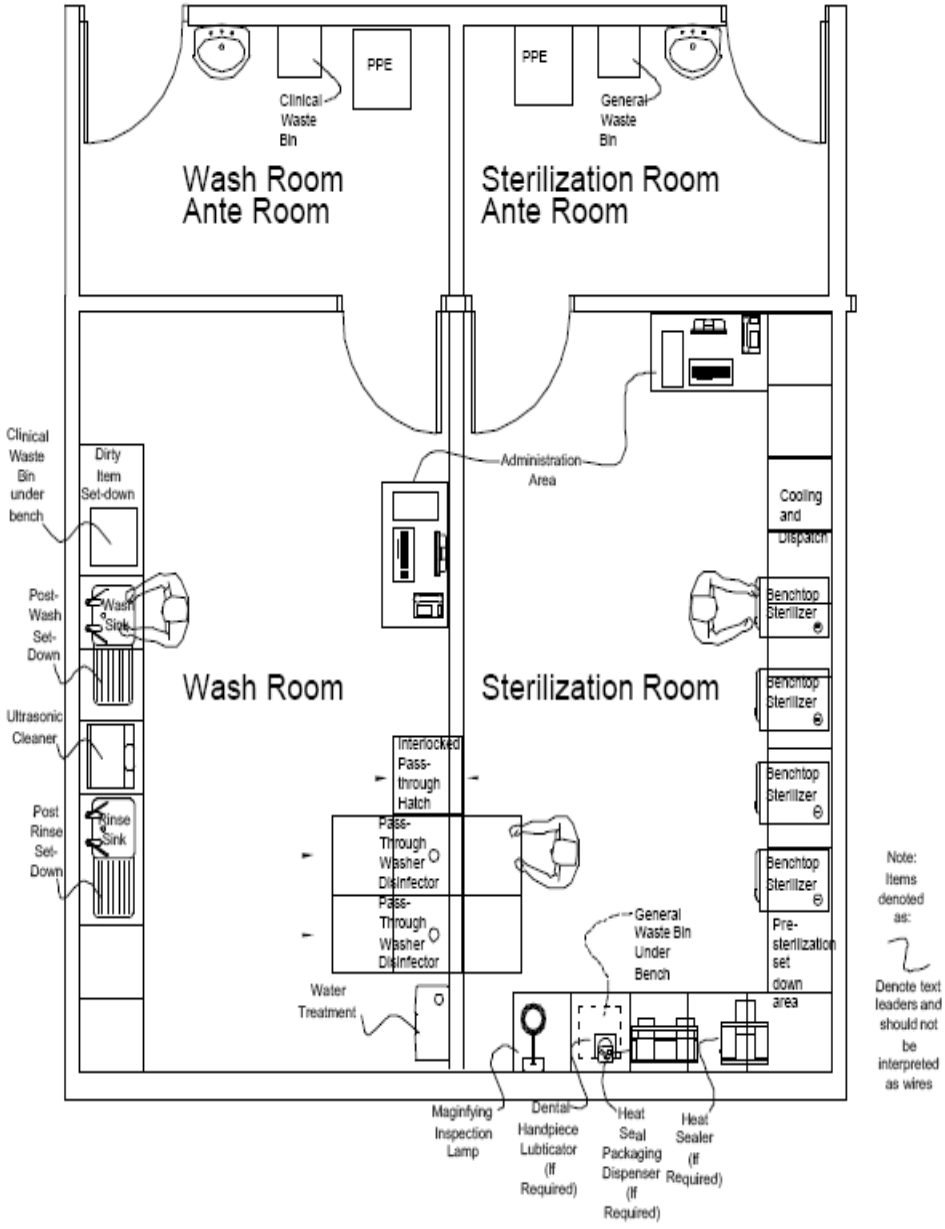


Figure 4: Two Room Local Decontamination Unit (with ante rooms)

Drawing NOT TO SCALE

The option appraisal will determine the type and number of each type of equipment. Other areas or rooms not shown are required to support this model, e.g. device storage, domestic services and trolley parking.

Two room local decontamination (with/without ante rooms)

4.12 Devices for reprocessing are transferred to the Wash Room, via its ante room where applicable, placed in the dirty set down area, sorted, disassembled (if appropriate), pre-cleaned in an ultrasonic cleaner if required and placed in a pass-through washer disinfector (WD) (or manually washed depending on manufacturer's instructions). Devices processed through the WD will be

removed from the WD in the Sterilization Room. Manually washed devices will be dried and passed through the interlocked hatch to the Sterilization Room. All devices are then reassembled, inspected for cleanliness, dryness, damage and functionality. Where required by manufacturer's instructions, dental hand pieces are lubricated. Devices failing the inspection process are returned to the dirty set down area for reprocessing or sent for repair or disposal as appropriate. Devices passing inspection are then either:

- wrapped prior to sterilization in a sterilizer designed for processing wrapped items, inspected and then transferred for immediate use or stored in the designated storage area;
- sterilized in a sterilizer for unwrapped items then either used immediately or bagged to protect from gross contamination for later use in procedures not requiring the item to be sterile at point of use, and stored in the designated storage area.

Environmental cleaning

4.13 For two room LDUs, 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

4.14 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

4.15 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

4.16 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.

5. Specific functional and design requirements

Single room local decontamination with type N sterilizer (for unwrapped, non-lumened devices

Function

5.1 Receive devices for reprocessing in the dirty set down area, sort (discard to waste any single-use devices not disposed of in the treatment room), disassemble (if appropriate), pre-clean in a ultrasonic cleaner if required, clean, disinfect, and dry reprocessable items. Transfer the devices to the inspection area, reassemble and, if passed inspection, move on to be sterilized in a type N Sterilizer (do not wrap the device). Following successful sterilization, transfer to clinical area for immediate use or bag to protect from gross contamination and transfer to storage area.

Location

5.2 In the same site in which the devices are used.

Key requirements

5.3 On entering the decontamination room, 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 devices for reprocessing, from the clinical area, in the dirty set down area, automated processing through a washer disinfector (WD), with a pre-clean in an ultrasonic cleaner if required, (wash and rinse sinks for devices requiring manual cleaning) then the cleaned, disinfected and dried items are transferred to the put down space in the inspection area. The devices are inspected, tested, lubricated (if necessary) and sterilized in a type N Sterilizer for unwrapped items. Devices are then either used immediately or bagged to protect from gross contamination and transferred to the designated storage area for later use in procedures not requiring devices to be sterile at point of use.

5.4 Devices failing the inspection process are returned to the dirty set down area for reprocessing or sent for repair or disposal as appropriate.

Equipment

5.5
- wash hand basin;
- PPE storage;
- wall mounted cartridge soap dispenser;
- wall mounted paper towel dispenser;
- hands free clinical waste bin;
- wash and rinse sinks with draining boards;

- ultrasonic cleaner, if required;
- washer disinfector;
- task lighting with magnifier;
- Type N sterilizer for unwrapped and non-lumened devices;
- dedicated cleaning equipment;
- telephone or intercom;
- computer for administration area.

Single room local decontamination with type B/type S sterilizer

Function

5.6 Receive devices for reprocessing in the dirty set down area, sort (discard to waste any single-use devices not disposed of in the treatment room), disassemble (if appropriate), pre-clean in an ultrasonic cleaner if required, clean, disinfect, and dry reprocessable items. Transfer the devices to the inspection area, reassemble and, if passed inspection, move on to be wrapped and sterilized in a type B or suitable type S sterilizer. Following successful sterilization, transfer to storage area or for use.

Location

5.7 In the same site in which the devices are used.

Key requirements

5.8 On entering the decontamination room 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 instruments for reprocessing, from the clinical area, in the dirty set down area, automated processing through a washer disinfector (WD) with a pre-clean in an ultrasonic cleaner if required (wash and rinse sinks for devices requiring manual cleaning) then the cleaned, disinfected and dried items are transferred to the put down space in the inspection area. The devices are inspected, tested, lubricated (if necessary), wrapped and sterilized in a type B or suitable type S sterilizer for wrapped items. Devices are then transferred to the designated storage area or for use.

Devices failing the inspection process are returned to the dirty set down area for reprocessing or sent for repair or disposal as appropriate.

Equipment

5.9
- wash hand basin;
- PPE storage;
- wall mounted cartridge soap dispenser;
- wall mounted paper towel dispenser;

- hands free clinical waste bin;
- wash and rinse sinks with draining boards;
- ultrasonic cleaner if required;
- washer disinfector;
- task lighting with magnifier;
- type B / type S sterilizer (if using a type S sterilizer confirm the model is suitable for processing wrapped devices);
- heat sealer and packaging dispenser (dependant on choice of packaging);
- dedicated cleaning equipment;
- telephone or intercom;
- computer for administration area.

Two room local decontamination unit with pass-through WD

Wash Room

Function

5.10 Receive devices for reprocessing in the Wash Room in the dirty set down area, sort (discard to waste any single-use devices not discarded in the treatment room), disassemble (if appropriate), and load into the pass-through washer disinfector (after pre-clean in an ultrasonic cleaner if required).

Location

5.11 Connected via a pass-through washer disinfector to the Sterilization Room of the decontamination unit.

Key requirements

5.12 On entering the Wash Room, staffs wash hands at the wash hand basin and put on PPE as per the COSHH assessment.

Work flows from the initial stage of receiving devices for reprocessing from the clinical area, sorting these, then placing in a pass-through washer disinfector. Ultrasonic cleaning for pre-cleaning or manual cleaning may be required for some devices. Wash and rinse sinks are required for devices requiring manual cleaning (if required by manufacturers' instructions).

Equipment

5.13
- wash hand basin;
- PPE storage;
- wall mounted cartridge soap dispenser;
- wall mounted paper towel dispenser;

- hands free clinical waste bin;
- wash and rinse sinks with draining boards;
- ultrasonic cleaner if required;
- pass-through washer disinfector;
- dedicated cleaning equipment;
- telephone or intercom;
- computer for administration area.

Two room local decontamination unit with pass-through WD

Wash Room Ante Room

Function

5.14 The Wash Room Ante Room provides controlled access from the corridor to the Wash Room. Devices for reprocessing enter via 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

5.15 Connects the corridor to the Wash Room.

Key requirements

5.16 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 devices for reprocessing from the clinical area. Devices enter the Wash Room via its ante room.

On leaving the ante room, remove PPE and wash hands.

Equipment

5.17
- wash hand basin;
- PPE storage;
- wall mounted cartridge soap dispenser;
- wall mounted paper towel dispenser;
- hands free clinical waste bin.

Two room local decontamination unit with pass-through WD

Sterilization Room

Function

5.18 Unload, clean disinfected devices from the WD or manually washed devices from the pass-through hatch, inspect, reassemble, test, lubricate (if necessary), wrap, sterilize in type B or suitable type S sterilizer and transfer to storage area or use (unwrapped non-lumen devices may be sterilized in a type N sterilizer).

Location

5.19 Connected, via a pass-through washer disinfector and interlocked pass-through hatch, to the Wash Room of the decontamination unit.

Key requirements

5.20 On entering the Sterilization Room where there is no ante room, staff should disinfect clean hands using alcohol gel and put on PPE as per the COSHH assessment.

Work flows from the initial stage of unloading cleaned, disinfected and dried devices from the pass-through washer disinfector, inspecting, testing, lubricating (if necessary), wrapping, sterilizing in a type B or suitable type S sterilizer and transfer of devices to the dedicated storage area or for use.

Equipment

5.21
- type B/type S sterilizer (if using a type S sterilizer confirm the model is suitable for processing the wrapped devices). If sterilizing unwrapped non-lumen devices a type N sterilizer may be considered;
- heat sealer and packaging dispenser if applicable;
- PPE storage;
- hands free general waste bin;
- task lighting with magnifier;
- telephone or intercom;
- computer for administration area.

Two room local decontamination unit with pass-through WD

Sterilization Room Ante Room

Function

5.22 The Sterilization Room Ante Room provides controlled access from the corridor to the Sterilization Room. Hand washing is performed in this area. PPE is put on or removed, as appropriate, in this area.

Location

5.23 Connects the corridor to the Sterilization Room.

Key requirements

5.24 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

5.25
- wash hand basin;
- PPE storage;
- wall mounted cartridge soap dispenser;
- wall mounted paper towel dispenser;
- hands free general waste bin.

Domestic Services Room

Function

5.26 This room is used to store domestic equipment used for cleaning the LDU.

Location

5.27 This room should be in the same corridor as the LDU.

Key requirements

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

Equipment

5.29
- wash hand 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.

Device storage

5.30 Devices, whether wrapped or bagged, must be stored in dedicated, clean, dry, dust-free containers, outwith the decontamination room. The storage area(s) must be well lit, secure and away from direct sunlight. Sterilized and sterile devices should be stored in separate designated areas. Both storage areas should ensure that wrapped or bagged devices are stored in a manner that does not interfere with the integrity of the packaging.

6. General guidance

Introduction

6.1 This Section presents guidance relating to the function and design aspects of local decontamination units in healthcare buildings when 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.

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

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

6.5 Having decided that an upgrade is the best option, the main requirement will be to assess how the facility can be adapted to best fit the design principles of the models presented. An upgrade project should of course address all current legislation.

6.6 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.

7. Engineering services

Introduction

7.1 This Section describes the engineering services supplied to the LDU (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.

7.2 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.

7.3 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, IT);
- 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.

7.4 The NHS Model Engineering Specifications are sufficiently flexible to reflect local needs. Where required, reference should be made to the engineering sections of SHTMs 2010: ‘Sterilization’, 2025: ‘Ventilation in healthcare premises’, 2030: ‘Washer Disinfectors’ and 2031: ‘Clean steam for sterilization’.

Economy and Value Management

7.5 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.

7.6 '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.

7.7 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.

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

7.9 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.

7.10 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'.

7.11 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.

Service requirements

7.12 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. Service requirements for planned or foreseeable future expansion in department workload should also be considered at the design stage.

7.13 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

7.14 Enough space should be provided for plant and services within the department (refer to paragraphs 4.3 to 4.9). 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 where required;
- ventilation and air conditioning;
- hot water generation;
- bulk chemical distribution.

7.15 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.

7.16 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.

7.17 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

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

Safety

7.19 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

7.20 Fire precautions should be as Scottish Health Technical Memorandum (SHTM) 81: Firecode: 'Fire precautions in new hospitals' by Health Facilities Scotland. Other SHTMs in the Firecode series give technical guidance on various building, engineering and equipment issues.

The design team will have to consider how the fire precaution requirements may affect the design (including upgrade) of the LDU.

Noise and speech privacy

7.21 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

7.22 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 AP(S) 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.

Equipment validation

7.23 Decontamination equipment should be validated in line with SHTMs 2010: 'Sterilization' or 2030: 'Washer Disinfectors', 2031: 'Clean steam for sterilization'

European/International Standards, as appropriate. The quality of product from an LDU is highly dependant on satisfactory validation of the equipment. The advice of an AP(S) should be sought.

Mechanical services

Heating

7.24 The controlled environments should be heated by the mechanical ventilation system. There should be no hot water radiators in the decontamination area of the LDU 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

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

Ventilation

7.26 Ventilation requirements are specified in SHTM 2025: 'Ventilation in Healthcare Premises'. It identifies the statutory requirements from COSHH and, the Health and Safety at Work Act.

7.27 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 and sterilizers. Washer disinfectors may require dedicated extract systems. Refer to SHTM 2030: 'Washer Disinfectors Part 1'.

7.28 Ventilation supply plant should include a pre-filter 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.

7.29 Extract discharge arrangements for extract systems should be protected against back-pressure from adverse wind effects.

7.30 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 packed if a separate area.

Ventilation - Single Room Local Decontamination Unit

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

7.31 This would require an air-handling system that would 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 would provide, at least, the minimum fresh air requirements of 8 litres/second/person (reference SHTM 2025: 'Ventilation in Healthcare Premises' Part 2, paragraph 3.15)

7.32 The supply air would enter the room through a ceiling diffuser. The diffuser could be fitted in the ceiling at either side of the room. The air would be filtered using a filter of minimum Class EU3. The air supply would be a minimum of 7 air changes per hour. There would be no recirculation of the supply air.

7.33 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 wash and rinse sinks. The air extract would be at 10 air changes per hour. The room pressure would be negative 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.

Ventilation - Two Room Local Decontamination Unit

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

Sterilization Room of Two Room LDU

7.34 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 8litres/second person. The Sterilization Room would be positive pressure with respect to adjoining areas;
- the supply air would enter the room through a ceiling diffuser. The air would be filtered using a filter of minimum Class EU3. The air supply would be a minimum of 10 air changes per hour;
- the air extract of 7 and changes per hour would 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 Sterilization Room and its ante room with a wall mounted extract grille connecting the Sterilization Room to its ante room.

Wash Room of Two Room LDU

7.35 This would require an air-handling system that would 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 would be at negative pressure with respect to adjoining areas.

7.36 The supply air would enter the room through a ceiling diffuser. The supply air would be filtered using a filter of minimum Class EU3. The air supply would be a minimum of 7 air changes per hour. There would be no recirculation of the supply air. Where an ante room is installed, the supply air would 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.

7.37 The air extract would 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 wash and rinse sinks. The air extract would be at 10 air changes per hour.

Hot and cold water services

7.38 Guidance on the design and installation of hot and cold water supply and distribution systems is contained in SHTM 2027: 'Hot and cold water supply, storage and mains services'. 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. Pipe-work work materials should be in accordance with Scottish Health Technical Note (SHTN) 2: 'Domestic Hot and Cold Water Systems for Scottish Healthcare Premises'. If the premises use private water supplies then the installation must comply with The Private Water Supplies (Scotland) Regulations.

The manufacturer of the WD shall specify the requirements for water supplied to the WD. Consult the device manufacturer's reprocessing instructions to confirm the intended water quality used to reprocess the device is fit for purpose with regard to patient safety and scope functionality. See BS EN ISO 15883-1 and BS EN ISO 15883-2 regarding the water treatment equipment and the water used for final (post disinfection) rinsing of devices. Consult an AP(S) regarding this matter.

7.39 The requirements for the control of *legionella* bacteria in hot and cold water systems are given in SHTM 2040: 'The control of legionellae in healthcare premises – a code of practice'.

Compressed air

7.40 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 SHTM 2010: 'Sterilization' and SHTM 2030: 'Washer-Disinfectors'.

Decontamination equipment

7.41 Guidance on choice, procurement, installation and validation of sterilizers and washer disinfectors is given in SHTM 2010: 'Sterilization' and SHTM 2030: 'Washer Disinfectors'. Also in Model Engineering Specification (MES) C15: sterilizers and MES C31: washer disinfectors. Advice should be sought from an AP(S).

Electrical services

Electrical installation

7.42 Electrical installation should comply with BS 7671 – 'Requirements for electrical installations'; IET Wiring Regulations.

7.43 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 LDU 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).

7.44 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

7.45 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.

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

7.47 Guidance on the abatement of electrical interference is given in SHTM 2014: 'Abatement of electrical interference'.

Lighting

7.48 Fluorescent luminaries should comply with BS EN 55015.

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

7.50 Luminaries 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 luminaries should be used unless their use can be shown to be inappropriate.

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

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

Socket-outlets and power connections

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

7.54 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.

7.55 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.

7.56 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.

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

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

7.59 Isolation switches should be provided adjacent to all engineering plant and equipment for use by maintenance staff. The location, type and facilities provided on the isolation of switches should be agreed with the Senior Authorised Person (Low Voltage) to ensure that the fixed installation enables NHS Board policies on low voltage operations to be maintained in the LDU. Such communication should be in writing and allow sufficient time for adequate consideration given the AP's other duties.

Emergency electrical supplies

7.60 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.

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

Internal external communications

7.62 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

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

Internal drainage

7.64 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, remains water and airtight and is sufficiently ventilated to retain the integrity of water seals (refer also to paragraph 4.2 – drainage);
- has a design of internal drainage that complies with BS EN 12056 and the current building regulations. Guidance is given in SHTM 2023: 'Access and accommodation for Engineering Services';
- have drains from steam sterilizers and washer-disinfectors that comply with local water regulations. Guidance is given in SHTM 2030: 'Washer Disinfectors';
- has a gradient of branch drains that is uniform and adequate to convey maximum discharge to the stack without blockage.

7.65 Where an LDU is served by a septic tank the following points should be considered:

- the tank volume needs to be sized to ensure the primary settlement process takes place with the increased discharge volumes associated with an automated washer disinfector;
- if the wastewater is at an elevated temperature entering the tank, ensure that there is no inhibition of the decomposition process;

- the level of chemical contaminants leaving the septic tank into the soak away or subsurface drainage system is within Scottish Environment Protection Agency (SEPA) guidelines.

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