Health Protection Scotland

NHS National Services Scotland

Local Decontamination Units:

Guidance on the Requirements for Equipment, Facilities and Management

(The facilities and equipment available in local decontamination units are only appropriate for reprocessing devices used on patients and in procedures that are low risk for transmission of TSEs.)

October 2005 (Amended August 2007)

Version 1.2
(See version control for changes)

Version Control

Version 1.0 **Issued October 2005**

Version 1.1 **Issued June 2007**

Amendments:
Annex 8 Schematic layouts of Local Decontamination Units removed as under revision.

Version 1.2 **Issued August 2007**

Amendments:
Reference to Neighbourhood Decontamination Units has been removed as this concept is not being taken forward and will not be included in the revision of SHPN 13.

Weblinks to Department of Health and HFS (formerly Property and Environment Forum) have been updated thoughout the document.

Foreword

This document has been prepared to provide as complete a summary as may be practicable of the options available to achieve compliance with current technical requirements (TRs) for decontamination of reusable medical devices in a primary care setting. It is not intended to replace expert advice available from Authorised Persons (Sterilizers) who should be consulted for further detailed guidance and, in particular, guidance on the choice, validation, maintenance, testing and operation of decontamination equipment. Also, it is not intended to replace the policy guidance promulgated by the SEHD through the Sterile Services Review Group (Glennie Group).

Decontamination practice is continually evolving and those with responsibility for decontamination need to ensure that they are kept aware of current developments. This includes not only changes in the nature of equipment etc that may be available but also includes changes in requirements in the light of new information about transmissible diseases.

All references to Neighbourhood Decontamination Units (NDUs) have been removed as this concept is not being taken forward and will not be included in the new SHPN 13 on decontamination facilities currently under development.

Contents

1. Introduction
   - Categorisation by risk for all types of CJD
   - Glennie Technical Requirements
   - Spaulding classification

2. Summary of requirements and methods of attainment
   - 2.1 Acquisition of medical devices and ancillary materials
   - 2.2 Processing environment
   - 2.3 Decontamination processes
   - 2.4 Choice of decontamination processes
   - 2.5 Cleaning
   - 2.6 Disinfection
   - 2.7 Drying
   - 2.8 Inspection
   - 2.9 Pre-sterilization packaging
   - 2.10 Sterilization
   - 2.11 Post sterilization packaging
   - 2.12 Storage
   - 2.13 Distribution of sterile items
   - 2.14 Return of used items for reprocessing
   - 2.15 Traceability
   - 2.16 Decontamination equipment
   - 2.17 Human resources
   - 2.18 Disposal of medical devices

3 Management
   - 3.1 General management
   - 3.2 Risk Management
   - 3.3 Health and Safety
   - 3.4 Training
   - 3.5 Quality management system
   - 3.6 Environmental cleaning

4. References
5. Bibliography
6. Contact details
7. Glossary
8. Abbreviations and symbols

Annex 1 Flow chart: Choice of decontamination processes

Annex 2 Flow chart: Choice of decontamination processes – cleaning

Annex 3 Flow chart: Choice of decontamination processes – sterilization

Annex 4 Ventilation in Local Decontamination Units

Annex 5 Local Decontamination Facilities

Annex 6 Personnel hygiene

Annex 7 Roles in Decontamination

Annex 8 Schematic Layouts for LDUs (Amended)

Annex 9 Primary care: Economic considerations in determining the method to be adopted for the provision of sterile medical devices and the location of any required facility for decontamination

1. Introduction

In late 1999 a Scottish Executive Health Department Working Group, chaired by Dr D Old, (The 'Old' WG) commissioned a review to assess decontamination practice in a sample of healthcare premises in Scotland. The stimulus for the establishment of the WG and the subsequent review was concern about the potential risk of person-to-person transmission of vCJD via re-usable surgical instruments. The findings of the review were included in the report of the WG published with (HDL(2001)10). As well as assessing practice in central decontamination units and local decontamination units (LDUs) within the secondary care sector, LDUs within general medical and dental practice were also reviewed. Whilst examples of good practice and appropriate equipment and facilities were observed, there were many examples where these were unacceptably poor.

As a result of the recommendations of the 'Old' WG a further WG was established - the "Glennie Group"- to review the sterile services provision across NHSScotland. Included in its remit was the development of a framework for change, specifically related to the technical and operational standards required. Technical requirements for the reprocessing of devices according to the potential risk for transmission of CJD for the particular procedure for which they were used, were specified in the Glennie WG Report [HDL(2001)66] and deadlines were set to achieve compliance. The risk categorisation (see below) and deadlines for compliance were amended in HDL(2003)42.

GLENNIE TECHNICAL REQUIREMENTS FOR DECONTAMINATION PROCESSES

Clinical procedures*
Categorisation by risk for all types of CJD

High Risk

All procedures that involve piercing the dura, or contact with the trigeminal and dorsal root ganglia, or the pineal and pituitary glands.
Procedures involving the optic nerve and retina.

Medium Risk

- Other procedures involving the eye, including conjunctiva, cornea, sclera and iris.
- Procedures involving contact with lymphoreticular system (LRS).
- Anaesthetic procedures that involve contact with LRS during tonsil surgery (for example laryngeal masks).
- Procedures in which biopsy forceps come into contact with LRS tissue.
- Procedures that involve contact with olfactory epithelium.

Low Risk

- All other invasive procedures including other anaesthetic procedures and procedures involving contact with the cerebral fluid.

*Further risk assessment has been undertaken on categorisation of dental tissues that are currently considered as low risk. (See http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4084662 and http://www.scotland.gov.uk/consultations/health/decontamination.pdf).(see also Head et al 2003)

The Glennie "procedure-specific" risk categorisation did not preclude the need to assess the "patient-specific" risk in accordance with the guidance of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee, "Transmissible spongiform encephalopathy agents: safe working and the prevention of infection" (see http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm). 'Risk' is a widely used term, it is important to distinguish between high-risk procedures/tissues and high-risk patients.

It must be stressed that Glennie Risk Categorisation refers only to the potential for transmission of CJD and not to the risk of healthcare associated infection (HAI) in general (See Spaulding Classification – page 3). The facilities and equipment available in local decontamination units are only appropriate for reprocessing devices used in Glennie low risk procedures. The technical requirements for Glennie high and medium risk procedures are such that these are achieved economically only in central decontamination units. LDUs intending to reprocess devices used in Glennie medium risk procedures will require to achieve the same level of segregation of clean and dirty activities, environmental controls, quality management system, qualified management and Medical Device Regulations accreditation as central decontamination units.

Risk Category	Function	Interim Requirements	Full Requirements
Low	Equipment	• Ability to demonstrate that washer disinfectors are fit for purpose, operating effectively, maintained adequately, and tested and validated in line with current guidance. • Compliance with SHTM 2010 (Sterilizers) • Compliance with Protocol on the local Decontamination of Surgical Instruments (manual cleaning) if neither a washer disinfector nor ultrasonic washer is reasonably practical.	Interim requirement plus compliance with: SHTM 2030 (If use of washer disinfector not reasonably practicable then utilisation of ultrasonic washer indicated).
	Facilities	• Effective separation of clean and dirty processes in accord with Protocol on the Local Decontamination of Surgical Instruments	As interim requirements.
	Staff	• All personnel carrying out decontamination processes have documented training needs assessment and record of training received	Training needs and records as part of a formal quality assurance system
	Management	• Senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes. • Senior Manager with overview in accord with HDL 2001(10) if decontamination taking place in NHS Trust.	Interim requirements plus compliance with: MDA Device Bulletin DB 9801 Medical Devices and Equipment Management for Hospital and Community based Organisation.

Devices used in invasive procedures classified as low risk under the Glennie categorisation, can present a significant risk for other HAIs, and must be reprocessed utilising validated decontamination processes. The risk of other HAIs is related to:

- The nature of the clinical procedure;
- The infection status of the previous patient;
- The immune status of the patient on whom the device is to be used.

The decontamination process required is commonly specified as one of three levels (based on the classification system first proposed by Dr E H Spaulding):

Classification	Type of Procedure	Level of Decontamination Required
Critical	Invasive devices that enter tissue that is usually sterile or enters the vascular system e.g., artery forceps, probes, biopsy forceps, dental extraction forceps/elevators	Requires sterilization
Semi-critical	Device contacts intact mucous membrane but does not penetrate sterile tissue; e.g., flexible endoscopes, dental mirrors, vaginal specula	Requires high level disinfection* (Sterilization preferred where practicable **)
Non-critical	Device only contacts intact skin e.g., stethoscope, sphygmomanometer cuff.	Can be processed by cleaning (and low level disinfection where necessary)
Note: * High level disinfection is a process designed to kill vegetative micro organisms, mycobacteria, viruses, fungal spores and some, but not all, bacterial spores. ****** See Safety Action Notice (SAN(SC)03/23) Re-usable Stainless Steel Vaginal Speculae *sic*: Risk of Cross Infection		

The guidance that follows identifies and expands on the principles of decontamination that were summarised within the Glennie TRs and the "Protocol for Local Decontamination of Surgical Instruments". Suggested methods by which these principles can be upheld and compliance with the TRs achieved are provided. In providing guidance it is recognised that there is a need to provide:

- optimal methods applicable to new units;
- methods that can be applied to existing units that recognise the diversity of:
  - management arrangements;
  - location of decontamination activities;
  - clinical activity;
  - facilities and equipment;
  - policies, procedures and records;
  - staff training / competencies;
  - quality assurance;
  - resources

It is recognised also that different solutions may be required for different types of clinical practice; for example it may be economical to meet the decontamination needs of a podiatrist by providing sufficient devices to utilise a centralised service because of the relatively low cost of each set of devices. A review of the experience of one primary care trust that adopted a centralised solution was reported by Wilson et al.

However, a clinical practice that required the use of many very expensive devices (eg high speed turbines for dentistry) would be more likely to find it economical to provide a compliant local decontamination unit (LDU). In either circumstance the primary consideration must be to provide a compliant decontamination procedure, which gives the necessary assurance of cleanliness and sterility for re-usable medical devices.

A key element in ensuring effective decontamination is ensuring the provision of appropriate documented policies, procedures and records to control the process. To assist practices in developing a system specific to their facilities and equipment a software program has been developed by HPS. This program, The Decontamination Documentation System, will be made available to all primary care practices in Scotland on http://www.hps.scot.nhs.uk/haiic/decontamination/dds.aspx?subjectid=00D

1.1 Decontamination Units; Classification, definition and summary of differences.

For the purpose of guidance on decontamination in primary care, three classes of decontamination unit are recognized:

- a central decontamination unit (eg sterile service department/unit) (CDU)
- a local decontamination unit (LDU)
- an endoscope re-processing unit (ERU)

Central decontamination Unit (CDU)

A CDU is characterized by the following features:

- staffed by dedicated management and operational staff
- equipped with a range of sophisticated automated decontamination equipment
- devices may be sterilized double wrapped and suitable for transport over long distances
- has a full quality management system complying with ISO 13485
- accredited under the Medical Device Regulations 2002
- may supply third parties

In addition it should be noted that, generally, the CDU:

1. has the full range of technical support, either in-house or under contract
2. supplies a wide range of devices to a range of clinical specialties

Local Decontamination Unit (LDU)

An LDU is characterized by the following operational features:

- sterilizes only singly wrapped or unwrapped items
- processed items are neither transported outside the building in which the LDU is located nor transferred off-site (other than for domiciliary visits by staff from the clinical unit of which the LDU is part where the items remain under the control of the clinical staff)
- under the control of one or more clinicians who use the re-processed devices
- does not supply a third party

In addition it should be noted that, generally:

- the re-usable devices that may be processed are restricted to small, relatively simple, devices that can be steam sterilized.
- the management and staff responsible for decontamination may have other eg clinical duties.
- the unit is equipped to process only low volumes of devices (and is likely to have only one sterilizer, one WD etc).
- an LDU often serves only one clinical specialty (although it may serve several clinical disciplines, eg general medicine, dentistry and podiatry located in the same building).
- an LDU may serve one or more clinics in the same building.

Note: The ability of an LDU to supply more than one clinic is dependent on both its location in relation to the clinical areas and the decontamination equipment being used. For example, if sterile devices are required in a particular clinic to which the LDU is connected only via a public corridor then an LDU equipped with a sterilizer for processing only unwrapped devices would be unable to supply that clinic.

In primary care, in particular, there may not be in-house technical support

- for assessment of decontamination requirements
- for procurement of medical devices
- for procurement of decontamination equipment
- for the maintenance and testing of decontamination equipment
- for quality system management
- for staff training
- for infection control

Endoscope Re-processing unit (ERU)

A unit set up to re-process only flexible, thermo-labile, usually fibre-optic, endoscopes and their accessories. The terminal decontamination process stage is high level disinfection using a liquid chemical disinfectant. Specialist washer-disinfectors called endoscope re-processors are used. An ERU may be set up as an LDU, supplying only adjacent endoscopy clinics in the same building, or as a CDU. Specific guidance on re-processing endoscopes is published separately.

2. Requirements and methods of attainment

Note: In the tables below where various options are given for methods by which the requirements may be met the options are numbered in order of preference. Where the options are un-numbered there is no preference for which method should be adopted.

2.1. Acquisition of medical devices and ancillary materials

Para	Principle	Methods to Achieve	Explanatory Notes
2.1.1	**Medical devices (including surgical devices)**		
2.1.2	Ensure that all re-usable medical devices that are currently in stock can be decontaminated by the available decontamination processes	Review of device manufacturer's instructions for reusable medical devices currently in stock. Review of available decontamination capability.	Devices purchased after 13/06/98 should bear the CE mark.
2.1.3	Ensure that all re-usable medical devices that are purchased can be decontaminated by the available decontamination processes or use single use devices	Documented policy for purchase of re-usable devices including: - review of device manufacturer's instructions prior to purchase - review of available decontamination capability - documented specification for the device being purchased	For devices not previously purchased a full specification may be required. Replacement of previously purchased devices may only require an unambiguous reference for the supplier.
2.1.4	Use of single use devices where appropriate.	Use of single-use devices where: - re-usable devices are impossible/difficult to clean/sterilize - economic - practicable	
2.1.5	Ensure that there are sufficient medical devices to allow the necessary time for re-processing without adversely affecting throughput.	Review clinical demand *versus* device stock and time required for reprocessing; maintain stocks at the required level.	

Para	Principle	Methods to Achieve	Explanatory Notes
2.1.6	**Ancillary materials** (Process chemicals, packaging, chemical indicators for use in sterilization processes etc)		
2.1.7	Ensure that all ancillary materials are appropriate for their intended use	Purchase from reputable suppliers. Purchase to relevant BS EN specifications. Review of device manufacturer's instructions for compatibility Review of decontamination equipment manufacturer's instructions for compatibility	Process chemicals should be chosen to ensure that they are compatible with the medical devices to be processed, the decontamination equipment to be used and the process in which they will be employed. Care should be taken to ensure that the facilities available are appropriate for storage, use and disposal of the process chemicals, particularly when toxic or noxious chemicals are involved. Packaging - see 2.9 below Chemical indicators for use in sterilization processes should comply with the relevant parts of EN 867. Process indicators (to BS EN 867-2) (eg autoclave indicator tape) may be used to separate processed items from those that have yet to be processed. Specific test indicators (to BS EN 867-3, BS EN 867-4) may be used for the Bowie Dick test for porous load sterilizers. Integrating indicators (ie those that respond to time, temperature and presence of sterilization conditions) may be used to monitor the performance of sterilizers not fitted with an independent process recorder.

2.2 Processing environment

Para	Principle	Methods to Achieve	Explanatory Notes
2.2.1	Ensure that the decontamination process has no adverse effect on the clinical environment	(i) Physical segregation of decontamination processes that have the potential to contaminate the clinical environment eg a designated decontamination area/room separated from the patient treatment area by means of a wall	Physical segregation would require those decontamination processes that may contribute to contamination of the environment (eg dis-assembly and cleaning of used devices) to be carried out in a separate room
2.2.2		(ii) Provision of ventilation to ensure that the flow of contamination arising from decontamination will be away from the patient area.	See Annex on Ventilation in local decontamination units.
2.2.3		(iii) Temporal separation of decontamination and clinical activity.	Temporal separation may be achieved by carrying out different activities at different times together with rigorous environmental cleaning between different types of decontamination processing activity to ensure that the first process does not affect the subsequent process(es).
2.2.4	Ensure that the decontamination process has no adverse effect on staff or third parties	Physical segregation of decontamination processes that have the potential to contaminate the external environment. Restricted access to decontamination area where these activities are carried out. Provision of appropriate PPE to staff within the decontamination area.	Decontamination should not be carried out in public access areas, corridors etc. Access to the decontamination area should be restricted to staff who have received appropriate training.
2.2.5	Ensure that elements of the decontamination process have no adverse effect on other medical devices	(i) Physical segregation of dirty decontamination processes from cleaned/sterilized/sterile devices. (ii) Mechanical ventilation to ensure that the flow of any contamination arising from the decontamination process will be away from cleaned/sterilized/sterile devices. (iii) Temporal separation of dirty decontamination processes from cleaned/sterilized/sterile devices.	Temporal separation may be achieved by carrying out different activities at different times together with rigorous environmental cleaning between different types of decontamination processing activity to ensure that the first process does not affect the subsequent process(es).
2.2.6	Ensure that there is no adverse effect from the environment in which clean and sterilized devices	Physical segregation of cleaned and sterilized devices from contaminated aerosols, water	

	are handled and stored	splashing etc	

2.3 Decontamination processes

Para	Principle	Methods to Achieve	Explanatory Notes
2.3.1	Decontamination processes should ensure that: • at the point of use, reprocessed devices are free from: – residues of previous procedures – residues from the decontamination process – adventitious contamination eg particulates and other environmental contaminants – microbial contamination (see note) • there is evidence of attainment of the required standards of decontamination.	Design of decontamination equipment and processes Choice of process chemicals Quality of water used in decontamination process Environmental control Use of appropriate disinfection / sterilization method Appropriate packaging and transport systems Validation, testing and record keeping	Removal of contamination present from previous use of the device is best assured by the use of effective, validated, cleaning processes in an automated WD. The choice of process chemicals will affect both the cleaning efficacy and the ease with which process residues may be removed. Only free rinsing detergents should be used; surgical hand scrubs are not a suitable substitute. The quality of water used for the final rinse will also affect the extent of process residues; hard water will leave lime-scale deposits. Control of adventitious contamination from the environment may be achieved by physical segregation from sources of contamination, ventilation to move airborne contaminants away from the device and appropriate environmental cleaning. Evidence of the required standards of decontamination can only be achieved through keeping records of appropriate testing, monitoring, maintenance and operation of the decontamination equipment.

Para	Principle	Methods to Achieve	Explanatory Notes
2.3.2	• the decontamination process is designed and carried out in a manner that minimises the risk of recontamination of clean devices.	Use of decontamination equipment that is designed and constructed to prevent environmental dispersal of contamination from devices being reprocessed.	Ultrasonic cleaners should only be operated with the lid in place. Automated WDs should be designed and constructed to ensure that the door does not leak or generate aerosol contamination.
2.3.3		Use of techniques that minimise generation and dispersal of environmental contamination eg aerosols (see Manual washing).	Manual washing procedures should be carried out with the device immersed.
2.3.4		Physical segregation of those elements of the decontamination process dealing with contaminated devices and those dealing with cleaned/disinfected devices.	Inspection, packing and sterilization of cleaned devices are clean procedures. The arrangements for decontamination should ensure that they cannot become contaminated by used devices or the cleaning process.
2.3.5		Provide a linear work flow and extract ventilation to ensure that the flow of any contamination arising from the decontamination process dealing with contaminated devices will be away from cleaned/disinfected devices	See LDU Design Guidance Notes on ventilation for local decontamination units.
2.3.6		Temporal separation of those elements of the decontamination process dealing with contaminated devices and those dealing with cleaned/disinfected devices together with rigorous environmental cleaning between different types of decontamination processing activity.	Temporal separation may be achieved by carrying out different activities at different times together with rigorous environmental cleaning between different types of decontamination processing activity to ensure that the first process does not affect the subsequent process(es).
2.3.7	Decontamination should be carried out only by trained staff	Process records verifiable against skills register	Process records should be kept indicating who was responsible for processing the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.17 below

2.4 Choice of decontamination processes

Para	Principle	Methods to Achieve	Explanatory Notes
2.4.1	Decontamination processes should be chosen to be:		
2.4.2	• Effective for the devices to be processed	Reference to device manufacturers' instructions. Validation of the cleaning process (see SHTM 2030, BS 2745).	Manufacturers of reusable medical devices are required to give instructions for reprocessing. See also BS EN ISO 17664.
2.4.3	• Compatible with the devices to be processed	Reference to device manufacturers' instructions. Reference to process chemical manufacturers' instructions.	
2.4.4	• Capable of providing the standard of decontamination required for the clinical procedures to be undertaken	Reference to device manufacturers' instructions. Validation of the cleaning process (see SHTM 2030, BS 2745).	
2.4.5	• Appropriate for the environment available for decontamination processing	Compatible with the chosen method of segregating dirty and clean devices eg pass-through washer-disinfectors.	
2.4.6	• Capable of providing the throughput required to maintain the desired level of clinical service	Reference to through put calculations (See SHPN 13 and SHTM 2030).	
2.4.7	• Amenable to independent verification of the decontamination standards achieved	Automated WDs provided with independent process verification recorder (see SHTM 2030).	prEN 15883-1 and prEN 15883-2, which are likely to become European standards during 2005, also embody requirements for independent process verification
2.4.8	• Value for money	Consideration of cost of providing and running compliant LDU *versus* cost of necessary instrumentation, transport and service from compliant CDU or cost of single-use devices whilst ensuring that the required standards are maintained.	See Annex on costing

2.5 Cleaning

Para	Principle	Methods to Achieve	Explanatory Notes
2.5.1	Cleaning should be carried out using a validated cleaning process.	(i) Whenever practicable use automated WD for cleaning and disinfection (ii) Use of an ultrasonic irrigator with disinfection and rinsing stages may be necessary for some devices. (iii) An ultrasonic cleaner followed by manual rinsing	
2.5.2	Manual washing should only be employed when: • required by the device manufacturer's instructions; • automated cleaning processes are not available.	Whenever practicable the choice of devices to be purchased should ensure that the devices can be cleaned and disinfected in an automated WD and then can be steam sterilized.	
2.5.3	Manual washing should be carried out in facilities, and using procedures, which: • ensure the safety of the operator; • provide an effective cleaning method; • minimise the possibility of cross-contamination of devices being cleaned; • minimise the possibility of contamination of devices with residual process chemicals; • do not damage the devices being cleaned;	See 'Manual washing'	
2.5.4	Cleaning should be carried out only by trained staff.	Process records verifiable against skills register	Batch records should be kept indicating who was responsible for cleaning the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register.

2.6 Disinfection

Para	Principle	Methods to Achieve	Explanatory Notes
2.6.1	The highest possible assurance of freedom from microbial contamination should be provided.	Devices to be disinfected (or sterilized) must be thoroughly cleaned first. Devices to be used on intact skin, and in procedures that are not invasive, may only require disinfection. Whenever practicable these devices should be sterilized.	Ensure that prior cleaning has been carried out effectively. Disinfection should only be used as a terminal decontamination process for devices that cannot withstand any of the available sterilization processes (eg flexible endoscopes) or for devices where there is no significant risk that they will be invasive.
2.6.2	Staff inspecting, testing, assembling and packing reprocessed devices should be protected from potential contamination	All used devices should be cleaned and disinfected before they are subjected to detailed inspection for cleanliness and functionality.	The extensive handling that may be required during the inspection, assembly and packing process may expose staff to greater risk of infection if the devices have not been effectively cleaned and disinfected.
2.6.3	Whenever practicable disinfection should be carried out using a thermal disinfection process.	Chemical disinfection should be employed only when: • required by the device manufacturer's instructions; • the device will not be used in an invasive procedure	Thermal disinfection is carried out using water at temperatures of 65^{o}C or above. Thermal disinfection processes are 'medium level disinfection' processes (see Glossary) Devices for use in invasive procedures should be sterilized.
2.6.4	Whenever practicable disinfection should be carried out using a validated disinfection process.	Use automated equipment (eg WD)	
2.6.5	Demonstration of attainment of the required temperature for the required time should be provided for all thermal disinfection processes.	Thermal disinfection equipment should be provided with means to independently monitor and/or record the time for which the load was exposed to the required temperature.	

Para	Principle	Methods to Achieve	Explanatory Notes
2.6.6	The thermal disinfection process should provide adequate assurance of the required microbial lethality	Thermal disinfection should achieve an A_o of not less than 600 for any device that has been, or is to be, used invasively.	The A_o value is used to define the extent of thermal disinfection without reference to a particular temperature. The A_o value is established by measuring the temperature and exposure time. An A_o of 600 is equivalent to 10 minutes at 80^{o}C or 1 minute at 90^{o}C.
2.6.7	Chemical disinfection processes should provide adequate assurance of the required microbial lethality	Chemical disinfection processes should be validated microbiologically (usually be the disinfectant manufacturer). This should define the concentration, contact time and min/max temperatures Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution. Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.	The manufacturer (or supplier) of the chemical disinfectant should be asked to supply data supporting the use of the disinfection conditions to be used (temperature range, concentration and contact time)
2.6.8	After chemical disinfection devices should be free from toxic residues.	After chemical disinfection devices should be rinsed free from disinfectant with purified water free from microbial contamination. The quality of water used should be appropriate to the clinical procedures to be undertaken.	Where devices are to be used in procedures which are deliberately, or likely to be inadvertently, invasive the final rinse should be with sterile water.
2.6.9	Disinfection should be carried out only by trained staff.	Process records verifiable against skills register	Process records should be kept indicating who was responsible for disinfecting the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.17 below

2.7 Drying

Para	Principle	Methods to Achieve	Explanatory Notes
2.7.1	Devices that are to be wrapped and then sterilized must be dried before being wrapped.	(i) Automated cleaning equipment with drying stage (ii) Hot air drying cabinet (iii) Manual drying with disposable non-linting wipe (iv) Manual drying with disposable non-linting wipe impregnated with 70% iso-propanol.	Vacuum benchtop steam sterilizers are the only benchtop sterilizers suitable for wrapped instruments. Benchtop sterilizers that do not have a vacuum air removal stage should be used only to process unwrapped items. Devices that are not dried before being wrapped and sterilized may not be dried during the drying stage of the process.
2.7.2	Devices that are to be stored after cleaning and/or disinfection before use and/or sterilization must be dried before being stored.	(i) Automated cleaning equipment with drying stage (ii) Hot air drying cabinet (iii) Manual drying with disposable non-linting wipe (iv) Manual drying with disposable non-linting wipe impregnated with 70% iso-propanol	Devices stored wet or damp may become contaminated with environmental micro-organisms which may proliferate rapidly in warm storage. Devices that are required to be sterilized (but which are not required to be sterile at the point of use) may be packed after sterilization to protect them from environmental contamination.
2.7.3	The drying method employed should be rapid and reliable and should not contaminate the device with chemical, microbial or particulate contaminants.	(i) Mechanical drying facility (hot air drier) – may be pass-through design to facilitate segregated work-flow. (ii) Clean, disposable, absorbent, non-linting 'cloths' may be used for manual drying. (iii)Wipes impregnated with 70% alcohol (spore free) may be used to facilitate air-drying.	
2.7.4	Drying should be carried out only by trained staff.	Batch records verifiable against skills register	Batch records should be kept indicating who was responsible for drying the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.17 below

2.8 Inspection

Para	Principle	Methods to Achieve	Explanatory Notes
2.8.1	All cleaned and disinfected devices should be inspected for cleanliness	Prior to sterilization all devices should be carefully examined for organic material (using task lighting and magnification where appropriate). Where practicable, inspection should be carried out by a person not responsible for cleaning the item. Records should be kept.	Instruments with small interstices, inspection of detailed profile etc. may require the use of a magnifier and higher levels of illumination than is available for general room lighting.
2.8.2	All cleaned and disinfected devices should be tested and or inspected for functionality	Prior to sterilization all devices should be carefully examined for damage (using task lighting and magnification where appropriate). Inspection, maintenance and testing of items should be carried out by trained persons in accordance with the manufacturer's instructions. Where practicable, inspection and testing should be carried out by a person not responsible for cleaning the item. Records should be kept.	Extent to which this is necessary depends on the nature of the device, the nature of the procedure for which it is being used and the ease with which the clinician can determine from its in-use performance that the device should be replaced / repaired before the defect becomes critical.
2.8.3	Devices that fail inspection for cleanliness or functionality should be segregated.	Redirect soiled items for further cleaning. Worn or damaged instruments quarantined pending repair or replacement.	Quarantine in locked storage prevents unauthorised access.

2.9 Pre-sterilization packaging

Para	Principle	Methods to Achieve	Explanatory Notes
2.9.1	Only when a porous load or vacuum benchtop steam sterilizer is to be used should devices be wrapped before sterilization.	The policy and methods in respect of wrapping should be documented.	The European standard (EN 13060) defines three classes of small steam sterilizers: Type B sterilizers, intended for the sterilization of wrapped solid, hollow or porous products ie vacuum benchtop steam sterilizers Type N sterilizers intended for the sterilization of non-wrapped solid products Type S sterilizers intended for the sterilization of products specified by the manufacturer of the sterilizer. Requirements for porous load sterilizers are defined in BS EN 285.
2.9.2	Only wrapping materials that are compatible with the steam sterilization process and validated to provide the required microbial barrier properties should be used.	Sterilization grade wrapping material complying with the relevant part of BS EN 868 should be used. Only a single layer of wrapping material should be used when a benchtop vacuum sterilizer is to be used.	The sterilization grade packaging material chosen may be • paper bags (plain top, self-seal or heat seal) • Plastic/paper reels/pouches (self or heat–seal) • Sheet wrapping material (folded and sealed with packaging tape) For some applications re-usable sterilization containers may be appropriate.
2.9.3	The method of sealing should ensure that the microbial barrier properties are preserved and that the pack can be opened aseptically.	Sheet wrapping material should be closed by the parcel fold or envelope fold method and retained securely with high temperature adhesive tape. Bags, pouches and reel material should be • closed with a multiple fold and secured with high temperature adhesive tape • heat sealed using a validated heat sealer • self-seal	See SHTM 2010 – Part 5
2.9.4	Each packaged device should be clearly labelled with its contents and a reference from which the processing history can be traced.	Labelling directly onto flexible packaging with felt tip or ballpoint pens should not be used as this may compromise microbial barrier properties.	Pre-written or pre-printed adhesive labels should be used

2.10 Sterilization

Para	Principle	Methods to Achieve	Explanatory Notes
2.10.1	All devices intended for use in invasive procedures should be sterile.	Documented policies and procedures for use of appropriate validated sterilization processes.	These are critical devices under the Spaulding classification (see page 3).
2.10.2	All sterilization should be carried out using a validated process.	See SHTM 2010 Part 3	Because it is not practicable to test units of product for sterility prior to release for use it is necessary to establish that the process when correctly operated will consistently and reliably produce the required outcome – this is demonstrated during the validation process. (see 2.16)
2.10.3	The devices that can be sterilized in the process, the nature of any packaging that may be used and the method of loading should be specified.	Benchtop B&I sterilizers should only be used to sterilize unwrapped items.	Devices to be sterilized in a B&I sterilizer should be unwrapped, without lumens or other constructional detail that would inhibit air removal and should be in trays or containers with sufficient perforations to allow the free passage of steam and air (see BS 3970 Part 4) – solid bottomed containers should not be used. Hydrogen peroxide plasma is a potential method of sterilization for heat sensitive medical devices that do not have long lumens.
2.10.4	Each sterilization process should be independently monitored to demonstrate that the process cycle conformed to validated parameters.	(i) The sterilizer should be fitted with an independent recorder to record the temperature and pressure in the chamber throughout the sterilization cycle. (ii) The sterilizer should be fitted with an independent recorder to record the temperature in the chamber throughout the sterilization cycle (iii) The operator should observe the cycle and manually record the readings from temperature and pressure gauges fitted to the sterilizer, which are independent of the controller.	Small, standalone, recorders for temperature and pressure are commercially available for retro-fitting to sterilizers that are not already equipped with an independent recorder. The presence of a recorder should not be taken to indicate that it is independent of the controller. This should be verified by reference to the manufacturer's specification or by examination by a suitably qualified engineer.

Para	Principle	Methods to Achieve	Explanatory Notes
2.10.5	The environment in the sterilizer chamber should not adversely affect the devices.	The steam, and for benchtop sterilizers the water supply, should be controlled to ensure that it is free from chemical contaminants and bacterial endotoxins to the extent required (see SHTM 2031).	SHTM 2031 recommends the use of Sterile Water for Irrigation BP. Non-sterile distilled or de-ionised water has similar chemical purity but rapidly becomes contaminated with microbial growth and should be used only if freshly prepared. The reservoir and chamber should be drained before re-filling; replenishing the reservoir without draining will allow build up of contamination in the reservoir. (for further guidance see SHTM 2031)
2.10.6	Sterilization should be carried out only by trained staff.	Process records verifiable against skills register	Process records should be kept indicating who was responsible for sterilizing the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.17 below
2.10.7	Each sterilization cycle should be reviewed and formally accepted as satisfactory before devices from that cycle are released as sterile and ready for use.	Sterile product release procedure: The operator should ensure that a) All maintenance and test records are up to date and satisfactory b) the sterilizer's automatic controller is indicating a satisfactory cycle c) the temperature and pressure record for the cycle shows attainment of the required conditions (typically 134-137^{o}C, 3-2 bar for 3-3.5 mins although other time / temperature / pressure conditions may be used. d) The load was correct for the type of sterilizer e) For goods sterilized wrapped verify, that the package is intact and not wet.	The sterile product release procedure is the final check that everything necessary to ensure the sterility of the product has been satisfactorily completed.

Para	Principle	Methods to Achieve	Explanatory Notes
2.10.8	Sterile devices should be labelled as 'STERILE'	The label on wrapped sterile goods must bear the legend 'STERILE' and be clearly distinguishable from similar items that are 'disinfected' or 'non-sterile'. The label should comply with EN 980: 1997	As well as information on the contents of the pack, the label should bear also a reference from which the processing history can be traced (see 2.15) and which will facilitate control of stock rotation. Where sterilized devices may be stored for some time the process date should also be included to facilitate stock rotation.
2.10.9	Means should be provided to segregate devices that have been sterilized from those that have not.	1. ensure clear physical separation 2. clear labelling 3. use of process indicator to BS EN 867-2	Process indicators may be provided by the use of packaging printed with a process indicator, or by the use of autoclave indicator tape. A changed process indicator only demonstrates that the item has been in the sterilizer, NOT that sterilizing conditions were attained.

2.11 Post sterilization packaging

Para	Principle	Methods to Achieve	Explanatory Notes
2.11.1	Devices that have been sterilized unwrapped in a B&I sterilizer that are not intended for immediate use and are not required to be sterile at the point of use should be stored dry and protected from recontamination. (see also 2.7 above)	Immediately after sterilization the devices should be examined visually for dryness and, if necessary, should be dried and then wrapped in clean, unused, sterilization grade wrapping material to prevent recontamination. Sterilized devices should not be labelled 'sterile' and should be clearly distinguishable from sterile devices.	Devices that are intended to be sterilized and then stored should be processed through a sterilizer with a drying stage. If this is not possible, the sterilized devices should be allow to 'flash dry' whilst cooling to a temperature at which they can be handled and then dried (see 2.7) Where sterilized devices may be stored for some time the process dates should also be included to facilitate stock rotation.

2.12 Storage

Para	Principle	Methods to Achieve	Explanatory Notes
2.12.1	Sterile devices and sterilized devices should be stored in a manner that will not compromise their status	Only devices that were sterilized as wrapped items may be stored and used as sterile devices. Sterile devices and sterilized devices must be stored in clean dry conditions away from sources of water and contamination. Sterile devices and sterilized devices must be segregated in storage to eliminate the risk of confusion. Stored devices should be used in strict date order ie 'first in, first out' (FIFO) to ensure that storage is not prolonged unnecessarily. Storage facilities for sterile and sterilized products should be secure.	Secure storage should ensure that the devices are only accessible to personnel who have a legitimate need.
2.12.2	Used devices and clinical waste must be stored safely	Used devices should be stored in solid sided leak proof containers and should be stored for the minimum possible time before being cleaned and disinfected.	Under most circumstances it should be possible to ensure that devices are cleaned within four hours of use. Prolonged storage will allow body fluids and tissues to dry onto the surface of the devices and make thorough cleaning more difficult.
2.12.3		Clinical waste should be stored in appropriate containers (SHTN 3)	

2.13 Distribution of sterile items

Para	Principle	Methods to Achieve	Explanatory Notes
2.13.1	Sterile devices should be transported in a manner that will not compromise their status.	Only sterile devices that were sterilized wrapped may be transported – devices sterilized unwrapped should be sterilized at the point of use and should be used immediately (ie opening the sterilizer door should be regarded as equivalent to opening a sterile pack). Sterile devices must be transported in clean dry conditions in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage to devices and flexible packaging.	
2.13.2	Sterilized devices should be transported in a manner that will not compromise their status.	Sterilized devices (ie those that have been sterilized but are required only to be disinfected or socially clean for their intended use) should be packaged (see 2.11 post-sterilization packaging) and transported in clean dry conditions in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage to devices and their packaging.	

2.14 Return of used items for reprocessing

Para	Principle	Methods to Achieve	Explanatory Notes
2.14.1	Used devices must be transported safely to where they will be decontaminated.	Used devices should be transported in solid walled leak proof containers and, when they will be transported through public access areas, should be appropriately labelled.	The labelling should indicate: • the sender • the intended recipient • that the contents may be contaminated. The containers should be lidded and the lid should be secured with a tamper evident seal.
2.14.2	Used devices should be decontaminated as soon as practicable after use.	Devices should be transferred to cleaning and as soon as they have been used.	Under most circumstances it should be possible to ensure that devices are cleaned within four hours of use. Prolonged storage will allow body fluids and tissues to dry onto the surface of the devices and make thorough cleaning more difficult.

2.15 Traceability

Para	Principle	Methods to Achieve	Explanatory Notes
2.15.1	**Through processing** The methods, operational cycles and personnel involved in processing a particular device, or set of devices should be traceable.	1. Record each process event either manually or on an IT system including the cycle number (WD & Sterilizer) and the person responsible for carrying out each stage of the process. 2. Recording by exception may be used (ie the devices rejected after unsatisfactory process stages recorded and details of the cycles used for 'rework').	
2.15.2	**To patients** For invasive procedures, and in particular those procedures regarded as medium (or high) risk for transmission of CJD, the device, or set of devices, used in a particular treatment episode should be traceable.	1. IT based systems may be used. 2. Manual (paper based) recording systems. Patient records may be annotated manually, using 'peel-off' labels or as part of an IT based system.	The requirement to trace the device(s) to the patient is a Glennie full technical requirement. It is needed to defend allegations of HAI arising from the use of inadequately decontaminated instruments. It is regarded as essential where there is a recognised risk of transmission of CJD (which should not be the case for devices being processed through an LDU) This requirement is currently difficult to achieve see HDL (2003)42.

2.16 Decontamination equipment

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.1	A. **MANUAL WASH FACILITY – IMMERSION WASHING**		
2.16.2	Specification	Separate sink(s) for decontamination (ie not also used as wash hand basins, filling kettles etc). Separate sinks for washing and rinsing if possible. Known fill volume in sink(s). Detergent dispensing in known volumes. PPE for staff.	The known fill volume may be determined by simple measurement and marking the required fill level on the sink. Unless the volume of water and the volume of detergent are known it is not possible
2.16.3	Services etc	Hot water (domestic hot water). Water for rinsing. Manual washing detergents (neutral or enzymatic).	The detergent should be specified by the detergent manufacturer as suitable for the purpose. Dishwashing detergents, surgical hand scrubs etc should not be used. Where the mains water supply is soft water of good quality (eg free from humic and fulvic acids) freshly drawn drinking water may be used for rinsing. In hard water areas, or where the water is discoloured, the water should be purified (eg by reverse osmosis). Softening alone is insufficient since this does not reduce the level of total dissolved solids, which can be left on the instruments as a residue.
2.16.4	Validation	Not applicable	
2.16.5	Routine testing	No periodic testing required	Testing of water temperature, dispensed volume of detergent, quality of rinse water may be necessary if there is concern that one or more of these variables has changed.

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.6	Maintenance	Normal housekeeping to maintain cleanliness. (see also 3.6 Environmental cleaning)	
2.16.7	Operation	Documented procedure Trained staff Controlled and monitored wash temperature Controlled detergent concentration Controlled soak time (where applicable) Brushes/water jet guns as appropriate All cleaning carried out with the device immersed fully. Drain off excess detergent solution before transferring to rinse Record details of items processed	Cleaning aids, eg brushes, pipe cleaners etc should be made of materials that will not damage the surface of instruments (eg natural bristle but not wire brushes or pot scourers). The cleaning aids should be single-use or, where practicable, subjected to thorough cleaning after use.
2.16.8	**B. AUTOMATED WD**		
2.16.9	Specification	To BS 2745 SHTM 2030 – design guidance Including: • Independent monitoring and recording of process temperature • Pass through design preferred • Choice of detergent • Choice of load carrier(s) appropriate to nature of devices to be processed. • Cycle in progress and failed cycle interlocks • Low level detergent alarm/interlock	(NB EN 15883 –1 and –2 due to be published 2004)

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.10	Services	Hot and cold soft water Purified water for final rinse Electrical connection (larger WDs require 3 phase supply) Steam for heating water (larger WDs only)	Where the mains water supply is soft water of good quality (eg free from humic and fulvic acids) freshly drawn drinking water may be used for rinsing. In hard water area, or where the water is discoloured, the water should be purified (eg by reverse osmosis). Softening alone is insufficient since this does not reduce the level of total dissolved solids which can be left on the instruments as a residue.
2.16.11	Validation	As per SHTM 2030	WD should be tested to BS 2745 Further detailed guidance on test methods is available also in HTM 2030
2.16.12	Routine testing	As per SHTM 2030 PAT testing Pressure vessel inspection / test if applicable	Further detailed guidance on test methods is available also in HTM 2030
2.16.13	Maintenance	As per manufacturers instructions	
2.16.14	Operation	Documented procedure Including loading procedure, choice of operating cycle, choice of detergent Trained staff Record details of items processed	See paragraph 3.5.1

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.15	**C. ULTRASONIC CLEANER**		
2.16.16	Specification	To SHTM 2030 – Design guidance Including:- • Control of process time and temperature • Lid interlock • Choice of detergent (see SAN(SC)03/11) • Dispenser for known volumes of detergent • Choice of load carrier(s) appropriate to nature of devices to be processed. • Irrigation system if lumen devices are to be processed • Chamber drain tap to allow chamber to be emptied	At the moment only larger (26 litre) ultrasonic cleaners are available with an interlock to prevent operation of the cleaner when the lid is open. The detergent chosen should be one specified by the manufacturer of the ultrasonic cleaner as suitable. This will typically be a low foaming detergent with good surfactant and soil dispersion properties. The operating temperature should be within the range specified for the detergent.
2.16.17	Services	Soft or purified water	
2.16.18	Validation	As per SHTM 2030	Further detailed guidance on test methods is available in HTM 2030
2.16.19	Routine testing	As per SHTM 2030 PAT testing	Further detailed guidance on test methods is available in HTM 2030
2.16.20	Maintenance	As per manufacturers instructions	
2.16.21	Operation	Documented procedure Including loading procedure, choice of operating cycle time and temperature choice of detergent Trained staff Record details of items processed Change water at intervals not exceeding 4 hours	If the ultrasonic cleaner does not have a lid interlock the procedure should specify The cleaner is not to be operated with the lid open Operators are not to put their hands in the water while the ultrasonics are active. The water in the chamber should also be drained and refilled if the water is visibly coloured or

			cloudy.

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.22	**D. STERILIZER - BENCHTOP UI&U (B&I)**		
2.16.23	Specification	BS 3970 Part 4 / EN 13060 Guidance in MDA DB 2002 (6) Including:- • Independent monitoring of temperature and pressure • Chart recorder or data logger • Door interlock • Failed cycle indication • Facility to drain reservoir and chamber.	(BS 3970 Part 4 was replaced by EN 13060 during 2004)
2.16.24	Services	WFI for steam generation (see SHTM 2031) Electrical connection	
2.16.25	Validation	As per SHTM 2010 and MDA DB 2002(06)	
2.16.26	Routine testing	As per SHTM 2010 and MDA DB 2002(06) PAT testing Pressure vessel inspection / test	
2.16.27	Maintenance	As per manufacturer's instructions	
2.16.28	Operation	Documented procedure Including loading procedure, choice of operating cycle, sterile product release. Trained staff Record details of items processed Drain water reservoir and chamber daily	NOTE See also DDS system NOTE Recoding by exception may be used The water reservoir and chamber should also be drained and refilled if the water is visibly coloured or cloudy.

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.29	**E. STERILIZER - BENCHTOP VACUUM**		
2.16.30	Specification	EN 13060 Guidance in MDA DB 2002 (6) Including:- • Independent monitoring of temperature and pressure • Chart recorder or data logger • Door interlock • Air detector • Failed cycle indication	
2.16.31	Services	WFI for steam generation (see SHTM 2031) Electrical connection	
2.16.32	Validation	As per MDA DB 2002(06)	
2.16.33	Routine testing	As per MDA DB 2002(06) PAT testing Pressure vessel inspection / test	
2.16.34	Maintenance	As per manufacturer's instructions	
2.16.35	Operation	Documented procedure Including loading procedure, choice of operating cycle, sterile product release. Trained staff Record details of items processed Change water at intervals not exceeding 4 hours	The water reservoir and chamber should also be drained and refilled if the water is visibly coloured or cloudy.

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.36	**F. HEAT SEALER**		
2.16.37	Specification	No BS or EN See Guidance in SHTM 2010	
2.16.38	Services	Electrical connection	
2.16.39	Validation	Temperature, pressure and dwell time to give required seal strength	
2.16.40	Routine testing	Temperature, pressure and dwell time to give required seal strength PAT testing	
2.16.41	Maintenance	As per manufacturer's instructions	
2.16.42	Operation	Documented procedure Trained staff	
2.16.43	**G. DRYING CABINET**		
2.16.44	Specification	No BS or EN Forced air circulation Temperature controlled Temperature indicator Cabinets of pass-through design should be fitted with interlocked doors.	
2.16.45	Services	Electrical connection	
2.16.46	Validation	Temperature profile throughout chamber Establish time/temperature required for drying	
2.16.47	Routine testing	PAT testing	
2.16.48	Maintenance	As per manufacturers instructions	
2.16.49	Operation	Documented procedure Trained staff	

Para	Principle	Methods to Achieve	Explanatory Notes
2.16.50	**H. TRANSIT CONTAINER AND CLEANING FACILITY**		
2.16.51	Specification for containers	Solid walled closed containers with tamper evident seal Suitable plastic bag to contain possible spillage Identification labelling	Requirements and guidance are given in: Carriage of Dangerous Goods Regulations 1996 Carriage of Dangerous Goods (Amendment) Regulations 1999 SHTN No 3: Management and Disposal of Clinical Waste
2.16.52	Specification for container cleaning facility	(i) Automated cart washer or automated WD for smaller containers (ii) Wet working area for steam clean and air dry. (iii) Wet working area for wash with detergent solution, rinse and wipe dry with 70% iso-propanol	
2.16.53	Services	Cart washer / WD: (Steam), electricity, water Steam clean: Steam lance Wash area: Hot & cold water, detergent	
2.16.54	Validation	Cart washer and WD should be validated as per SHTM 2030 Not applicable for other solutions	
2.16.55	Routine testing	Cart washer and WD should be validated as per SHTM 2030 Not applicable for other solutions	
2.16.56	Maintenance	As per manufacturers instructions where applicable	
2.16.57	Operation	Documented procedure Trained staff	

2.17 Human resources

Para	Principle	Methods to Achieve	Explanatory Notes
2.17.1	**A. TRAINING**		
2.17.2	All decontamination processes should be carried out by trained staff.	There should be documented training procedures for all staff who will carry out decontamination. Training should include competency assessment. Training records should be kept. Training should be subject to periodic review and reinforcement training. A skills register should be maintained.	A national training programme is currently under consideration. ***(See also Section 3.)***
2.17.3	All clinical staff should be aware of the implications of decontamination on clinical practice, selection of reusable devices, scheduling of procedures *versus* available instrumentation.	All clinical staff should have awareness training on decontamination.	See 'Decontamination – Cleaning, Disinfection and Sterilization' guidance leaflet published by NHSScotland and PEFE A national training programme is currently under consideration.

Para	Principle	Methods to Achieve	Explanatory Notes
2.17.4	**B. H&SAW ETC - COSHH**		
2.17.5	Ensure that decontamination is carried out in a manner that minimises the risk to staff from: • contamination on used devices • process chemicals	Identification of decontamination processes that may produce, or involve the use of, substances hazardous to health. Containment of these processes. Environmental controls to prevent dispersal. Working practices.(eg sharps disposal) (see also eg manual washing). Standard infection control precautions. Staff training. Personal protective equipment. Emergency facilities available (Spillage kits, eye wash bottles, first aid kit).	
2.17.6	Ensure that decontamination is carried out in a manner that minimises the risk to 3rd parties (eg patients) from contamination on used devices	Identification of decontamination processes that may generate substance hazardous to health Segregation of these processes from patient areas Containment of these processes	

2.18 Disposal of medical devices

Para	Principle	Methods to Achieve	Explanatory Notes
2.18.1	Before despatch from the clinical unit for repair, refurbishment or disposal all re-usable devices must be rendered safe to handle	All reusable devices despatched from the clinical unit must be decontaminated before despatch and be accompanied by a certificate stating the method by which they were decontaminated	See MHRA DB 2003(05)
2.18.2	Scrapped devices must not fall into the hands of those who may mis-use them	Devices that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.	

3. Management

3.1 General management

Para	Principle	Methods to Achieve	Explanatory Notes
3.1.1	Senior member of staff with documented responsibility for decontamination processes and capable of assessing risks associated with ineffective decontamination processes. (Senior Manager HDL(2001)10 if in NHSScotland Trust).	Overall control of the decontamination of re-usable medical devices is the defined responsibility of the decontamination manager. The decontamination manager has undertaken periodic training to update their knowledge, skills and competence to manage the decontamination service. The decontamination manager's job description sets out their responsibilities to run the decontamination service in accordance with legal requirements and national standards (including best practice guidance published by SEHD)	The Decontamination Manager of an LDU would fulfil the role of "user" as specified in SHTM2010/2030/2031. See also definition of Decontamination Manager in Glossary. For information on other personnel with responsibilities for decontamination see Annex A personnel.
3.1.2	Compliance with guidance in MDA Device Bulletin DB9801 (Medical Devices and Equipment Management for Hospital and Community based Organisation	Documented defined accountability for: • all parts of the decontamination cycle including acquisition and disposal of devices. • contractors where the organisation buys in services. • professional liability where the organisation sells services to other organisations. (Note: Provision of a service to a third party may require registration under the Medical Devices Regulations 2002) Written policies and procedures which: • define, document, and control all stages of the decontamination process. • are available for all personnel involved in any aspect of decontamination. Access to up to date legislation and guidance.	

3.2 Risk management

Para	Principle	Methods to Achieve	Explanatory Notes
3.2.1	All premises, equipment and processes used to decontaminate re-usable medical devices contain elements of risk and hazards which need to be identified, monitored, controlled and managed.	Comprehensive, written, decontamination policy with clear reference to risk management to cover services, equipment, processes and premises involved in decontamination that includes: • Health and Safety • Management arrangements for emergencies and untoward incidents • Provision to learn from incidents • Formal arrangements for making and recording contracts • Compliance with all relevant legislation including the Health and Safety at Work Act and Medical Devices Regulations.	
3.2.2	There is appropriate assurance that all risks associated with decontamination premises, equipment and services are identified, assessed and managed.	Identify and assess all risks associated with all stages of the decontamination process. Institute control measures for identified risks. Undertake monitoring to verify compliance with policies and procedures. Document arrangements for responding to emergencies. Have arrangements for access to technical advice outwith the knowledge and competence of staff. Provide a staff training programme. Identify, record, analyse and learn from adverse events and 'near misses'. Reporting procedure for reporting accidents and incidents to the relevant authorities.	
3.2.3	Staff should be aware of the legislation and guidance related to their work activity.	Have arrangements in place to deal with Health Department Letters (HDLs) and Safety Action Notices. Maintain a secure readily available filing system for information on medical devices, including, acquisition, use, decontamination and eventual disposal that is accessible to all staff who may need the information.	

3.3 Health and Safety

Para	Principle	Methods to Achieve	Explanatory Notes
3.3.1	Health and Safety measures are in place	Have arrangements to obtain competent health and safety advice. Ensure decontamination facilities and activities comply with relevant legislation: • Health and Safety at Work Act 1974 • Management of Health and Safety at Work regulations 1999 • Workplace (Health, Safety and Welfare) Regulations 1992 • Provision and use of Work Equipment Regulations 1999 • Electricity at Work Regulations 1989 • Health and Safety (First Aid) Regulations 1981 • Control of Substances Hazardous to Health Regulations (COSHH) 2002 • Manual Handling Operation Regulations 1992 • Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1985 • Pressure Systems Safety Regulations 2002 Access to occupational health services for all staff. Provide personal protective equipment/clothing where indicated by COSHH assessment. Record accidents, incidents and near misses (e.g. sharps injuries).	Hot handling, wet handling. Spills etc

Para	Principle	Methods to Achieve	Explanatory Notes
3.3.2	Process chemicals are stored, handled and used safely and in accordance with the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations	Written policy and procedures, accessible to staff, covering all aspects of process chemicals in the establishment, which covers: • ordering, (procurement), receipt, storage, use and disposal • the action to be taken in case of inhalation, ingestion, skin contact or environmental spillage • error reporting (to encourage open reporting in a non-blame culture) Emergency treatment kits for contact with personnel (neutralisation) and spillages. For all process chemicals: • formal process qualification (validation) and re-validation of automated equipment if there is a change in the process chemical(s). • validate for a specific process and do not use for other processes without prior validation. • use in accordance with the instructions for use provided by the manufacturer • use in accordance with the instructions provided by the manufacturer of the medical device being decontaminated. • use in accordance with the instructions provided by the manufacturer of the decontamination equipment being used (ie WD or ultrasonic cleaner). • lockable storage • store below head height. • storage organised with due regard for chemical properties eg strong oxidising agents should not be stored with flammable materials, high and low pH materials should not be stored together. • keys of all storage cupboards held securely, including spare keys.	

Para	Principle	Methods to Achieve	Explanatory Notes
		Prepare all in-use dilutions of process chemicals: • from the container in which they are delivered • immediately prior to their use. Information should be given to staff about the use, benefits and potential harms of the process chemicals being employed. The establishment should have up to date, relevant, reference sources, accessible to staff, for every product used, e.g., the Material Safety Data sheet. Records of ordering, receipt, supply to the production area, use and disposal of all process chemicals to maintain an audit trail.	
3.3.3	Minimize the risk of transmission of healthcare associated infections to patients, staff and visitors.	The undernoted aspects of the CSBS (now NHS QIS) Healthcare Associated Infection (HAI) Infection Control and Cleaning Services Standards (2001) are of particular relevance to decontamination: Establishment of links and liaison with: • local infection control team (NHS Board/Trust/Hospital) • Consultant in Public Health Medicine for Communicable Diseases/Environmental Health. • Occupational Health Services Key written infection control policies / procedures / guidance which reflect relevant legislation and published professional guidance: • Standard precautions • Hand hygiene • Prevention of exposure to blood borne viruses (BBVs) including sharps injuries	

Para	Principle	Methods to Achieve	Explanatory Notes
		• Collecting, packaging, handling and delivery of laboratory specimens • Safe handling and disposal of healthcare waste • Single use devices • Occupational health policies for prevention and management of communicable infections in healthcare workers. • Housekeeping and cleaning regimens for all patient and decontamination areas • Relevant training for all staff Current copies of approved policies / procedures / guidance pertinent to activities in each area, readily accessible to staff. Access to infection control and specialist support particularly in relation to: • planning new facilities for clinical procedures and/or decontamination. • development of engineering and building services • purchase of decontamination equipment (WDs, ultrasonic cleaners, sterilizers). • purchase of medical devices. • Contracting out services with infection control implications (e.g., cleaning, laundry, clinical waste, decontamination).	

3.4 Training

Para	Principle	Methods to Achieve	Explanatory Notes
3.4.1	Decontamination of re-usable medical devices is carried out only by appropriately trained and qualified staff.	Planned training programme to ensure that: • staff undertaking decontamination: - are qualified and trained for the roles they undertake. - receive on-going education in the techniques and skills relevant to decontamination and the procedures they are undertaking. - have completed training in the safe use of the equipment. ▪ For all staff there is: - on-going education including up-date of policies, feedback of audit results and actions needed to correct deficiencies. - education and training in decontamination and infection control. - Infection control included in induction training for all new staff. - Simulation exercises undertaken to familiarise staff with emergency procedures. - Documented record of all training.	The quality of a product depends to a large extent upon the personnel involved with its manufacture. Each individual has a responsibility for carrying out satisfactorily a particular stage, or stages, in decontamination, and adequate training is important to ensure that each one understands the nature of the work for which he/she is responsible and the possible consequences of failure to observe Best Practice There should be sufficient personnel at all levels with the ability, training, experience and professional and technical qualifications appropriate for the tasks assigned to them. Their duties and responsibilities should be clearly explained and recorded, eg as a job description.

3.5 Quality management system

Para	Principle	Methods to Achieve	Explanatory Notes
3.5.1	LDUs will not require a system as extensive as that applied in CDUs but will still require documented policies, procedures and records for all the key elements of the decontamination process.	Implement policies and procedures to control the decontamination process where the absence of such procedures may affect adversely the quality of the decontamination service. Non-batch related records including, but not limited to: - Sterilizer purchase specification - Sterilizer validation - Sterilizer maintenance - Sterilizer periodic test - Sterilizer water reservoir replenishment - WD/ultrasonic cleaner purchase specification - WD/ultrasonic cleaner validation - WD/ultrasonic cleaner maintenance - WD/ultrasonic cleaner periodic test - WD/ultrasonic cleaner water treatment - Environmental cleaning - Staff training - Device purchase specifications - Facilities maintenance - Audit Batch related records including, but not limited to: - Manual washing records - Washer disinfector records - Inspection records - Sterilizer cycle records - Sterile product release records	Step-wise procedures should be written for each stage of the process; these procedures may then be used also as in-house training documents. Quality records are in two categories; batch related and non-batch related.

Para	Principle	Methods to Achieve	Explanatory Notes
3.5.2	Policies and procedures should be audited periodically to ensure: – Staff compliance – Relevance to activities – Compliance with regulatory requirements and guidance.	Documented review of policies and procedures undertaken not less than annually.	
3.5.3.	Records are maintained, securely stored and readily accessible to permit traceability to the extent required (see 2.15).	Traceability records: - covering all items cleaned and sterilized within the unit - that provide evidence (an audit trail) that all re-usable medical devices used on patients have been subjected to a satisfactory decontamination process since their use on a previous patient.	The effectiveness of the traceability system should be demonstrated periodically by a practical trial of the ability of the system to permit retrieval of the appropriate process records.

3.6 Environmental cleaning

Para	Principle	Methods to Achieve	Explanatory Notes
3.6.1	The cleaning procedures and schedules adopted must ensure that contamination from handling used devices, clinical waste and process chemicals is removed from the environment and not dispersed to clean areas.	**Segregation of cleaning equipment** (i) Separate DSRs for clean and dirty areas (ii) Separate cleaning equipment for clean and dirty areas stored in the same DSR (iii) The same equipment used for both clean and dirty areas. The cleaning equipment thoroughly cleaned after use; clean areas cleaned first followed by dirty areas.	Control of environmental cleaning is a key aspect of the day to day operation of a decontamination unit. Dispersal of contamination to clean areas may occur through the use of inappropriate cleaning equipment and/or techniques or through the use of contaminated cleaning equipment. Cleaning equipment should be stored in a clean, dry and tidy manner, and be well maintained.
3.6.2	The equipment and methods used should minimise the dispersal of contamination	**Choice of floor cleaning equipment and method** (i) Mop and bucket using 'two bucket' system and a free rinsing detergent (ii) Vacuum fitted with HEPA filtered exhaust (iii) Rotary scrubbers and polishers should not be used (unless all devices are first removed from the area and all horizontal work surfaces are cleaned after the floors)	The schedule should specify materials and methods to be used, the frequency of cleaning and the persons responsible for carrying it out. [The schedule should be approved by the Microbiologist.] Cleaning equipment which raises dust should not be used.
3.6.3	The cleaning agents should be appropriate	**Choice of floor cleaning agents** (i) Free rinsing neutral detergent in hot water (ii) Disinfectants are not required (iii) If disinfectants are used they should be: a. Only used following thorough cleaning b. Freshly diluted from concentrate immediately before use c. Rotated quarterly to prevent build up of resistant organisms	The schedule should specify materials and methods to be used, the frequency of cleaning and the persons responsible for carrying it out. [The schedule should be approved by the Microbiologist.]. Solutions of detergents and disinfectants should be made afresh before cleaning operations, as they may lose their effectiveness and become a microbiological hazard.

Para	Principle	Methods to Achieve	Explanatory Notes
3.6.4	Cleaning should be at a frequency that will maintain the required standard of cleanliness	<u>Schedule for floor cleaning</u> (i) Floors should be cleaned daily (ii) Floors should be cleaned also when visibly soiled	There should be a written schedule for all areas and equipment.
3.6.5	Work surfaces should be clean and free from contamination	(i) Work surfaces should be cleaned a. at least daily b. with a hot aqueous solution of a free rinsing detergent c. and dried after cleaning (ii) Work surfaces should be wiped down a. periodically during the working day b. using spore free 70% iso-propanol (this provides both a disinfection and drying effect) c. whenever necessary	
3.6.6	Provision should be made to deal with spillages	The dirty areas should be equipped with spillage kits to contain and remove spillages of body fluids.	
		The wash area should be equipped with spillage kits to contain, neutralise if necessary and remove spillages of process chemicals (guidance on the specific requirements should be found in the Material Safety Data Sheet supplied by the process chemical manufacturer).	
3.6.7	The adequacy of cleaning should be verified	The cleaning should be monitored by regular documented inspection of the cleanliness of the environment and the cleaning equipment.	

4. References

- Glennie Group (NHSScotland Sterile Services Provision Review Group) Report [HDL(2001)66] http://www.show.scot.nhs.uk/sehd/mels/HDL2001_66.pdf
- Head et al, British Dental Journal, 195, 339-343 (2003) http://www.nature.com/bdj/journal/v195/n6/abs/4810526a.html
- HDL(2003)42 Decontamination. – NHSScotland Sterile Services Provision Review Group (Glennie Group) http://www.show.scot.nhs.uk/sehd/mels/HDL2003_42.pdf
- **HTM 2030 Washer-disinfectors: Validation and verification, NHS Estates** 199 www.decontamination.nhsestates.gov.uk/downloads/PAT_pt1_annex_A.doc
- Spaulding EH. Chemical disinfection of medical and surgical materials. In: Block SS, ed. Disinfection, http://www.infectioncontroltoday.com/artrefs/181refs.html
- Sterilization and preservation, 4th edn. Philadelphia: Lea & Febiger, 1968 www.blackwell-synergy.com/doi/abs/10.1111/j.1601-5037.2005.00145.x
- MDA DB 2002(06) Benchtop Steam Sterilizers – Guidance on Purchase, Operation and Maintenance http://devices.mhra.gov.uk/mda/mdawebsitev2.nsf/0/A8426EAAB6BEC5D880256C8B004F4955?OPEN
- MHRA DB 2003(05) Management of Medical Devices Prior to Repair Service or Investigation http://devices.mhra.gov.uk/mda/mdawebsitev2.nsf/0/5EC97FD1EF5E62E180256D4E00542622?OPEN
- SAN(SC)03/11 NHSScotland Safety Action Notice: Decontamination of Re-usable Medical Devices: Control of Aqueous Solutions in Ultrasonic Cleaners http://www.show.scot.nhs.uk/shs/hazards_safety/SANPDF/SAN0311.pdf
- SHTM 2010 Sterilization Part 3 Validation and verification, NHSScotland, Property & Environment Forum, June 2001 http://www.hfs.scot.nhs.uk/guest/decontamination/CDVer2/SHTM 2010/2010 Part 3 Ver2.pdf
- SHTM 2030 Washer Disinfectors Part 3 Validation and verification, NHSScotland, Property & Environment Forum, October 2001 http://www.hfs.scot.nhs.uk/guest/decontamination/CDVer2/SHTM 2030/SHTM 2030 Part 1 Ver2.pdf
- SHTM 2031 Steam for sterilization, NHSScotland, Property & Environment Forum, June 2001 http://www.hfs.scot.nhs.uk/guest/decontamination/CDVer2/SHTM%202031/2031%20Part%201.pdf

- SHTN 3 Management and disposal of clinical waste, NHSScotland, Property & Environment Forum, October 2002

  http://www.hfs.scot.nhs.uk/secure/clinicalwaste/SHTN3V4/index.htm

- Wilson et al Journal of Hospital Infection, 43, 246-247 (1999)

  http://scholar.google.com/scholar?hl=en&lr=&sa=X&oi=scholart&q=%C2%B7%09Wilson+et+al+Journal+of+Hospital+Infection,+43,+246-247+(1999)

5. Bibliography

Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee, "Transmissible spongiform encephalopathy agents: safe working and the prevention of infection" (see http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm).

MDA DB 2000(04) Single-use Medical Devices: Implications and Consequences of Reuse

Safety Action Notice (SAN(SC)03/23) Re-usable Stainless Steel Vaginal Speculae *sic*: Risk of Cross Infection

http://www.show.scot.nhs.uk/shs/hazards_safety/SANPDF/SAN0323.pdf

Risk assessment undertaken on categorisation of dental tissues that are currently considered as low risk. (See http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4084662 and http://www.scotland.gov.uk/consultations/health/decontamination.pdf).

6. Contact Details

Service	Organisation	Address	Contact Number
For procurement	Scottish Healthcare Supplies	Gyle Square 1 South Gyle Crescent Edinburgh EH12 9EB	0131 275 6778
For installation, validation, maintenance and testing	Scottish Healthcare Supplies	Gyle Square 1 South Gyle Crescent Edinburgh EH12 9EB	0131 275 6390
For general guidance and enquiries	Health Protection Scotland	1 Cadogan Square Cadogan St Glasgow G2 7HF	0141 300 1153

7. Glossary

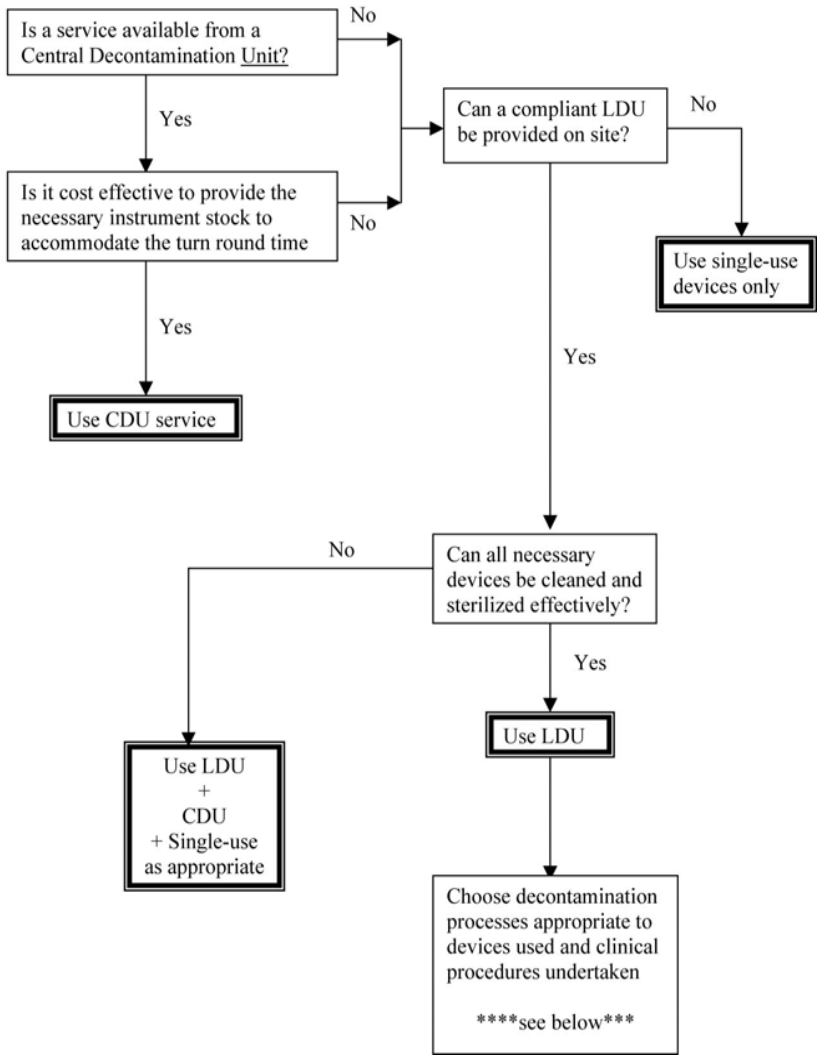
Adventitious contamination	Accidental, extraneous, contamination arising by chance
Batch	Items processed at the same time under the same process conditions
Decontamination	Totality of the processes required to render a used re-usable medical device fit for use on a subsequent patient. (This will normally include at least cleaning, inspection for cleanliness and functionality and disinfection and/or sterilization)
Decontamination manager	Person with designated, written, responsibility and authority to manage all aspects of the decontamination service. (In a small practice this may be the practitioner or nurse)
Hazard	The potential to cause harm including ill health and injury, damage to property, plant, products or the environment, production losses or increased liabilities.
Medical Devices	As defined in the Medical Device Directive (42/93/EEC); includes surgical instruments.
High level disinfection	Capable of killing all micro-organisms with the exception of high numbers of bacterial spores [Summarised from - Rutala W A APIC (Association of Professionals In Infection Control and Epidemiology) Guidelines for selection and use of disinfectants. Am J Infect Control 1996, 24, 313-342.]
Low level disinfection	Capable of killing most bacteria, some viruses and some fungi but cannot be relied upon to kill resistant bacteria [Summarised from - Rutala W A APIC (Association of Professionals In Infection Control and Epidemiology) Guidelines for selection and use of disinfectants. Am J Infect Control 1996, 24, 313-342.]
Medium level disinfection	Capable of killing Mycobacteria, vegetative bacteria, most viruses and most fungi but not necessarily bacterial spores [Summarised from - Rutala W A APIC (Association of Professionals In Infection Control and Epidemiology) Guidelines for selection and use of disinfectants. Am J Infect Control 1996, 24, 313-342.]
Invasive procedure:	A medical or surgical procedure which penetrates intact skin or mucous membrane or penetrates a sterile body cavity
Non-linting wipe	Wipe which in normal use does not shed fibres
Policy	A statement of intent; in particular with reference to an operational matter.
Procedure	A statement of steps required to fulfil a policy.
Re-usable medical device	A medical device designated by its manufacturer as suitable for multiple episodes of use; either for a defined maximum number of use cycles or until inspection reveals wear or damage to the extent that the device must be repaired or replaced
Risk	The likelihood and impact of a hazard occurring.
Single-use medical device	A medical device designated by its manufacturer as suitable for a single episode of use.

8. Abbreviations and symbols used

A_o	Integrated lethality unit for thermal disinfection. One A_o unit is equivalent to 1 second at 80°C. Permits direct comparison of different time/temperature relationships for thermal disinfection eg 600 seconds (10 minutes) at 80°C is equivalent to 60 seconds (1 minute) at 90°C.
BS	British Standard
B & I	Bowl and Instrument
CDU	Central Decontamination Unit
CJD	Creutzfeld Jacob Disease
COSHH	Control of Substances Hazardous to Health
DSR	Domestic services room
EN	European Standard
FIFO	First in first out
HAI	Healthcare Associated Infection
H&SAW	Health and Safety At Work Act
ISO	International Standards Organisation
LDU	Local Decontamination Unit
NHS QIS	National Health Service - Quality Improvement Scotland
PAT	Portable Appliance Testing
PPE	Person protective equipment
PrEN	Draft European Standard
SHTM	Scottish Health Technical Memorandum
SHTN	Scottish Health Technical Note
SHPN	Scottish Health Planning Note
TR	Technical Requirement
WD	Washer-disinfector
WFI	Water for irrigation BP

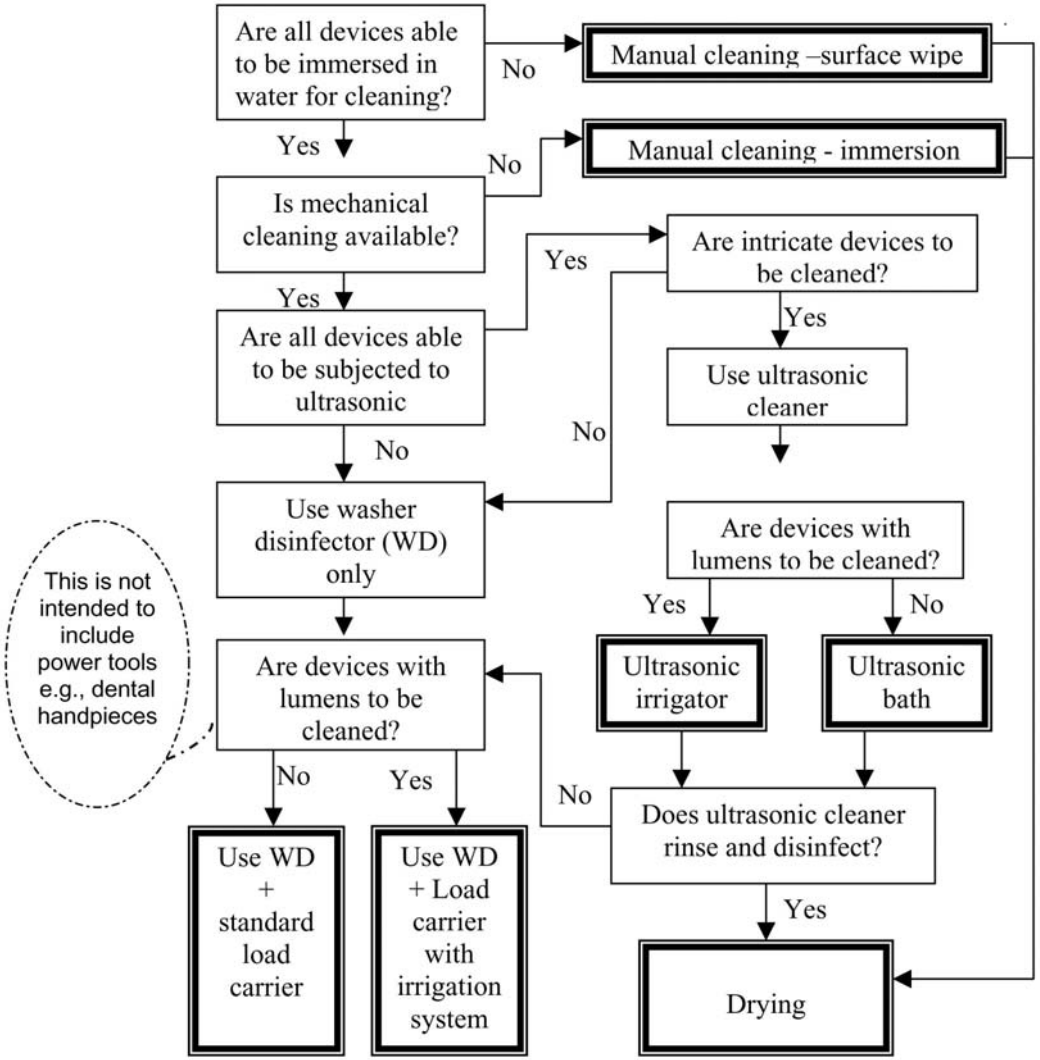
ANNEX 1

Choice of decontamination processes



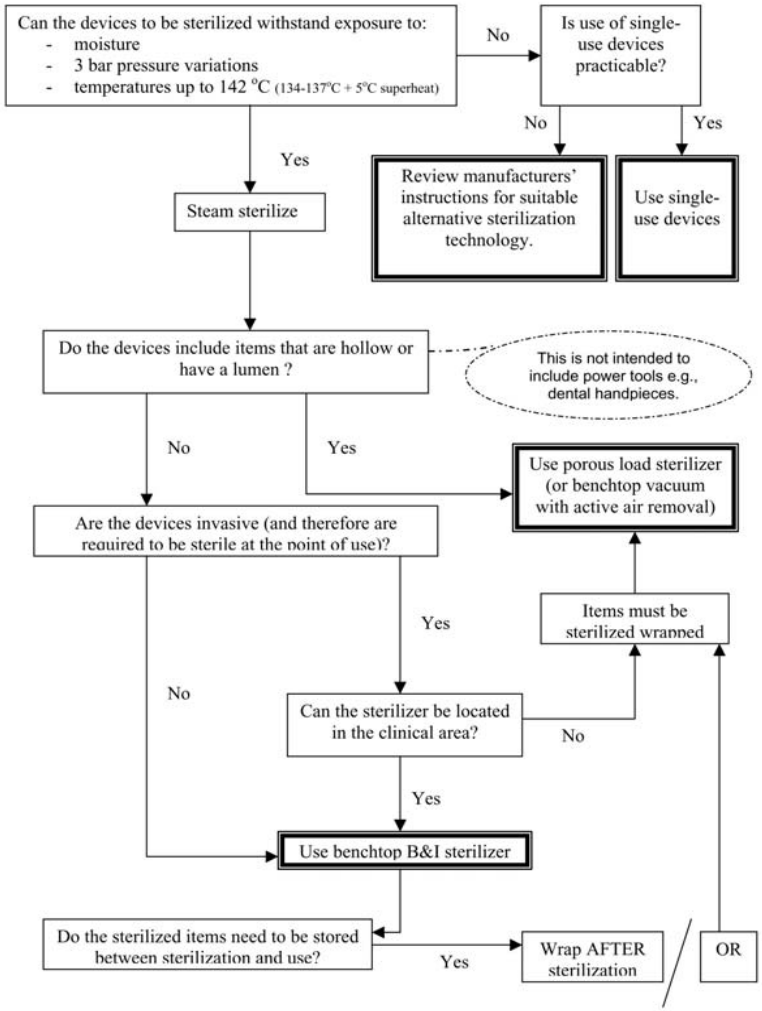
Annex 2

Choice Of Decontamination Processes - Cleaning



ANNEX 3

Choice Of Decontamination Processes - Sterilization



Annex 4. Ventilation in local decontamination units.

[Note: Work is in progress on design guidance and this is interim advice]

For detailed guidance on ventilation see SHTM 2025

A.1 Basic ventilation requirements

In addition to the ventilation which is essential in all occupied premises there are a number of other factors which determine the ventilation requirements for local decontamination units and associated clinical treatment areas.

These include:

- Extraction of odours, aerosols etc some of which may be infectious or toxic
- Dilution and control of airborne pathogenic material
- Removal of heat generated by equipment (eg benchtop steam sterilizers, automated WDs)
- Reduction of moisture levels / removal of moisture generated by equipment (eg benchtop steam sterilizers, automated WDs)

Activity areas

The activity areas associated with a local decontamination unit will include, typically:-

A 'Dirty' utility area where reception of used devices and the cleaning stage of the Decontamination process take place.

A 'Clean' area where the sterilization stage of Decontamination takes place. When the sterilizer is a benchtop B&I steam sterilizer and sterile (as opposed to sterilized) devices are required this may be within the Clinical area (ie treatment room or surgery).

The ventilation of these areas must be designed to accommodate the requirements summarised in A.1 above. Note: in designing the ventilation systems fire compartmentation requirements must be maintained.

Ventilation – Dirty areas

General extract ventilation alone is unlikely to be adequate for 'dirty' activities (see HTM 2025 Pt 2 §2.7). A foul extract ventilation system should be used to ensure that the room is maintained at negative pressure while in use to prevent egress of contaminated air.

A dual motor/fan extract unit should be used, equipped with automatic change over, and providing an extract rate of not less than 10 air changes/hour.

Comfort cooling may be required where calculations (see HTM 2025 Pt 2 §3.40) show that excessive levels of ventilation would be required to maintain acceptable levels of comfort. Typically, not less than 7 air changes per hour may be required for a room in which an automated WD is operated which will contribute significant heat and humidity to the environment. (Details of the heat output from WDs should be available from the equipment supplier.) Where practicable the discharge vent from the WD should be vented outside the building., alternatively the WD chamber vent should be fitted with a condenser. Full air conditioning is not likely to be required except in the largest units.

The complexity of the system will depend on local circumstances and may range from simple wall mounted fans to a ducted distribution system.

If individual units are used, the ventilation may be designed to operate only when the room is occupied. If so, it should be designed so that it continues to run for 20-30 minutes after the room is vacated.

The make-up air may be provided by overspill from the clean area.

The air flow within the room should be designed to ensure that air flows from the cleanest activity in the room towards the dirtiest in the room when it is occupied and operational.

Ventilation – Clean areas

Supply only ventilation should be provided for clean activity areas to ensure that room is maintained at positive pressure while in use to prevent the ingress of less clean air from adjacent areas used for 'dirty' decontamination activities. The air supply should be filtered. The minimum filter standard is EU 3 but the use of EU 6/8 filters is highly desirable where reprocessing of instruments used in invasive procedures will be undertaken.

Note: Natural ventilation or supply and extract ventilation would often be used for treatment areas: in this case the room is maintained at neutral pressure and the pressure variation that occurs due to movement of doors, personnel etc will facilitate the ingress of contaminated air from adjacent areas.

Comfort cooling may be required where calculations (see HTM 2025 Pt 2 §3.40) show that excessive levels of ventilation would be required to maintain acceptable levels of comfort. Typically, not less than 7 air changes per hour may be required for a room in which the benchtop steam sterilizer is operated. (Details of the heat output from sterilizers should be available from the equipment supplier) Full air conditioning is not likely to be required except in the largest units.

The fresh air should be tempered and filtered to avoid discomfort.

Annex 5: Local Decontamination Facilities

[Note: Work is in progress on design guidance and this is interim advice]

Principle

The environment is one of the three main sources of contamination of a product prior to its sterilization (the others being personnel and raw materials/components). The design and construction of the facilities has a major effect on environmental contamination.

Basic considerations for Premises

Ideally, buildings should be purpose-designed and built but whether newly constructed or modified the following are basic considerations:

- part or all of the decontamination should take place in a controlled area separate from clinical areas;
- passage of all materials and personnel should be controlled;
- appropriately designed and situated cloakroom and toilet facilities should be provided;
- special storage areas and conditions may be required;
- cleaning requirements may involve special facilities;
- maintenance, repair, building activities, pest control and other normal services need special provision.

Facilities for decontamination may be divided into three areas:

A. 'dirty' area where cleaning of used devices takes place,

B. 'clean' inspection, assembly and packing (IAP) area,

C. 'clean' area where sterilization and post-sterilization storage of devices takes place.

Areas B and C above may be combined with a clinical treatment area.

Common requirements for all decontamination areas

The changing areas and washing facilities should be at the lowest end of any air pressure gradient.

The interior should be designed to avoid dust traps and to permit ease of cleaning.

The junctions between walls, floors and ceilings should be coved where possible.

Walls, floors and other surfaces should be of a smooth water resistant finish able to withstand frequent cleaning.

Furniture should be made of non-shedding materials which are easy to clean.

Fitments should have smooth cleanable surfaces free from sharp corners which may act as dirt traps.

Cloakrooms and toilets must be segregated from the decontamination area but the changing areas and washing facilities for the decontamination area should be adjacent, so that personnel enter these areas after using the facilities provided.

The gowning areas and washing facilities should be maintained in a clean and tidy condition to minimise microbial contamination, by providing for example:

- soap or other hand detergents;
- single-use paper towels;
- waste bins with foot-operated lids;
- nail brushes when considered to be necessary should be single-use ;
- mirrors to assist correct adjustment of head covering;
- wash basins with :
    - taps fitted with foot or elbow-operated controls or automatic sensor control;
    - mixer or thermostatically controlled taps
    - no overflow or plug;
    - taps that do not discharge directly into the waste;
    - running trap remote from the hand basin.

Wash area ('dirty') requirements

Waste material should not be allowed to accumulate. It should be collected in suitable containers for regular and frequent removal.

Waste storage areas should not be used for storage or as a general right of way for either personnel or for transport of materials.

The wash area should be provided with extract ventilation (see Annex 4).

IAP and sterilization area requirements

The IAP area should be provided with a flow of filtered air (see Annex 4).

Equipment and Materials

Equipment used in decontamination should be designed to facilitate cleaning and to prevent foreign matter, or machine lubricants, from coming into contact with devices.

It should be demonstrated as being capable of carrying out the processes for which it is intended and of being operated to the necessary hygienic standards.

Equipment should be adequately spaced to avoid congestion and accidental mixing of different products.

Containers used for temporary storage and handling should be constructed from non-shedding materials and should be cleaned as necessary.

All ancillary materials should be adequately identified and labeled e.g., lubricant, cleaning agents.

Liquids should be contained in properly labelled dispensers. All labels should clearly specify the contents and, if applicable, display the appropriate hazard warning and safety precautions.

All filters for compressed air supplies should be regularly maintained.

Cleaning and cleaning schedules

All vessels and pipelines used for water should be regularly cleaned and maintained in good condition. If necessary, they should be sterilized or disinfected periodically.

Containers, for solvents and other solutions that may support bacterial growth, should be cleaned regularly and thoroughly, and unused contents discarded.

Annex 6: Personnel Hygiene

Individuals spread both micro-organisms and particles which constitute contamination risks.

The human body is an ideal environment for multiplication of micro-organisms, eg on the skin, on the hair, in the nose, throat, oral cavity, and intestines. An individual can liberate millions of bacteria-carrying particles per minute. Movement of people creates air currents and turbulence that stir up particles and delay sedimentation.

It is a management responsibility to ensure that the under-noted requirements are met:

- no person known to have skin lesions on exposed surfaces of the body, or to be suffering from a disease in communicable form, or to be the carrier of such a disease, or likely to constitute a contamination hazard, should be employed on decontamination;
- personnel in contact with a product or its environment shall be clean, healthy and suitably attired;
- any personnel who by observation or by medical examination appear to have a medical condition which could adversely affect the product, should be excluded from those operations until they have recovered;
- personnel should be instructed and encouraged to report such conditions;
- a list of rules should be issued to all personnel, and steps taken to ensure that they are read and understood. Those which apply to clean rooms should also be prominently displayed at their entrances;
- the rules and procedures for entry into and behavior in decontamination areas should be followed by ALL persons entering the areas, including visitors, maintenance staff and cleaners;
- no person should enter except through a changing area in which outdoor clothing should be left;
- all persons must be required to wash their hands immediately on entering;
- protective clothing must be worn by all persons, and not be worn outside the decontamination area;
- eating, drinking, smoking or chewing must not be permitted;
- the use of cosmetics should be discouraged; those which can shed particles, e.g., powder based cosmetics, hair lacquers and nail varnishes, should not be worn;
- no personal belongings, eg. purses, handbags and easily removable jewellery, should be taken into these areas;
- lockers should be provided for storage of personal belongings or valuables.

Protective Clothing: Clean rooms for 'Clean' decontamination processes.

The protective clothing provided for personnel and for visitors to clean rooms should be of essentially non-linting material, and designed to cover the wearer and everyday clothes effectively.

Where gloves or other hand coverings are to be worn by personnel handling devices, they should be of essentially non-linting and non-shedding materials and should be discarded when leaving the clean room.

Clean gloves should be available for personnel re-entering the room and at any time during the working day when gloves need to be changed.

Clean room protective clothing should be stored in a separate area from outer clothing, and should be maintained in a good and clean condition. The garments should be regularly and frequently laundered or be disposable.

Protective Clothing: Controlled areas for decontamination processes.

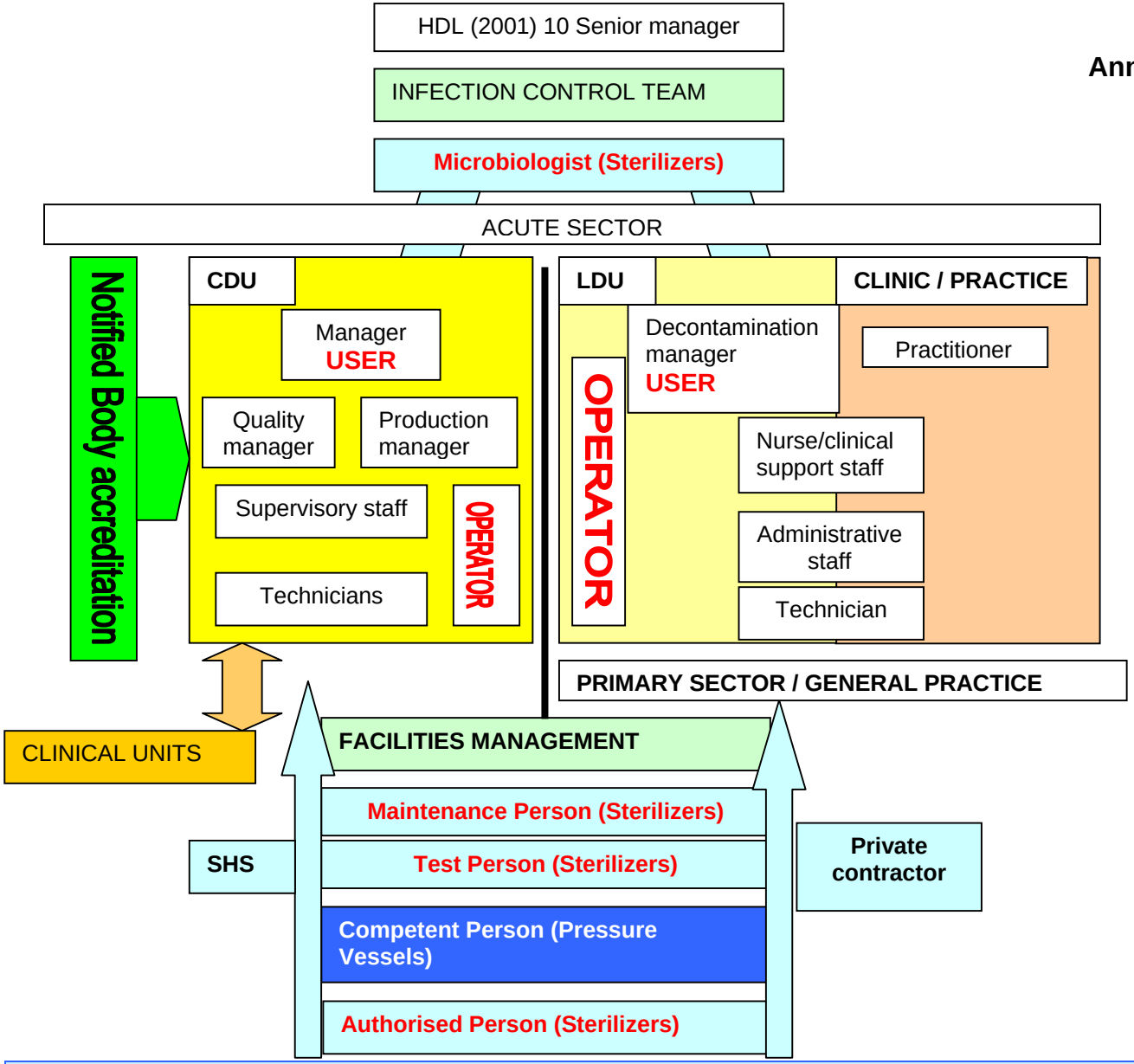
The type of protective clothing must be appropriate for the area and operation in which it is used.

The protective clothing provided for personnel and for visitors to controlled areas should be of essentially non-linting material, and designed to cover the wearer and everyday clothes effectively.

The protective clothing should be regularly and frequently laundered or be disposable.

It is a management responsibility to ensure that the above requirements are met.

Annex 7: Roles In Decontamination



KEY: All legends in red indicate roles defined in SHTM 2010 and SHTM 2030.

The overlap between the acute and primary/general practice sectors indicates the use of LDUs within the acute sector.

For details on the responsibilities of each role see SHTM 2010 and SHTM 2030.

Annex 8 - Schematic Layouts for LDUs

[Note: The Layouts have been removed as they are under review. They will be included in Draft SHPN 13 which will be available soon. If you require urgent advice on layouts please contact the Decontamination team at decon_team@hps.scot.nhs.uk

Annex 9
Primary care: Economic considerations in determining the method to be adopted for the provision of sterile medical devices and the location of any required facility for decontamination.

1. Introduction

In determining the means by which sterile medical devices may be provided for primary care there are three methods that may be considered:

- single-use sterile medical devices;
- re-usable medical devices processed through a central decontamination unit (CDU);
- re-usable medical devices processed through a local decontamination unit (LDU).

Any one, or any combination, of these methods may be satisfactory. In some cases there will be no choice. For example, if a) there are no single-use devices of the type required available, b) there is no possibility of access to a CDU service, and then a Local Decontamination Unit would be the only solution.

Where there are no other over-riding factors the preference is for single-use and/or a supply from a CDU. Clearly, the cost of providing the decontamination service is a major factor influencing the decision when a choice is available.

The financial implications need to be considered carefully and all aspects of the costs must be included in any determination of the preferred method. The major elements that may need to be taken into account are discussed below.

2. Financial considerations

2.1 Requirements of the clinical unit:

Before any realistic comparison of costs can be made it is necessary to establish the quantity and type of medical devices that needs to be reprocessed. Clinical units may not have this information readily to hand. The requirements for sterile medical devices may need to be determined; this is best done by:

- listing all the procedures that are undertaken;
- for each procedure, listing the devices that are required (both those that are always needed, those that may occasionally be needed and essential back-up (duplicate) instruments that may be required);
- from existing records, or as a specific exercise, determining the number and nature of procedures carried out each day.

From these data the daily requirements for sterile medical devices may be calculated. Some additional allowance may be needed to accommodate changes in clinical practice which may occur in the future.

The calculated requirements may then be used to obtain an accurate estimate of the costs involved for provision of:

- single-use devices;
- a service from a CDU, or,
- compliant decontamination facilities for an LDU to re-process re-usable devices.

If the devices are not to be decontaminated in an LDU in the clinical unit immediately after use there will be a delay before used devices are returned to service. There must, therefore, be sufficient instruments of the type required available for procedures that will be undertaken prior to the return of instruments.
This may require purchase of additional instruments and the cost of these instruments, amortised over the life of the instruments, will need to be taken into account.

The cost of additional instruments may be calculated from:

$$\text{Additional instruments required} = \left(\text{Instruments used per day} \times \text{Turn round time (days)} \right) - \text{Current instrument inventory}$$

The cost of providing the additional instruments required to ensure a reliable service may then be determined. (Note: The longer service life of individual instruments, because of the reduced usage rate, may also need to be considered.)

3. Summary of costs for CDU service

Item	Costs			
	Capital	Revenue		
		'One-off'	Fixed	Variable
Instruments				
Additional instrument* inventory	Purchase	Allocation into set		Repairs; replacement, refurbishment
Transit containers*	Purchase			Repairs; refurbishment; Security tags
Facilities				
Storage for sterile re-usable devices	Construction (new or refurbished)		Heating, lighting, maintenance and cleaning	Repairs; refurbishment
Storage for used devices pending return to CDU	Construction (new or refurbished)		Heating, lighting, maintenance and cleaning	Repairs; refurbishment;
Services				
Clinical waste disposal			Contract fee	Volume charge
CDU contract				
Re-processing			Contract fee	Price per item
Transport			Contract fee	
Instrument repair/replacement				Price per item
Staff (in clinical unit)				
Reception/storage/distribution/preparation for return; Record keeping				Hourly rate

4. Summary of costs for single-use devices

Item	Costs			
	Capital	Revenue		
		'One-off'	Fixed	Variable
Instruments				
Single-use devices	Purchase		Purchase	Transfer to storage / distribution
Facilities				
Storage for sterile single-use	Construction (new or refurbished)		Heating, lighting, maintenance and cleaning	Repairs; refurbishment
Services				
Clinical waste disposal			Contract fee	Volume charge

5. Summary of costs for an LDU

Item	Costs			
	Capital	Revenue		
		'One-off'	Fixed	Variable
Facilities				
Segregated decontamination area with separation of clean/dirty	Construction (new or refurbished)	Design; Planning consent; commissioning	Capital charges; Maintenance; Insurance; Rates; environmental cleaning	Repairs; refurbishment
Services				
Ventilation system	Purchase and Installation	Validation	Maintenance and testing	Repairs; refurbishment
RO water unit	Purchase and Installation	Validation	Maintenance and testing	Repairs; refurbishment; water and sewerage charges
Electricity supply	Purchase and Installation	Design	Maintenance and testing; Standing charge	Repairs; refurbishment; Usage charge
Equipment				
Washer-disinfector	Purchase and Installation	Validation	Capital charges & depreciation; Maintenance and testing	Consumables (water, detergent, electricity)
Ultrasonic bath	Purchase and Installation	Validation	Capital charges & depreciation; Maintenance and testing	Consumables (water, detergent, electricity)
Heat sealer	Purchase and Installation	Validation	Capital charges & depreciation; Maintenance and testing	Electricity
Sterilizer	Purchase and Installation	Validation	Capital charges & depreciation; Maintenance and testing; Insurance	Consumables (water, electricity)
Ancillary equipment (containers etc)	Purchase			Repair; replacement
Consumables				
				Packaging
				Indicators
				Packing tape
				Brushes/cleaning aids
				Disinfectants
Staff				
Management		Recruitment; Induction training; development of QC system	Training Remuneration (inc NI etc); Maintenance of QC records; Internal audit	
Operator(s)		Recruitment; Induction training	Training Remuneration (inc NI etc)	PPE
Clinical waste				
Disposal			Contract fee	Volume charge

6. Other considerations

The examples given above are not exhaustive; they summarise the principle areas in which expenditure will be incurred.

Non-recoverable VAT will need to be included, as appropriate, when calculating the costs for the various elements listed above.

Some items of equipment e.g., washer-disinfectors, sterilizers, that represent significant capital investment, may be available on lease.

Financial considerations alone should not determine the nature of the service provision; due consideration must be given to other, less easily quantifiable factors such as security of service, financial and other risks arising from a decontamination failure.

Some elements of the requirements eg qualified test and maintenance personnel may be in short supply. If indicative prices are being obtained from providers of these services they should also be asked to confirm their availability to carry out the work required.