



**HBN 13**  
Sterile Services  
Department

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# HBN 13

## Sterile Services Department

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# Executive summary

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## PURPOSE OF THE DOCUMENT

This Health Building Note (HBN) provides guidance to help health planners, estates and facilities managers, sterile services managers and capital planning and design teams to plan and design a sterile services department.

It supersedes HBN 13: 'Sterile services departments' published in 1992.

## OVERVIEW OF TOPICS

It discusses the objectives of a sterile services department (SSD) and service requirements, particularly focusing on:

- Raising standards in decontamination services by optimising the built environment.
- Service requirements strategy.
- Calculating the optimum capacity of an SSD to eradicate bottlenecks (using a simulation model provided on a CD-ROM included with this guidance).
- Determining the most appropriate location of an SSD.

Design guidance based on the above service objectives is outlined. Finally, the finer details of the individual spaces within an SSD are discussed.

## RECOMMENDATIONS

- Emphasis should be placed on **centralising** the decontamination of surgical instruments into **purpose-built departments** with equipment fit for purpose.
- The inspection, assembly and packing (IAP) room should be a Class 8 clean-room with a pressure differential higher than that of adjoining rooms.

- Automated washer-disinfectors through which most (but not all) items will be transferred from the wash room to the IAP room should be built directly into the separating wall.
- Planning and design should include input from relevant experts including those involved in decontamination, engineering, building and design, service users and suppliers of specialised equipment such as sterilizers and washer-disinfectors.
- When designing an SSD, consideration should be given to the future development of the department's capacity (for example, the need for more washer-disinfectors, sterilizers, and storage requirements to meet increased production capacity).
- A management information system (MIS) should be in place to track products through the decontamination processes. In any new SSD development:
  - i. such systems are likely to be computer-based and will require the appropriate integration of IT systems;
  - ii. all operational rooms, training rooms and offices should have enough computer terminal points to make efficient and effective use of an MIS.
- Continuous training of staff is essential for maintaining acceptable standards of management, service and productivity. Therefore, a training and seminar room should be provided within the SSD or elsewhere, but readily accessible for SSD staff.

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# Contents

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## Executive summary

Purpose of the document  
Overview of topics  
Recommendations

---

## Acknowledgements

---

### 1.0 Introduction

page 3

Range of provision  
Procurement/capital investment  
Equipment

---

### 2.0 General service considerations

page 5

Introduction  
Standards, regulations and guidance  
National approach to raising standards  
Service strategy considerations  
Service objectives  
Service requirements  
Sizing a department  
Location of the SSD  
Operational policies

---

### 3.0 General functional and design requirements

page 13

Introduction  
Workflow  
Capacity planning  
Environment  
Maintenance  
Cleaning  
Finishes  
Security

---

### 4.0 Specific functional and design requirements

page 19

Introduction  
Entrance areas  
Contaminated returns lobby  
Contaminated returns holding area  
Gowning room/area (wash room)  
Wash room

Domestic services room (wash-room area)  
Gowning room (for the IAP room)  
Inspection, assembly and packing (IAP) room  
IAP domestic services room  
Materials transfer room  
Packed product transfer facility  
Sterilizer loading area  
Sterilizer plant room  
Unloading/cooling area  
Processed products store  
Despatch area  
Materials store  
Offices  
Manager's office  
Deputy manager's office  
Office(s): general  
Staff room  
Staff changing/WC/shower room  
Training room  
General areas: domestic services area  
General waste disposal/laundry returns  
Test equipment and data room

---

### 5.0 General guidance

page 38

Introduction  
Economy  
Upgrading or adaptation of existing buildings  
Damage in health buildings  
Signposting  
Disabled people

---

### 6.0 Engineering services

page 40

Introduction  
Model specifications and technical manuals  
Economy and value management  
Service requirements  
Space for plant and services  
Access to control and isolation devices  
Activity data  
Safety  
Fire precautions  
Noise and speech privacy  
Engineering commissioning  
Equipment validation  
Mechanical services

Electrical services  
Internal drainage

---

**7.0 Cost information** **page 49**

Introduction  
Departmental Cost Allowance Guides  
On-costs  
Locational factors  
Schedules of Accommodation  
Dimensions and areas  
Circulation  
Communications  
Land costs  
Engineering services

---

**Appendix 1 Environmental needs** **page 60**

**Appendix 2 Layout diagrams** **page 62**

**Appendix 3 Recommended finishes** **page 68**

**Appendix 4 Glossary of terms** **page 70**

**References** **page 72**

Acts and regulations  
British Standards  
NHS Estates guidance  
Other publications

---

**About NHS Estates guidance and publications**  
**page 76**

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# 1. Introduction

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**1.1** This Health Building Note (HBN) provides information to assist individuals and organisations to make informed decisions about the provision of sterile services. It replaces and builds on HBN 13: 'Sterile services departments' published in 1992.

**1.2** Organisations can determine the most suitable means of providing sterile services by undertaking an option appraisal exercise, whereby they quantify and where possible value the costs, benefits, risks and uncertainties associated with each of the following options:

- a. procure a new build;
- b. upgrade existing facilities; or
- c. obtain services from a third party.

**1.3** This HBN contains information on the building and operating principles for these three main models for service delivery; primarily, it provides guidance for the planning and design of a new-build sterile services department (SSD). Emphasis is placed on:

- centralising the decontamination of surgical instruments into purpose-built departments with equipment fit for purpose; and
- operating in facilities with appropriately segregated processes and effective environmental control.

**1.4** Where the SSD is built as a stand-alone, purpose-built facility, it should contain all of the design and functional requirements detailed in [Chapter 4](#).

**1.5** Parts of the document may appear repetitive if read from start to finish. However, important points are reiterated as and when necessary to enable a busy design team to find information quickly and in one place.

## RANGE OF PROVISION

### Inclusions

**1.6** The primary functions undertaken in an SSD are:

- Disassembling, cleaning and disinfecting instruments, trays, utensils, containers and other reprocessable items. Most of these items will have been used in

surgical or medical procedures carried out in operating theatres or other clinical areas.

- Preparing, assembling, inspecting and packaging instrument trays and packs, including device functionality and safety checks.
- Sterilizing completed trays and packs and providing disinfected items acceptable for patient use in this condition.
- Storing raw materials/components before they are assembled into instrument trays/packs.
- Storing goods processed in the department until they are ready for transfer to point of use.
- Collecting used items and distributing sterile products.

### Exclusions

**1.7** The scope of this HBN does not provide for the following functions:

- Repairing surgical instruments or accessories.
- Processing instruments and utensils used in post-mortems and mortuaries (see HBN 20: 'Facilities for mortuary and post-mortem room services').
- Producing sterile fluids (see HBN 29: 'Accommodation for pharmaceutical services').
- Disinfecting domestic cleaning equipment.
- Inspecting or folding/preparing textiles.
- Cleaning, testing and servicing medical equipment, for example incubators and ventilators.
- Storing commercially sourced sterile products, for example medical and surgical sundries, surgeons' gloves, syringes etc.
- Reprocessing flexible endoscopes and heat-labile accessories. However, the principles of decontamination apply equally to this range of equipment.

## PROCUREMENT/CAPITAL INVESTMENT

**1.8** This HBN advises project owners of health building schemes to follow extant capital procurement and capital investment guidance.

**1.9** Some equipment suppliers may offer a “turnkey” procurement option, whereby the detailed design, construction and equipping of the SSD is provided as a single-point design/build service.

## EQUIPMENT

**1.10** It is important for project teams to identify the make and type of key equipment at an early stage of development of the project. “Key equipment” particularly refers to sterilizers and to other major items such as washer-disinfectors, ultrasonic cleaners etc. Early decisions on the model and supplier of such key equipment will allow better integration of departmental layouts.

## 2. General service considerations

### INTRODUCTION

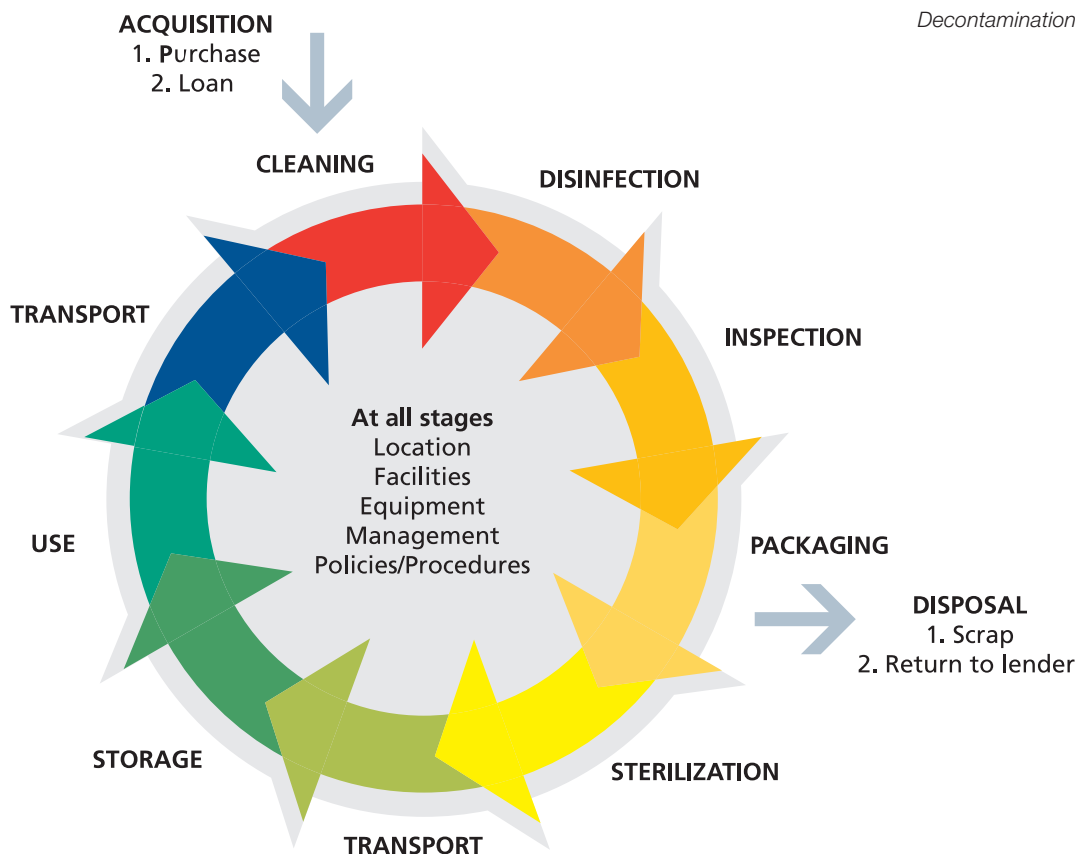
**2.1** The decontamination life cycle (see below) represents each stage of the decontamination process. For effective decontamination, minimum acceptable standards need to be reached against all stages of the decontamination life cycle. In addition, at all stages of the life cycle, the following issues are always relevant:

- Management of decontamination processes.
- Location for decontamination activities.
- Activity at each location.
- Facilities and equipment at each location.
- Validation, testing and maintenance of equipment.
- Policies and procedures.
- Training of personnel.

See NHS Estates' decontamination website:  
<http://www.decontamination.nhsestates.gov.uk>

**2.2** A number of principles have been identified which help to achieve the highest standards for decontaminating surgical instruments. These are:

- An effective management control system should be in place covering all aspects of the life cycle.
- Instruments should be decontaminated using automated and validated processes.
- Equipment (washer-disinfectors and sterilizers) for validated processes requires planned preventative maintenance and periodic calibration and testing to ensure it operates to the same parameters as those set up when it was commissioned.



- Validated processes require that monitoring of the critical variables of each cycle is carried out and this should be independent of the controller.
- Equipment should be fit for its intended purpose, well maintained, validated and tested.
- Processes that require validation should only be carried out using automated equipment to ensure reproducibility, including cleaning.
- Decontamination processes should be segregated to prevent adventitious recontamination.
- Environmental conditions under which devices are prepared should be controlled to prevent adventitious contamination (this includes both microbial and particulate contamination). (“Environmental conditions” refers to the cleanliness of surfaces, fittings and equipment, and also to ventilation and air quality in respect of filtration, airflow patterns and relative air pressures.)
- Systems should be in place to track surgical instruments through the decontamination processes and to the patients on whom devices have been used.
- Reprocessing requirements for all reusable devices should be considered and formally reviewed before such devices are bought.
- Single-use instruments must not be reused.
- Appropriate, dedicated facilities should be provided for decontamination.
- Processes should be undertaken to ensure that there is no health and safety risk to patients, staff and visitors.
- A system for managing stocks of instruments and other reusable devices should exist to ensure that an optimum supply is available and maintained for users of the service.

## STANDARDS, REGULATIONS AND GUIDANCE

**2.3** It is important to be aware that quality assurance standards relating to the preparation of sterile products – including those prepared by SSDs – are being continually developed.

**2.4** General medical devices are covered by the Medical Devices Directive 93/42/EC and implemented into UK law under the Medical Devices Regulations 2002. It applies to manufacturers of medical devices and to SSDs.

**2.5** The expectation is that the standards applied to the manufacturing of medical devices within the NHS should be consistent across all SSDs regardless of whether

their activities are thought to fall within the scope of the Medical Devices Regulations 2002.

**2.6** It is essential that up-to-date guidance and information is applied at all times in the manufacture of devices and that details of current guidance and standards can be readily accessed by all staff involved in the decontamination.

**2.7** The Institute of Sterile Services Management has published a guide to standards – ‘Standards and Practice’ (2001) – which details the standards, regulations and best practice appropriate to the manufacture of sterile products.

**2.8** For sterile products, good practice requires that adventitious contamination be minimised by all practicable means.

**2.9** There are three main sources of contamination of a device before it is sterilized:

- a. materials/products used during the processing;
- b. personnel;
- c. the manufacturing environment.

**2.10** Contamination can be minimised by controlling the building and engineering services that directly affect the manufacturing processes, personnel and manufacturing environment. This can be achieved by providing:

- facilities for, and the segregation of, production processes;
- facilities for the control of personnel;
- a suitable environment for the production of sterile products.

**2.11** Production processes in which components are handled or exposed for significant periods to the environment should be carried out in controlled conditions, as specified in the department’s quality control manual. The accepted standard for environmental control is BS EN ISO 14644 with special attention being paid to particle contamination levels. The inspection, assembly and packing (IAP) room standards are set at Class 8 (ISO 14644). It is also importance to ensure that microbial contamination levels are routinely monitored and maintained within defined levels.

**2.12** Standards for the production of sterile products also recognise the importance of quality assurance and quality control. They recommend that one or more persons be designated to take sole responsibility for the policy and day-to-day functions. Specific details of quality systems will be contained within quality system documentation required for accreditation to the Medical Devices Regulations 2002.

**2.13** The procedures contained within a quality system aim to prevent errors occurring but also include checks to ensure that non-conforming products are not released. Systems also provide evidence in the form of documented procedures and records (which can be independently audited) that show the operation is being conducted in an appropriate and consistent manner. It is common for BS EN ISO 9001 and BS EN ISO 13485 quality systems to be used by SSDs to demonstrate compliance with the Medical Devices Regulations 2002.

**2.14** The above standards without exception should be applied to all areas within an organisation where the reprocessing of medical devices is undertaken.

### NATIONAL APPROACH TO RAISING STANDARDS

**2.15** Decontamination facilities are reviewed and assessed against guidance and standards that aim to highlight areas of non-conformity. The purpose is to increase awareness of existing standards and to assist the service to apply them. The way this has been achieved has differed between countries, but has included the following as a basis for the reviews:

- assessing all SSDs against extant guidance and standards, including controls assurance standards;
- agreeing and monitoring the implementation of action plans with local management to address areas of concerns and to minimise risks;
- a programme of significant investment in decontamination services and careful managing of the investment process to ensure funding meets the need to provide appropriate facilities and equipment;
- implementing a programme of work to improve standards and support for the NHS;
- extending the programme to other healthcare settings, for example primary care.

### SERVICE STRATEGY CONSIDERATIONS

**2.16** Current service strategies have evolved in response to differing local service policies and demands and, consequently, vary considerably throughout the country.

**2.17** Existing policies for sterile services and associated accommodation should be critically reviewed and assessed:

- when considering the needs of a new development project, or;
- in response to a change in clinical service requirements.

**2.18** Any of the following issues may render an existing department unsuitable for future development:

- Limited life expectancy of decontamination equipment or building fabric.
- Where a department does not conform to current best practice, standards or guidance and where it is uneconomical or impractical to upgrade.
- Insufficient space to extend a department where increased capacity is required.

**2.19** The size of an SSD will be influenced by:

- the local sterile services policy;
- workload, including external supply to potential third parties;
- potential future demand, for example the emergence of Treatment Centres (TCs).

**2.20** Continuity of delivery of a quality decontamination service to customers is of paramount importance. Anything that could affect quality, efficiency and continuity of service should be considered and addressed at the design stage, and contingency plans put in place. Examples of issues to be considered include:

- quality and continuity of utility and building services;
- transportation and delivery of raw materials, goods for processing and processed goods;
- equipment “down-time” including break-down maintenance and periodic testing.

### SERVICE OBJECTIVES

**2.21** To appreciate the special requirements needed for producing sterile products, it is necessary to identify the basic service objectives. By establishing these principles, the process flow of the department can more easily be justified and understood by those involved in the design and construction of the SSD.

- Decontaminate to a level compatible with the intended use of the product.
- Minimise adventitious contamination through control of the environment, personnel and materials.
- Produce items that are fit for their intended purpose within the specified life-time.

**2.22** Decontaminate products in such a way as to safeguard patients and staff:

- Within the constraints of the service, provide products in a timely manner.

- Ensure the location and facilities provide a high quality and cost-effective service.
- Provide adequate labelling and instructions for safe use.
- Ensure the process is validated, controlled and monitored.
- Hold appropriate documentation/records to demonstrate compliance.

## SERVICE REQUIREMENTS

**2.23** The service can be described under the following headings, which are used to provide an overview of the requirements of the sterile services function.

|             |  |
|-------------|--|
| Environment | <ul style="list-style-type: none"> <li>• Segregation of process</li> <li>• Control through environment, personnel, and materials</li> </ul>  |
| Equipment   | <ul style="list-style-type: none"> <li>• Fit for purpose</li> <li>• Validated and maintained to current guidance and standards</li> </ul>  |
| Management  | <ul style="list-style-type: none"> <li>• Documentation to demonstrate compliance with national training scheme stated standards</li> <li>• Validated training and qualifications for all those involved in decontamination</li> <li>• Individual training records regularly updated</li> </ul> |

## SIZING A DEPARTMENT

**2.24** The workload demand on an SSD will depend on a locally agreed sterile services policy. The policy should identify the user units to be served, both in the hospital and community settings, and any other user areas, for example endoscopy suites, theatres, out-patient departments etc. The policy therefore needs to be determined as early as possible, allowing for foreseeable future requirements to be identified.

**2.25** It is important that the design and layout of the department should allow for growth in the department's capacity, for example the need for additional washer-disinfectors and sterilizers.

### Calculating the optimum capacity of an SSD

**2.26** When determining the size of a new-build SSD, it is essential to try to calculate the department's capacity. A CD-ROM provided with this guidance contains a spreadsheet-based simulation model of an SSD. This program allows planners and designers to:

- calculate the optimum capacity of an SSD before bottlenecks start occurring;
- model the overall installed production capability of an SSD;
- assess the effects of changing:

- a. the number and size of processing machines, and
- b. number of staff

on throughputs and turn-round times (both for fast-track and normal deliveries).

**2.27** The model can also:

- represent changes in delivery levels and patterns throughout the week;
- provide statistics on queues and performance;
- demonstrate – via an animated schematic of an SSD working week – how and where queues, and therefore bottlenecks, might develop.

**2.28** Also included on the CD-ROM is a virtual-reality fly-through of a typical SSD. This short video guides the viewer through a three-dimensional SSD, demonstrating the path that surgical instruments take through the department as well as visiting the offices and support areas. The video will help planners and designers to imagine how the department may look.

**Note:** An online user guide on the CD-ROM provides detailed information about basic data (number of resources, machines etc) that must be input first for the program to generate meaningful results. It is essential that users refer to this guide to familiarise themselves with this initial set-up.

## LOCATION OF THE SSD

**2.29** When choosing the location of a new build, vehicular access and effective delivery to and collection from the site are important considerations. In addition, the following issues may be taken into consideration when determining the location of the department:

- Availability of site/premises.
- Distance from main users.
- Revenue and capital costs.
- Transport requirements/constraints.
- Turnaround time.
- Instrument inventory.
- Quality and quantity of engineering services.
- Personnel issues.
- Security issues.
- Planning permission requirement.
- Customer base.

- Healthcare providers' strategies.
- Geographical and environmental constraints.

**2.30** Other locational aspects that project teams should consider include the following:

- Fire precaution requirements: as this department is designated a high fire-risk/load department in HTM 81: 'Fire precautions in new hospitals', it is essential to locate this department away from the high fire-risk departments and to ensure good access for the fire brigade.
- Daylight with a pleasant outlook, particularly for staff rooms and those operational areas occupied by staff throughout the daytime, for example, the wash room and the IAP room.

## OPERATIONAL POLICIES

### Used instrument/equipment reception area

**2.31** Contaminated instruments and equipment should be delivered to the SSD in sealed containers. This area/room will connect directly to the wash room and be clearly segregated. The door into the reception area should be secured against unauthorised access.

### Cleaning and disinfection

**2.32** All reprocessible items returned to the department should be treated as potentially contaminated and be subjected to standard precautions except TSE-contaminated items in which cases specific guidance should be consulted (ACDP/SEAC, 1998).

**2.33** Cleaning should completely remove all soil. Cleaning followed by thermal disinfection minimises the infection risk to staff.

**2.34** The function of all cleaning and drying processes is to consistently produce clean, dry and disinfected equipment. It is recommended that this process is automated, but should in all cases be controlled and validated.

**2.35** A steam sterilizer dedicated for decontaminating contaminated equipment is not appropriate. All returned items should be thermally disinfected in a validated washer-disinfector conforming to HTM 2030: 'Washer-disinfectors', MES C30: 'Washer-disinfectors for surgical instruments' and relevant European and International standards.

**2.36** Most reprocessed items will be sterilized after cleaning and disinfection. However, some reprocessed items will be acceptable to users in a clean, dry and disinfected condition and do not therefore need to be sterilized.

**2.37** Enough washer-disinfectors should be installed to maintain production; servicing and maintenance should be planned around, and not be disruptive to, production. It is important to locate washer-disinfectors in such a way as to facilitate the installation of additional machines should workloads increase.

**2.38** Consideration should be given to the advantages of having washer-disinfectors with interchangeable load-handling equipment. Washer-disinfectors should be of a pass-through design. In some instances where the device manufacturer recommends manual cleaning and mechanical drying, a drying cycle should be used (where appropriate). Furthermore, there are benefits in having an automated washer-disinfector programmed with a dry-only cycle for these items.

**2.39** At the end of the process, clean, dry and disinfected equipment should not be compromised by being exposed unnecessarily to further handling or to the environment of the wash room.

**2.40** Only those items considered by the original device manufacturer to be unsuitable for machine processing should be manually cleaned. Cleaning should be in accordance with the manufacturer's instructions and NHS decontamination guidance.

**2.41** The pressure in the wash room should not be positive in relation to adjacent areas to minimise the risk of dispersion of infective aerosols.

**2.42** An area or room next to the wash room should be designated for staff's changing into personal protective equipment before they enter the wash room.

**2.43** A dedicated cleaner's room ("cleaner's room" is henceforth referred to in this document as "domestic services room") needs to have direct access from the wash room.

### Inspection, assembly and packing room (IAP room)

**2.44** The IAP room will receive goods from the wash room and materials from the materials transfer room. These will then be inspected and assembled onto trays and procedure packs to prepare for sterilization. For sterile products, adventitious contamination should be minimised by all practicable means. The IAP room should be a Class 8 clean-room with a pressure differential higher than that of adjoining rooms.

**2.45** An area or room next to the IAP room should be designated for staff's changing into personal protective equipment before they enter the IAP room.

**2.46** A dedicated domestic services room needs to have direct access from the IAP room.

**2.47** Controlled entry and exit of personnel and materials via air locks/transfer hatches should be incorporated to maintain the integrity of the room. A positive pressure should be maintained in the IAP room. The gowning room, materials transfer room and transfer facilities linking the IAP room with the sterilizer loading and wash room should have interlocking doors which will provide an acceptable level of protection. People shall not be able to leave or enter the IAP room other than via the gowning room, unless in an emergency. Trolleys shall not pass into or out of the IAP room.

**2.48** All wet processes including hand-washing should take place outside the IAP room. This will help to minimise the contamination of devices during preparation or production.

### **Sterilization and disinfection**

**2.49** Most reprocessed items will be sterilized by steam. However, a department may require, in support, a specialised process for sterilizing or disinfecting those items that cannot withstand porous-load steam sterilization, for example heat-sensitive items. Where specialist sterilization/disinfection processes are to be provided, appropriate accommodation will be needed, meeting health and safety and associated standards. These may include product preconditioning, degassing and quarantine areas where product release is based on results from microbiological indicators.

**2.50** The choice, purchase, installation, testing and maintenance of porous-load steam sterilizers and specialised processing machines should conform to the requirements given in HTM 2010: 'Sterilization', HTM 2031: 'Clean steam for sterilization', MES C14: 'Sterilizers' and relevant European and international standards.

**2.51** Consideration should be given to the benefits of having sterilization equipment with interchangeable load-handling equipment. There is an advantage in choosing a common size of chamber for all steam sterilizers. Enough sterilizers should be installed to maintain production, but their regular servicing and maintenance should be ensured without disruption to production. It is important to locate sterilizers in such a way as to facilitate the installation of additional machines should workloads increase.

**2.52** Experience suggests 0.6 m<sup>3</sup> or 0.8 m<sup>3</sup> single-door sterilizers are particularly suited to hospital-type loads. Before considering alternative sterilizer sizes and configurations, issues such as loads, frequency of use, working practices, load types and mass should be addressed to ensure performance requirements will be consistently met.

**2.53** Project teams should consider the potential for change in load types historically processed.

**2.54** Guidance relating to ethylene oxide sterilization equipment and facilities is provided in Supplement 1 to this HBN and BS EN 550.

### **Textile supply**

**2.55** Textiles entering the SSD for inclusion in packs or for sterilizing may be single-use or reusable. They should have been manufactured/launched, inspected, packed for transportation/sterilization and validated in a controlled environment so that the microbiological status of the pack is not compromised and the sterility of finished items can be assured.

**2.56** Whichever option or combination is selected, all textiles, including overgowns for use in the IAP room, should be delivered to the materials store fully protected, thereby eliminating the possibility of recontamination during transit and handling. They should be held in the materials store in their protective wrapping until required in the IAP room or, in the case of IAP overgowns, in the gowning room.

### **Staff facilities**

#### **Changing/toilets/showers**

**2.57** Staff will require changing from outdoor clothing to working dress. Full changing facilities for male and female staff should be provided within the SSD.

**2.58** The number of staff employed will dictate the number of lockers needed. Determining how the lockers are allocated should remain with the project team; however, it is advisable that permanently employed SSD staff should be assigned personal lockers.

**2.59** Staff working in, and visitors entering, the IAP room may only do so via the adjoining gowning room. Visitors will also need protective clothing if entering the department. The type and specification for protective clothing will be determined by the area to be visited.

**2.60** Where staff are required to wear special protective clothing over their normal working dress, for example PPE, the additional cover may be put on at point of use.

**2.61** WCs with hand-wash basins should be separated from, but accessible to, the main work areas. The number needed should be assessed in accordance with the requirements of the Workplace (Health, Safety & Welfare) Regulations 1992, relating to the number of staff working at any one time.

### **Education and training**

**2.62** All grades of staff, both managerial and technical, working within the SSD need regular training. A



documented training scheme should be in operation and individual training records available for all members of staff. Accordingly, a training room should be provided within the department if such an area is not available nearby. It should be separate from the main work areas, providing a space where teaching material and work samples will be secure. (If located away from the department, the managerial/tutorial staff member may find it difficult being separated from the activities of the department.)

### Management information systems (MIS)

**2.63** Management information systems (MIS) track and trace medical devices passing through the decontamination process. All operational rooms, training rooms and offices should have enough computer terminal points to make efficient and effective use of an MIS. In addition, the designers and project manager should be aware that considerable advancements are being made in the design of new systems. Emerging systems do not need a manual link-up but can communicate by a wireless system; thus, no cables need to be laid. The merits of available systems need to be assessed before building an SSD.

### Staff rest room

**2.64** An area for preparing hot and cold drinks should be provided in association with the staff rest room. Eating and drinking should be restricted to the dedicated areas only.

### Domestic services

**2.65** High standards of cleanliness are essential in all sections of the SSD. Therefore, a number of domestic services rooms are required so that cleaning equipment used can be segregated to the specific areas of use, thus minimising the risk of contamination from dirty area to clean.

**2.66** Cleaning schedules and protocols should be agreed by the department's manager, cleaning services manager and the consultant microbiologist/infection control team.

### Waste disposal

**2.67** The arrangements for the handling and temporary storage of waste awaiting collection within the SSD should be part of the hospital's waste management programme and should conform to current legislation and guidance. All waste containers that have lids should be foot-operated.

### Materials – procurement and storage

**2.68** Only production materials and those items that are to be processed, or have value added, should be stored or passed through the department.

**2.69** Sufficient stock levels of raw materials are important for a department to operate smoothly. It is essential that enough storage space is provided for these items within the design of the department.

**2.70** Two storage spaces are required within the SSD, namely:

- A store for raw materials.
- A store for processed products.

**2.71** The raw material store contains those items used in the production process. Control of Substances Hazardous to Health Regulations 2002 need to be considered when storing chemicals. The processed goods store should be used as a holding area for items awaiting transport to users who will have their own storage areas.

### Trolleys and transportation

**2.72** A designated area should be provided next to the processed goods store for trolleys and containers used to despatch processed goods. A designated area should be provided next to the wash room for receipt of trolleys/transit containers holding used items. Facilities should be provided for automated decontamination of trolleys and transit containers. Different types of trolley will be used for:

- transporting goods within and between the various areas of the SSD;
- transporting medical devices to and from customers.

**2.73** As different trolleys are required for different functions, the choice of model will rest with the project team and should take into account manual handling issues. Where the customer is some distance from the department, vehicular containership will be required.

**2.74** Trolleys, transport containers, product packaging and vehicular transport design and arrangements should ensure that the condition and sterility of processed goods is not compromised and do not pose a risk of transfer of contamination during transportation.

**2.75** Consideration should be given to the trolley's dimensions when designing the related work area so that adequate space is allocated and to ensure that lifting and handling techniques are not compromised. In addition, where motorised vehicles are used, suitable loading/delivery bays need to be incorporated into the overall design of the department.

**2.76** At the design stage, the project team needs to ensure that a designated area is included – next to the wash area – for the effective cleaning of each collection trolley/container before its re-use as a delivery trolley. Maintenance and repair of trolleys within the SSD is not recommended.

**2.77** Where battery-powered vehicles are used, special consideration should be given to ventilation and other health and safety aspects associated with maintenance and recharging of batteries. The need for garaging facilities should also be considered.

# 3. General functional and design requirements

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## INTRODUCTION

**3.1** This chapter provides design guidance based on the service objectives outlined in Chapter 2. It includes discussion on a range of topics that should be taken into account when designing an SSD.

## WORKFLOW

**3.2** Two classifications of goods will be received at the SSD, namely **contaminated** items and **raw materials**.

**3.3** Design solutions should follow workflow principles, separating clean and dirty product, to avoid creating routes and cross-flows which could potentially recontaminate processed items, or adversely affect the microbiological status of raw materials. [Figures 1 and 2](#) (overleaf) illustrate the workflow.

**3.4** A more detailed explanation of the workflow within the principal spaces is given in [Chapter 4](#).

## CAPACITY PLANNING

**3.5** Service strategies should be assessed as these may have a direct impact on the department's production capacity. This should take account of service developments in the foreseeable future.

**3.6** It is advisable to make capacity provision for extra machinery in the event of increased production demand.

**3.7** The standards set out in this guidance are equally applicable to the upgrade or adaptation of existing buildings. During upgrade work, the production environment should not be compromised.

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

- instrument inventory to suit processing turnaround time;
- transportation facilities;
- staffing issues;
- availability and cost of land;
- service and maintenance issues.

**3.9** Service continuity arrangements and decant costs should be included.

Figure 1 SSD layout: single-door sterilizer configuration

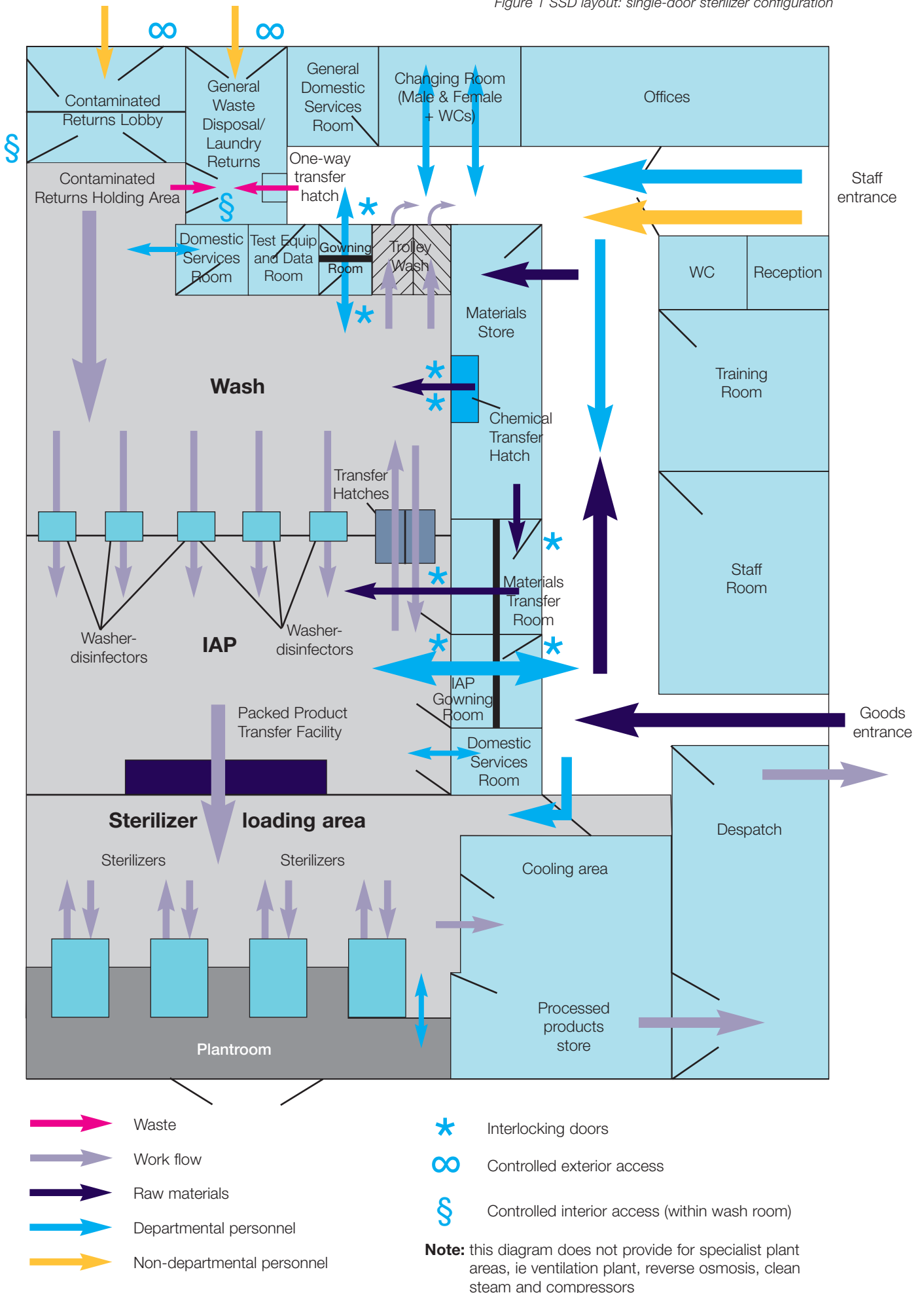
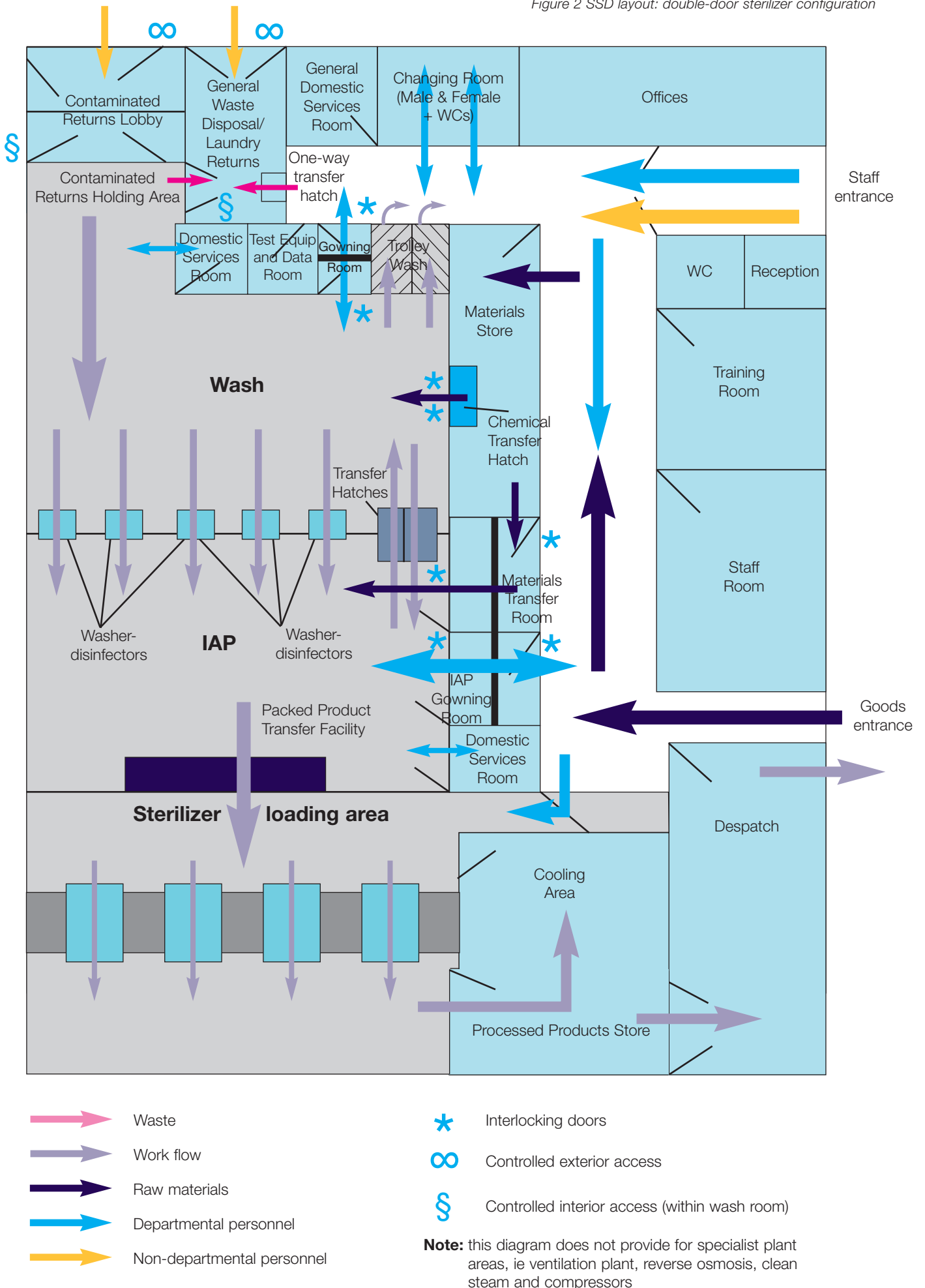


Figure 2 SSD layout: double-door sterilizer configuration



**3.10** Planning and design should include input from relevant experts including those involved in decontamination, engineering, building and design, and service users.

## ENVIRONMENT

**3.11** Good interior design can contribute to staff morale. The aim should be to create an attractive and cheerful environment throughout the department.

### Natural lighting (HTM 55)

**3.12** Natural lighting in the wash room and IAP room makes visual inspection easier and also has a positive effect on staff morale.

**3.13** Windows should also be provided in offices, the staff rest room and the training room. Although desirable in most spaces, it may not be possible to provide natural lighting in all other areas. Where external windows cannot be provided, glazed panels between rooms should be considered. Windows are not desirable in storage areas. Glazed panels can also assist communication, especially where intercom facilities are nearby. [Appendix 1](#) and [paragraphs 3.48 to 3.49](#) give further guidance on the provision of windows.

**3.14** Roof lights are not recommended in the processing and storage areas. If unavoidable, they should be insect-proof and waterproof, be double-glazed and have drainage channels to prevent contaminating goods below.

**3.15** To avoid excessive and undesirable glare and solar gain, the building's orientation should be considered early in the planning stage. Tinted glass, low window heads and blinds can reduce glare. Where provided, blinds should be within double windows to avoid unnecessary ledges on which dust may collect. External screens/louvres may also be used to control solar gain. Curtains are not acceptable in work areas (see also HFN 30: 'Infection control in the built environment').

### Artificial lighting

**3.16** The quality of the lighting is crucial in all aspects of decontamination and should be appropriate for the activity carried out in each operational area. Switching should permit control of lighting in different work areas of large rooms (CIBSE 'Lighting guide: hospitals and health care buildings'). Careful consideration should be given to the colour balance between artificial lighting and daylight, with particular attention to deep plan areas. The aim should be to achieve an equal colour balance across all work areas of the department.

**3.17** Task lighting, including magnification inspection lights, is required where instruments and other items are

inspected and should preferably be adjustable to suit the operative and the task being undertaken. Guidance on where task lighting should be provided can be found in [Appendix 1](#). Light fittings and controls in processing and storage areas should be carefully selected to avoid ledges or crevices where dust can collect.

**3.18** In storage areas, lighting should be good enough to enable labels on stored items to be read easily.

### Ventilation

**3.19** In the SSD, natural ventilation with openable windows is limited to offices and staff rooms. Processing and storage areas will require mechanical ventilation; see [Table 1 in Chapter 4](#). (Additional guidance can also be found in HTM 2025: 'Ventilation in healthcare premises'.)

**3.20** It is essential that there is air-conditioning in the wash room and IAP room.

**3.21** Washer-disinfectors and sterilizers emit considerable heat and humidity; as a result, electronic controls essential for the correct operating of equipment can be affected. Therefore the ventilation should take this into account. Working conditions can become intolerable unless fully insulated machines are selected, all pipework is insulated and extract ventilation is provided that is specific to these machines. To conserve energy and minimise operating costs, heat recovery from ventilation systems should be incorporated where appropriate.

**3.22** Adequate ventilation of all plant rooms/areas is essential.

**3.23** The IAP room is a Class 8 clean-room as defined in BS EN ISO 14644. It should have a nominal 20 air changes per hour with a pressure differential of not less than 10 Pa between it and adjoining rooms. Pressure differential indicators, visible from outside the IAP room, should be provided to enable the pressure differential to be routinely monitored. Should this pressure differential fall below specified limits, an alarm system in the IAP room should indicate this (see also [paragraph 6.49](#)).

### Noise

**3.24** Careful consideration should be given to the choice of building finishes especially in the wash and IAP rooms to achieve sound absorption while meeting cleaning and microbiological requirements (HTM 2045: 'Acoustics').

**3.25** The offices, training room and staff room should be sited away from noisy areas.

## MAINTENANCE

**3.26** Building and engineering maintenance/testing can compromise the integrity of the product or the production environment. Such maintenance and testing cannot be undertaken within the IAP room at times when goods are being produced or processed. Design solutions can and should minimise the effects of these activities.

**3.27** Test and maintenance equipment, tools etc brought into the IAP room should not pose a risk of contamination or compromise the room's environment or the integrity of the items processed in it. Where dedicated equipment is needed for the IAP room, a suitable store accessible only from the IAP room should be provided.

**3.28** Materials and finishes requiring minimal maintenance should be chosen. Building finishes requiring frequent redecoration or which are difficult to clean should be avoided.

**3.29** Locating the plant areas of the department on an outside wall at ground-floor level will help maintenance staff to access these areas easily.

## CLEANING

**3.30** An assessment of the cleaning methods, frequency and equipment required throughout the department should be made before finishes are chosen.

## FINISHES

**3.31** In processing areas, finishes should be suitable for frequent cleaning and tolerant to surface-cleaning agents. Joints should be avoided as they can hold moisture, encouraging the growth of organisms. Worktops, sinks etc should be built up to walls and any gaps sealed. Where gaps are unavoidable, they should be wide enough for easy cleaning. However, to permit easy cleaning and maintenance of the IAP room, it is advisable that workstations and storage units should not be fixed.

**3.32** Ledges trap dust particles and should be avoided. This is particularly important in the IAP room, which requires finishes that are easily cleaned and low in maintenance (see also HFN 30: 'Infection control in the built environment').

**3.33** Finishes of areas where heavily loaded trolleys are in use should provide protection against accidental damage.

### Floors (HTM 61)

**3.34** Throughout the processing areas, stores and circulation spaces, a uniform floor level should be

maintained. The finish, the screed and sub-floor should be suitable for heavy trolley traffic. The flooring should be turned up at walls using an integral coved skirting. This should be:

- a. **continuous with the floor** and
- b. **finished flush with the wall**, so that the junction between the skirting and the wall does not provide a ledge for the collection of dust.

**3.35** The finish should be hard-wearing, non-slip and easy to clean. Floor finishes and design, particularly in the wash room and plant areas, should protect against damage and disfigurement caused by malfunctioning equipment and should facilitate maintenance (see also HFN 30: 'Infection control in the built environment').

**3.36** Doorways between adjoining rooms are points of stress in the floor finish; thus, their design requires particular attention.

**3.37** A soft floor finish is suitable in the offices, staff rest room and training room.

**3.38** Structural expansion joints should be positioned with care to avoid heavily trafficked areas, particularly where trolleys turn corners. They are unacceptable within the IAP room.

## Walls

**3.39** In storage and processing areas in particular, hollow-wall constructions pose an infestation risk and are liable to trolley damage – choice of materials and construction should eliminate these risks. Solid walls should be rendered to a hard smooth finish to withstand heavy treatment and for ease of repair. Epoxy coating or a sprayed paint finish is appropriate in processing areas. These finishes, or emulsion paint, are also appropriate in stores and circulation areas. Spongeable wallpaper or emulsion paint is suitable in staff areas and offices.

**3.40** Where hollow walls, partitioning or boxing is used, consideration should be given to means of access and inspection.

**3.41** Walls should be protected against accidental damage from wheeled traffic by buffer rails and corner guards, which should be appropriately sited to reflect the specifications of trolleys in use.

### Ceilings (HTM 60)

**3.42** Building services are regularly located above suspended ceilings and access to them can pose risks of contamination to the processing environment. Routing of services should eliminate these risks as far as possible.

**3.43** Ceiling design solutions should not allow access to engineering services from the IAP room or rooms accessible from the IAP room. The IAP room ceiling should be to clean-room standard and sealed “to prevent ingress of airborne particles or other contaminants from the ceiling void” (BS EN ISO 14644-4: 2001, E.2.1.2).

**3.44** Ceilings should be resistant to humidity in spaces where steam and moisture may be encountered.

#### **Door sets**

**3.45** Doors should be adequately sized to allow clear passage of equipment. Where door closers are necessary, the type should be carefully considered. Automatic/semi-automatic doors make it easier for collection and distribution trolleys to pass unimpeded and prolong the fabric of the building. Where door interlocks are provided, for example in the IAP room, gowning and materials transfer rooms, the door should open towards the higher pressure side where possible to overcome problems with weakening door closers, which may lead to lock-outs. Doors should be fail-safe to allow emergency exit in the event of fire, or power failure.

**3.46** All emergency exits should have a means of indicating they have been opened.

**3.47** Where trolley movement occurs, protection is essential on all doors and door linings. Vision panels should also be provided in doors that are frequently used. Consideration should be given to fire precautions.

#### **Windows (HTM 55)**

**3.48** Windows in the wash room and IAP room should be non-opening, sealed and flush fitting. Windows should not be installed in storage areas. Openable windows may, however, be considered for offices and staff rooms.

**3.49** Good access, internally and externally, should be provided to all windows to facilitate cleaning.

#### **SECURITY**

**3.50** Consideration should be given to the provision of CCTV and other security measures (MES C56: ‘Internal security systems’; C57: ‘Security of access and control’; C58: ‘Closed circuit television (CCTV) systems’). All entrances should be secure and controlled to prevent unauthorised access.



# 4. Specific functional and design requirements

## INTRODUCTION

**4.1** This chapter describes in greater detail the following individual spaces within an SSD, incorporating operational patterns and, where appropriate, a description of the workflow:

- Entrance areas
- Contaminated returns lobby
- Contaminated returns holding area
- Wash room: gowning room/area
- Wash room
- Wash room: domestic services room
- IAP gowning room
- Inspection, assembly and packing (IAP) room
- IAP domestic services room
- Materials store
- Materials transfer room
- Packed product transfer facility
- Sterilizer loading area
- Sterilizer plant room
- Unloading/cooling area
- Processed products store
- Despatch area
- Manager's office
- Deputy manager's office
- Office(s): general
- Staff room
- Training room
- Staff changing/WC/shower room
- General areas: domestic services room

- General waste disposal/laundry returns
- Test equipment and data room.

**4.2** Engineering, mechanical and environmental specifications for each room are given in [Table 1](#).

**4.3** In the design of the SSD, consideration should be given to the requirements of the Disability Discrimination Act 1995 throughout the facility.

## ENTRANCE AREAS

### Function

**4.4** Access for staff and visitors, the delivery of supplies, the return of contaminated goods and collection of waste.

**4.5** All entrances should be secure and controlled to prevent unauthorised access. A means of communication from entrance points to staff-occupied areas should be considered. Staff and goods entrances should be segregated. Workflow and location of supplies and return of contaminated goods should be considered carefully with regard to minimising the risk of cross-contamination.

**4.6** A visitors' reception area should be incorporated into the staff/visitors' entrance area.

**4.7** An accessible toilet should be available for visitors and staff within the entrance area.

### Other services

**4.8** Other services which should be provided near the staff/visitors' entrance include:

- Fire alarm panel.
- Security access panel.

**4.9** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## CONTAMINATED RETURNS LOBBY

### Function

**4.10** The contaminated returns lobby:

- provides secure and controlled access from outside the department to the contaminated returns lobby only;
- is a receiving area for contaminated return containers/trolleys;
- is the area from which wash-room staff collect goods.

### Location

**4.11** It should:

- have direct access to an exterior corridor/loading bay;
- be next to the contaminated returns holding area of the wash room.

**4.12** Sufficient space should be provided to accommodate the departmental workload and profile, including circulation space for trolleys and containers with demarcation between the two areas.

**4.13** A controlled door access system should be incorporated:

- External doors are operated from outside the department.
- Internal doors are operated from controls within the wash room.

**4.14** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## CONTAMINATED RETURNS HOLDING AREA

### Function

**4.15** The contaminated returns holding area has the following functions:

- Holding area for contaminated returns.
- Houses sufficiently sized designated areas for all locally generated clinical waste, textiles (if appropriate) and any associated waste products from the contaminated returns holding area and the wash room.

### Location

**4.16** It should:

- be adjacent to the contaminated returns lobby;
- be within the wash room;
- have direct access to the general waste disposal room.

**4.17** Operational policies should state that all single-use components and single-use drapes should be disposed of at the point of use.

**4.18** There should be secure and controlled access from the exterior of the department by means of an automated/interlocked door system.

**4.19** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## GOWNING ROOM/AREA (WASH ROOM)

### Function

**4.20** The main functions of this area are to:

- provide controlled entry and exit from the wash room for personnel;
- provide staff with a facility for changing into and out of protective clothing essential for wash-room activities;
- transfer test equipment in and out of the wash room.

### Location

**4.21** The area should have:

- direct access to the wash room;
- direct access from the departmental corridor.

### Key requirements

**4.22** Before entering the wash area, all staff and visitors should don overgarments, that is, dedicated footwear and personal protective equipment (PPE).

**4.23** To facilitate change between the clean and dirty areas, a demarcation barrier (either a step-over or a line demarcation) should be provided. The barrier should be designed to enable wheelchair access.

**4.24** Hand-washing and paper-towel drying facilities should be provided on the corridor side of the gowning room/area. Hands-free taps and soap dispensers should be provided. (See HFN 30: 'Infection control in the built environment', Chapter 4.)

**4.25** Doors should have an interlocking device so that only one can be opened at any one time.

**4.26** Doors should have vision panels.

### Equipment

**4.27** Equipment may include the following:

- footwear storage;
- overgarment hanging facilities;

- PPE storage;
- waste containers;
- mirror;
- wall-mounted paper-towel dispenser;
- hand-wash basin with no plug or overflow (see HFN 30: 'Infection control in the built environment');
- hands-free taps that do not discharge directly into the drain aperture;
- foot-operated waste bins;
- wall-mounted cartridge soap dispenser.

### Mechanical

**4.28** Requirements include:

- hot and cold water;
- drainage.

**4.29** (See Table 1 for recommended environmental, ventilation, lighting and power specifications for this area.)

### WASH ROOM

#### Function

**4.30** The main functions of the wash room are the following:

- Disassembly and preparation of reusable medical devices and associated equipment before cleaning, disinfecting and drying.
- Sorting and loading of medical devices into washer-disinfectors and other cleaning equipment such as ultrasonic cleaners.
- Checking contaminated returns.
- Selective manual cleaning of medical devices and accessories deemed unsuitable for automated cleaning, for example at open sinks.
- Transfer processed items to the IAP room.
- To facilitate validation and routine testing of washer-disinfectors.
- To facilitate maintenance of quality assurance/traceability records.

#### Location

**4.31** The wash room should:

- be adjacent to the IAP room;

- have direct access to wash-room materials transfer hatches;
- have direct access to the contaminated returns lobby;
- have direct access to general waste disposal/laundry returns area;
- have direct access to the wash-room gowning room/area;
- have direct access to the wash-room domestic services room.

### Key requirements

**4.32** All items, including trays and containers, should be cleaned and dried using an automated process. Manufacturers' instructions should be adhered to at all times.

**4.33** Facilities should be provided to manually clean those medical devices deemed unsuitable for automated processing by the manufacturer.

**4.34** A cold-water spray-gun should also be included at a sink position to facilitate the cleaning of instruments with lumens (that is, hollow, tubular instruments). Local screening may be provided at spray-gun points subject to risk assessment. Installation must comply with the Water Supply (Water Fittings) Regulations 1999.

**4.35** Where the lubrication and function-testing of power tools using compressed medical-quality air is undertaken within this area, local extract ventilation shall be provided.

**4.36** Most items will be transferred from the wash room to the IAP room via an automated washer-disinfector, which should be built directly into the separating wall. However, a separate pass-through hatch is needed to transfer manually cleaned items, which cannot be passed through a washer-disinfector for drying. Basket and instrument trays are to be returned to the wash room through a separate hatch. All hatches linking the wash room to the IAP room should be airlocks with inner and outer interlocking doors. Intercoms should be installed between the wash room and the IAP room, adjacent to the hatches.

**4.37** Suitable access should be provided to enable the delivery and removal of equipment.

**4.38** Load-handling equipment, sorting benches, worktops and sink depths should be designed to minimise manual handling and comply with manual-handling legislation and guidance.

**4.39** Proper insulation of washer-disinfectors, and of exposed pipework, can minimise the excessive heat

generated from these machines (see HTM 2030: 'Washer-disinfectors'). Integral insulation will form part of the construction of the equipment as supplied, and the installation should be planned to minimise any exposed pipework.

**4.40** Adequate facilities and clear space need to be provided for servicing, maintenance and cleaning requirements. (For specific information regarding maintenance access, refer to MES C30: 'Washer-disinfectors for surgical instruments'.)

**4.41** A materials-transfer hatch should provide suitable transfer facilities for consumables into the wash room. It should be large enough to be able to transfer only materials and positioned carefully to minimise the risks of manual handling.

**4.42** Several staff will usually be working in the wash room, typically at cleaning/sorting workstations and loading the washer-disinfectors. Cleaning/sorting workstations will comprise stainless-steel inspection layout tables. Stainless-steel storage racking should also be provided. These items should be free-standing for flexibility of layout planning and for ease of cleaning; fixed benching should be kept to a minimum. Mobile load-handling equipment may be used, for instance for loading washer-disinfectors, and adequate space must be planned for holding and manoeuvring such equipment.

**4.43** Staff access to the wash room should be via the wash-room gowning room/area only.

## IT

**4.44** Sufficient computer terminal points need to be installed in the wash room to enable the use of MIS in the tracking and tracing of medical devices passing through the decontamination process.

## Mechanical

**4.45** Consideration should be given to the following:

- minimum spacing between washer-disinfectors;
- cold-water supply for the water spray-gun shall comply with the Water Regulations 1999 with particular reference to the prevention of back-siphonage;
- steam;
- high-quality rinse water (see HTM 2030: 'Washer-disinfectors' and MES C30: 'Washer-disinfectors for surgical instruments');
- hot water (see HTM 2030: 'Washer-disinfectors' and MES C30: 'Washer-disinfectors for surgical instruments');

- cold water (see HTM 2030: 'Washer-disinfectors' and MES C30: 'Washer-disinfectors for surgical instruments');
- medical-grade compressed air for the testing of power tools;
- drainage;
- general room supply and extract ventilation;
- exhaust ventilation required by specific equipment;
- negative pressure in this area;
- access for maintenance and testing of all plant and equipment.

## Equipment

**4.46** The various items of equipment should include:

- thermal washer-disinfectors for surgical instruments and container/trolley washer-disinfectors compliant with HTM 2030: 'Washer-disinfectors' and MES C30: 'Washer-disinfectors for surgical instruments';
- accessories and associated equipment and fittings for washer-disinfectors;
- conveyor systems (these may be required);
- ultrasonic cleaners/irrigators in compliance with HTM 2030;
- accessories and associated equipment for ultrasonic cleaners/irrigators;
- accessories and associated cleaning equipment for specialised medical devices, for example Phaco devices and dental hand-pieces;
- double sink(s) for manual cleaning;
- storage facilities for baskets and associated carriages not in use;
- loading trolleys;
- inspection tables;
- instrument baskets;
- cold-water spray-guns;
- medical devices transfer hatches – return carriages and medical devices from IAP room; manually cleaned items to IAP room;
- materials transfer hatch – detergents, raw materials etc to wash room from materials store;
- storage facilities for wash-room consumables, for example detergents, cleaning brushes etc;

- eye-wash station.

**4.47** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

### DOMESTIC SERVICES ROOM (WASH-ROOM AREA)

#### Function

**4.48** This room is for storing domestic equipment and supplies used for cleaning the wash room, the contaminated returns holding area and contaminated returns lobby.

#### Location

**4.49** This room has direct access to the wash room.

#### Key requirements

**4.50** This room supports:

- the domestic cleaning activities within the wash room environment;
- the storage of domestic cleaning equipment;
- the disposal of waste cleaning materials.

**4.51** Shelving and vertical storage required to hold a limited amount of cleaning materials and supplies should not encroach on the working space, and it should be easily cleaned.

#### Equipment

**4.52** Equipment should include the following:

- low-level bucket sink;
- hand-wash basin;
- wall-mounted cartridge soap dispenser;
- wall-mounted paper-towel dispenser;
- stainless sink and drainer;
- equipment storage/hanging facilities.

#### Mechanical

**4.53** Requirements include:

- hot and cold water;
- drainage.

**4.54** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

### GOWNING ROOM (FOR THE IAP ROOM)

#### Function

**4.55** The main functions of this area are to:

- provide controlled entry to, or exit from, the IAP room for all personnel;
- provide a facility for changing into, and out of, overgarments and footwear;
- facilitate hand-washing before entering the IAP room.

#### Location

**4.56** The IAP gowning room has:

- direct access to the IAP room;
- direct access to the departmental corridor.

#### Key requirements

**4.57** Before entering the IAP room, all staff and visitors should don overgarments and dedicated footwear.

**4.58** To facilitate change between the clean and dirty areas, a demarcation barrier should be provided. The barrier should be designed to enable wheelchair access.

**4.59** Hand-washing and paper-towel drying facilities should be provided on the IAP room side of the demarcation barrier.

**4.60** Hands-free taps and soap dispensers should be provided.

**4.61** This room will provide controlled access to the IAP room.

**4.62** Doors should have an interlocking device so that only one can be opened at any time and the doors should open towards the higher pressure IAP-room side to overcome problems with weakening door closers, which cause lock-out and hamper staff movement.

**4.63** Doors should have vision panels.

#### Finishes

**4.64** Finishes to ceilings, walls, floors, doors and fixtures should be to standards that allow ease of cleaning as described in [paragraphs 3.31–3.33](#).

#### Equipment

**4.65** Main items include:

- footwear and overgarment storage;
- foot operated waste containers;
- mirror;

- wall-mounted paper-towel dispenser;
- hand-wash basin with no plug or overflow;
- hands-free taps that do not discharge directly into the drain aperture;
- wall-mounted cartridge soap dispenser.

### Mechanical

**4.66** Mechanical supply and extract ventilation systems, balanced flap dampers etc should be provided such that the IAP gowning room is maintained at a relative air pressure intermediate between that of the IAP room and that of adjacent access corridors.

**4.67** Other requirements are:

- hot and cold water;
- drainage.

**4.68** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## INSPECTION, ASSEMBLY AND PACKING (IAP) ROOM

### Function

**4.69** The IAP room's main functions are:

- Inspecting, function testing, assembling and packing cleaned and disinfected medical devices and raw materials in preparation for sterilization.
- Transferring packaged goods to the packed products transfer facility.
- Maintenance of quality assurance/traceability records.

### Location

**4.70** The IAP room:

- has direct access from the IAP gowning room;
- has direct access to the IAP domestic services room and IAP materials transfer room;
- is adjacent to both the wash room and to the sterilizer loading area with airlock transfer facilities to each;
- should not provide access to any other area.

### Key requirements

**4.71** The IAP room is a controlled environment. As such, it should be mechanically ventilated with filtered air to the standard as defined for a Class 8 clean-room (BS EN ISO 14644-1). The positive air pressure differential

should be maintained above that of surrounding areas. Indicators and alarm systems should be provided to alert staff to any failure of the ventilation system (see [paragraphs 3.23](#), and [6.49–6.54](#)).

**4.72** The room should provide a comfortable working environment; full air-conditioning should therefore be installed. Humidification will be required to avoid dehydration and subsequent processing problems associated with absorbent materials.

**4.73** Washed and disinfected reprocessed goods received from the wash room, together with raw materials from the materials transfer room, will be inspected, assembled and then packed for sterilization. For sterile products, it is essential that adventitious contamination be minimised by all practicable means. Workflow should accommodate the following principal activities:

- inspecting, assembling, function testing, packing and labelling of discharged items from the wash room together with other materials from the materials store and manually cleaned items from the wash-room transfer hatch;
- discharging items to the sterilizer loading area; and
- returning wash containers and carriers to the wash room.

**4.74** The room should be sufficiently sized and suitably arranged to accommodate enough workstations for the smooth running and flexibility of the workflow.

**4.75** Inspection, assembly, function testing, packing and labelling work will mainly take place on stainless-steel tables. Stainless-steel storage racking should also be provided in the IAP room together with hangers used for holding fabric and paper-wrapping sheets. These items should be free-standing for flexibility of layout planning and cleaning; fixed benching should be kept to a minimum.

**4.76** Standardised, mobile load-handling equipment may be used, for example when unloading through-wall washer-disinfectors; thus, adequate space must be planned for parking and manoeuvring such equipment.

**4.77** Suitable access should be provided to enable the delivery and removal of equipment such as workstation tables, trolleys, racks and mobile load-handling equipment.

**4.78** The amount of equipment used in this room should be minimised to achieve the desired output. This may include a workstation for paperwork which needs to be completed in the IAP room; however, it is not recommended that any other administrative activities are carried out in this room.

**4.79** The inclusion of an office opening off the IAP room is not recommended.

**4.80** Equipment and shelving used in this area should be free-standing, mobile and easily cleaned.

**4.81** High-quality lighting is essential at workstations where items are individually checked for cleanliness and defects. This will need to be supplemented by task lighting which may include local magnification.

**4.82** Where the lubrication and function-testing of power tools using compressed medical quality air is carried out, it should be performed within a specialist cabinet to ensure the integrity of the environment is not compromised.

**4.83** Production materials, for example raw materials, should be kept to a minimum level to avoid adventitious contamination; ideally they should be used within 24 hours.

**4.84** Packs for sterilization will be transferred to the sterilizer loading area via the packed-goods transfer facility.

**4.85** A demarcation area within the IAP room should be provided to segregate non-conforming products.

**4.86** There should be vision panels in doors and walls.

**4.87** All wet processes, including hand-washing, should take place outside the IAP room.

### Finishes

**4.88** Finishes to ceilings, walls, floors, doors and fixtures should be to standards that allow ease of cleaning as described in [paragraphs 3.31–3.33](#).

### IT

**4.89** There should be enough computer terminal points suitably positioned to facilitate the use of the MIS in the tracking and tracing of products passing through the decontamination process.

### Mechanical

**4.90** Hot and cold water supply, drainage manholes and fire-hose reels are not appropriate in the IAP room. Service-maintenance access points should be planned out of this area as noted in [paragraphs 3.42 and 3.43](#). (See also IAP room “Key requirements” at [paragraphs 4.71–4.87](#).)

### Equipment

**4.91** Various items of equipment may include:

- illuminated magnifier(s);
- heat sealer(s);

- video microscope(s);
- mobile, height-adjustable workstations;
- mobile trolleys;
- mobile storage racks/shelves;
- mobile, height-adjustable chairs/stools;
- IT terminals and printer(s) and associated sundry items;
- tape dispensers;
- specialist cabinet for product lubrication and air testing (if required);
- ventilation system status indicators/alarm;
- additional equipment to assist work practices.

### Other services

**4.92** Medical grade compressed air (if required).

**4.93** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## IAP DOMESTIC SERVICES ROOM

### Function

**4.94** This room is for storing domestic equipment and supplies dedicated for cleaning the IAP room.

### Location

**4.95** It has direct access from the IAP room.

### Key requirements

**4.96** This room supports the domestic cleaning activities within the IAP environment, and on the IAP room side of the gowning room, materials transfer room and packed products transfer facility. This room is a controlled environment and shares the same clean-room classification as the IAP room, that is Class 8.

**4.97** Domestic equipment will be stored in this room.

**Note: The use of floor-scrubbing equipment is not appropriate for this area.**

**4.98** If vacuum cleaners are to be used in this area, they need to be supplied with high efficiency particulate air (HEPA) filters. A departmental, piped vacuum-cleaning system may be an appropriate solution.

**4.99** The supplies required in the IAP domestic services room should be delivered from the materials store via the materials transfer room.

**4.100** Shelving and vertical storage required to hold a limited amount of cleaning materials and supplies should not encroach on the working space, and it should be easily cleaned.

### Finishes

**4.101** Finishes to ceilings, walls, floors, doors and fixtures should be to standards that allow ease of cleaning as described in [paragraphs 3.31–3.33](#).

### Equipment

**4.102** Consideration should be given to providing the following:

- low-level bucket sinks;
- hand-wash basin;
- soap dispenser;
- hand-towel dispenser;
- stainless sink and drainer;
- equipment storage/hanging facilities.

### Mechanical

**4.103** Requirements include:

- hot and cold water;
- drainage.

**4.104** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## MATERIALS TRANSFER ROOM

### Function

**4.105** This room is used to:

- transfer raw materials from the material store to the IAP room;
- provide an air-lock between the IAP room and surrounding area;
- remove waste from the IAP room.

### Location

**4.106** The room adjoins:

- the IAP room;
- (ideally) the materials store.

### Key requirements

**4.107** Materials components for trays and packs such as tray wraps, swabs, textiles etc are delivered from the raw materials store to the IAP room via the materials transfer room.

**4.108** All exterior packaging should be removed from the items immediately before transfer.

**4.109** It is not appropriate to use this room/facility as a storage area.

**4.110** A transfer barrier should be constructed in such a way as to prevent staff and trolleys passing from one side to the other. For example, shelving or a counter top may accomplish this.

**4.111** The materials transfer room should have interlocking doors, whereby only one door can be opened at any time; the doors should open towards the higher pressure IAP-room side to overcome problems with weakening door closers, which cause lock-out and hamper staff movement.

### Finishes

**4.112** Finishes to ceilings, walls, floors, doors and fixtures should be to standards that allow ease of cleaning as described in [paragraphs 3.31–3.33](#).

### Equipment

**4.113** A transfer barrier should be included.

**4.114** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## PACKED PRODUCT TRANSFER FACILITY

### Function

**4.115** The packed product transfer facility:

- is used for transferring packed products from the IAP room to the sterilizer loading area;
- prevents passage of personnel and trolleys between the two areas;
- should maintain the integrity of the IAP room environment.

### Location

**4.116** The facility adjoins:

- the IAP room; and
- the sterilizer loading area.



### Key requirements

**4.117** Packaged products are passed from IAP room to the sterilizer loading area via the packed product transfer facility.

**4.118** The packed product transfer facility should have interlocking doors with vision panels. Doors should have an interlocking device so that only one can be opened at any time and the doors should open towards the higher pressure IAP-room side to overcome problems with weakening door closers, which may cause lock-out and hamper staff movement.

**4.119** (See Table 1 for recommended environmental, ventilation, lighting and power specifications for this area.)

### STERILIZER LOADING AREA

#### Function

**4.120** The various functions of this room include the following:

- To receive packaged products before sterilization.
- To provide a holding area for loaded and empty carriages/trolleys.
- For loading sterilizers.
- For unloading sterilizers where single-door sterilizers are in use.
- To facilitate validation and routine testing and maintenance of sterilizers.
- To facilitate maintenance of quality assurance/traceability records.
- For the labelling of sterilized packs for sterilization and product release.

**Note:** for double-door sterilizers, for which a separate unloading area will be required, the same requirements will apply.

#### Location

**4.121** This area will have:

- direct access to the cooling area where single-door sterilizers are in use;
- direct access to the packaged products transfer facility; and
- direct access to the sterilizers and sterilizer plant room.

### Key requirements

**4.122** Packed products will be received from the IAP room via the packaged product transfer facility for loading into sterilizers on designated carriages. Enough space should be provided for the storage and movement of sterilizer loading trolleys and carriages. Where single-door sterilizers are used, products waiting to be sterilized should be segregated from those that have been processed.

**4.123** There should be a facility to maintain quality assurance records, including those that permit traceability of products to the sterilization process cycle, final release of the product and current log-books.

**4.124** Facilities should enable terminally disinfected items, or those requiring a sterilization process other than high-pressure steam, to be identified and segregated to prevent improper processing.

**4.125** A designated area is needed to segregate and hold (a) any item that is visibly defective following sterilization and (b) the contents of a "failed" processing cycle until consideration can be given to its disposition.

**4.126** A storage facility should be provided for PPE used in this area, for example heat-resistant gloves. Space should also be provided for the storage of sterilizer test materials.

### Sterilizer installation

**4.127** The detailed design, supply and installation of the sterilizers and of supporting equipment within the sterilizer plant room will be carried out by specialist suppliers/subcontractors. Typically, several double-ended or single-door sterilizers will be installed together in a bank or row with the sterilizer plant room behind.

**4.128** For maintenance purposes, easy direct access is needed between the front of the sterilizers in the loading/unloading area and the sterilizer plant room in the case of single-door units; for double-door machines, access to the plant room will be from the discharge side of the machine.

**4.129** A common and convenient arrangement is for a large structural opening to be left for the installation of the sterilizers. This approach allows greater flexibility for future change and reduces the extent of co-ordination and sealing needed.

### Mechanical

**4.130** Considerable heat loads may be generated by sterilizers. Additional heat and humid air are released when the sterilizer doors are opened for unloading. Sterilizer suppliers should be consulted at an early stage in the design of the SSD ventilation system and plant.

Planned frequency of use of the sterilizers should be estimated by the project team, so that local supply and extract ventilation systems, including comfort cooling if necessary, can be specified accordingly.

## IT

**4.131** Data points are needed for traceability, sterilizer cycle records and quality assurance records (product and process records).

## Communications

**4.132** For the sterilizer loading area, the following communications equipment may be needed:

- telephone/voice communication system;
- public address system;
- IT terminal, writing surface and hand-held data code readers.

**4.133** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## STERILIZER PLANTROOM

### Function

**4.134** The sterilizer plantroom is used for the following:

- Accommodating sterilizers and associated plant (which may include clean steam generation and high-quality water generation equipment).
- Maintenance and repair of sterilizers.
- Validation and routine testing of sterilizers.
- Sampling facilities for steam and water quality.

### Location

**4.135** Consideration should be given to the following:

- It should be adjacent to the sterilizer loading area.
- It should be located to provide for ease of installation and removal of equipment.
- It should have a secure door (or doors) for authorised access – one door giving access to the sterilizer loading area. Ideally, direct access, or access via an adjacent general plantroom, should be provided to a double external door, large enough for the removal or delivery of sterilizers.

### Key requirements

**4.136** Adequate space for maintenance and periodic testing is essential. Manufacturers' recommendations should be followed with regard to the access space

required. As an indication at early planning stages, sufficient space should be allowed around each sterilizer and other items of plant to facilitate ease of maintenance and installation without interruption to production.

**4.137** The area should include maintenance workbenches with engineering vices, stainless steel sinks and a hand-wash basin.

**4.138** A writing area and secure cupboard should be provided for maintenance record-keeping.

### Equipment

**4.139** The room will include sterilizers together with associated plant and equipment.

### Mechanical

**4.140** Even with the most practicable extent of insulation to the sterilizers and to incoming steam mains, considerable heat will be generated in the sterilizer plantroom. Local supply and extract ventilation systems, including comfort-cooling if necessary, will be required.

**4.141** Careful consideration should be given to incorporating thermal insulation within the construction of the walls, doors and ceilings between the plantroom and surrounding rooms.

**4.142** Where double-door sterilizers are used, provision of sufficient sound insulation should be considered.

### Other services

**4.143** Steam, in accordance with HTM 2031: 'Clean steam for sterilization', and condensate, hot and cold water, compressed air, power, drainage, general supply and extract ventilation.

**4.144** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## UNLOADING/COOLING AREA

### General arrangement

**4.145** Where single-door sterilizers are installed, the sterilizers will be both loaded and unloaded in the same area.

**4.146** In the case of double-door sterilizers, the unloading area is separate from the loading area.

**4.147** For either arrangement, there should be a separate cooling area to that of the general unloading area.

### Function

**4.148** This room is used for:

- the cooling of instrument trays, packs and supplementary items following sterilization; and
- product release.

### Location

**4.149** It will have direct access:

- from the sterilizer loading area; and
- to the processed products store and despatch area.

### Key requirements

**4.150** Space is required for the number of trolleys/carriages expected to be held at any one time until they have been cooled and inspected. This may be achieved by:

- retaining loaded carriers on sterilizer loading trolleys;
- by transferring and parking the loaded carriers onto fixed rails provided on a purpose-built parking bay;
- space should allow the trolleys to be manoeuvred without difficulty;
- sterilizer loading trolleys may be used after cooling to transport loaded carriages to the processed products store.

### IT

**4.151** There should be data points for traceability.

### Communications

**4.152** The following should be considered for inclusion:

- telephone/voice communication system;
- public address system;
- distribution and control equipment;
- IT terminal, writing surface and hand-held data code readers;
- current log book storage.

**4.153** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## PROCESSED PRODUCTS STORE

### Function

**4.154** This room is used for the short-term storage of processed products released for distribution.

### Location

**4.155** It will have direct access:

- from the cooling area;
- to the despatch area.

### Key requirements

**4.156** Shelving shall facilitate storage of products and ensure first-in, first-out stock rotation. Shelving or racking systems should have smooth surfaces to prevent damage to products, and should be movable, flexible and easily cleaned.

**4.157** The large proportion of processed products will typically comprise wrapped trays of surgical instruments intended for specific clinical procedures in operating theatres or elsewhere. Appropriately sized and spaced shelving should be provided to allow good circulation of air and prevent damage to products.

**4.158** Space should be provided between shelving and racking to allow trolleys to be manoeuvred without difficulty.

**4.159** Adequate space is required between the lowest storage shelving and the floor to facilitate floor cleaning and to prevent infestation. The storage environment should not compromise the condition and integrity of the product.

### Equipment

**4.160** Items for consideration include:

- storage systems; and
- trolleys.

**4.161** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## DESPATCH AREA

### Function

**4.162** The following are the main functions of this area:

- Assembling batches of processed products for distribution.
- Loading of transportation containers and trolleys.
- Parking decontaminated distribution trolleys and transport containers to be loaded with products for despatch.
- Receipt of decontaminated trolleys and containers.

## Location

**4.163** It will have direct access:

- from the processed products store.
- to internal SSD corridors or external distribution networks (corridors, roads etc).

## Arrangement

**4.164** Where loaded trolleys or carriages are to be despatched by vehicle or tug to off-site customers or to remote on-site users, an external lobby should be provided in which pre-loaded trolleys/carriages may be held. The lobby will require double inner and outer doors, which may be automatic. The provision of a canopy and vehicle loading bay should be considered.

## Key requirements

**4.165** Space is required for the number of trolleys expected to be held at any one time and should allow the trolleys to be manoeuvred without difficulty. At the design stage, project teams should decide the nature, size and numbers of trolleys or other containers to be used, based on predicted workload/throughput.

**4.166** This area should be secure and controlled to prevent unauthorised access.

**4.167** Sufficient space is required to incorporate the administrative function of despatch of products.

**4.168** Maintenance of quality control records should be taken into account.

## Equipment

**4.169** Items for inclusion comprise:

- filing cabinet;
- desk;
- computer terminal;
- data point;
- telephone;
- chair; and
- work bench.

**4.170** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## MATERIALS STORE

### Function

**4.171** The materials store has the following functions:

- Receiving and storing of raw materials and consumables (for example, production materials and wraps) used in the manufacturing process. The raw materials and consumables predominantly comprise: paper, used to wrap trays of instruments; detergents; PPE; and single-use raw materials.
- Distribution of goods to process areas.
- Facilitating the disposal of unwanted packaging.

### Location

**4.172** It should:

- ideally adjoin the materials transfer room; and
- have direct access to internal SSD corridors or external distribution networks (for example, hospital corridors/site roads).

### Key requirements

**4.173** The area should be large enough to receive deliveries of cartons and pallets.

**4.174** The size of the materials store will depend on the needs of the department and on local supplies distribution/storage policy.

**4.175** Shelving should facilitate storage of goods, first-in, first-out stock rotation and good manual handling and ergonomic principles.

**4.176** Shelving or racking should be provided for the storage of a variety of packaged incoming goods of different shapes and sizes, for example packs of sheet paper; paper or plastics rolls; boxed small instruments; and boxed swabs.

**4.177** Shelving or racking systems should have smooth surfaces to prevent damage to products, and should be movable, flexible and easily cleaned. As an indication, racking arranged five-to-six shelves high, with each shelf 400–450 mm deep, will provide appropriate storage for most items held in the materials store. In addition, some specialised storage will be required for tubular items and large flat packs of, for example, paper sheets.

**4.178** Space should be provided between shelving and racking to allow trolleys to be manoeuvred without difficulty.

**4.179** Adequate space is required between the lowest storage shelving and the floor to facilitate floor cleaning and to prevent infestation. The storage environment should not compromise the condition and integrity of the product.

**4.180** Provision should be made for segregation of incompatible goods. Provision should also be made for

products with special handling/storage requirements (for example chemical detergents).

**4.181** Provision should be made for receipt, quarantine, inspection and acceptance of materials.

**4.182** It should provide a secure area for rejected materials. Secure storage for holding stocks of surgical instruments not yet in use should also be provided.

**4.183** An appropriate area within the store should be designated to administrative duties (for example, receiving and signing for incoming goods, and checking current stock). A small worktop or counter should be a suitable workstation.

**4.184** Hand-washing and drying facilities should be provided and situated to prevent water contamination of the materials.

### Equipment

**4.185** Items for inclusion comprise:

- storage systems;
- trolleys;
- materials handling equipment;
- hand-wash basin;
- soap dispenser;
- wall-mounted paper towel holder;
- waste containers;
- filing cabinet, desk, chair and work bench;
- telephone point;
- computer terminal for stockholding management.

**4.186** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## OFFICES

**4.187** The department will require a number of offices to meet the needs of the organisational structure and size of the unit. As a minimum, this should include separate offices for the manager and deputy in addition to general office space.

### MANAGER'S OFFICE

#### Function

**4.188** The manager's office provides an appropriate environment to undertake managerial duties.

#### Location

**4.189** It should be:

- accessible to visitors and SSD personnel;
- close to administrative offices.

#### Key requirements

**4.190** The essential features are:

- privacy;
- space for small meetings;
- security of contents.

#### Communications

**4.191** Items for inclusion comprise a telephone and intercom/PA system.

#### Equipment

**4.192** Main considerations are:

- IT terminal;
- office furniture.

**4.193** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## DEPUTY MANAGER'S OFFICE

#### Function

**4.194** This room provides an appropriate environment to undertake managerial duties.

#### Location

**4.195** It should be close to:

- production areas; and
- administrative offices.

#### Key requirements

**4.196** The essential features are:

- privacy;
- seating space for visitors;
- security of contents.

#### Communications

**4.197** Items for inclusion comprise a telephone and intercom/PA system.

## Equipment

**4.198** Main considerations are:

- IT terminal;
- office furniture.

**4.199** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## OFFICE(S): GENERAL

### Function

**4.200** In general, the offices' main functions are the following:

- Administrative and clerical office space in support of the department's activities.
- Quality assurance.

### Location

**4.201** The general office should be located within the department, close to the visitors' entrance.

### Key requirements

**4.202** This space may be configured as one or more offices depending on the number of staff and the functions being undertaken.

**4.203** Sufficient space should be provided to carry out the following activities, taking into account local arrangements:–

- control and retention of records;
- traceability operating system;
- financial management;
- processing of production documentation and data;
- processing of personnel documentation and data;
- purchasing and stock management.

**4.204** The general office space should be:

- the main control point for contact and access to the department;
- close to the manager's office;
- adjacent to the main entrance of the department.

**4.205** Quality assurance administration may be sited in the general office space or in separate office accommodation elsewhere in the department.

## IT

**4.206** There should be enough:

- computer terminal points suitably positioned to facilitate the use of the MIS in the tracking and tracing of products passing through the decontamination process;
- data points to provide external and internal IT communications;
- space to house the necessary number of computer servers and network hubs. (Depending on the size and configuration of the SSD, a separate, dedicated server room may be needed if there is not enough room in the general offices.)

## Communications

**4.207** Items for inclusion comprise a telephone, fax, intercom, CCTV and access control.

## Equipment

**4.208** Equipment will include the following:

- photocopier;
- computer workstations;
- desks;
- shelving.

**4.209** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## STAFF ROOM

### Function

**4.210** This room is used for the following:

- the preparation and consumption of drinks and snacks; and
- staff breaks.

### Location

**4.211** It should have

- convenient access to the training room;
- ease of access from the entrance and to the work areas;
- ease of access to staff-changing facilities.

### Key requirements

**4.212** If staff breaks are staggered, the size of the room and facilities provided may be calculated to serve the needs of 60 per cent of the maximum number of staff on duty at one time.

**4.213** A preparation area, washing-up facilities, hand-wash basin and appropriate seating will be required.

**4.214** Equipment/appliances should be supplied to enable staff to prepare light meals and drinks.

**4.215** The seating area should be furnished with easy chairs.

### Communications

**4.216** Items for inclusion comprise a telephone/voice communication system and TV sockets.

### Equipment

**4.217** Items may include the following:

- refrigerator;
- microwave oven;
- toaster;
- water cooler;
- hot-water boiler;
- easy chairs;
- tables;
- storage cupboards;
- sink and drainer;
- hand-wash basin
- hand-towel dispenser;
- foot-operated waste bin;
- soap dispenser.

**4.218** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## STAFF CHANGING/WC/SHOWER ROOM

### Function

**4.219** This facility has the following functions:

- For changing clothing.
- Security for personal valuables.

- Providing use of WC and shower.
- For grooming and hand-washing.

### Location

**4.220** It should provide ease of access to work areas.

### Key requirements

**4.221** Full separate changing facilities for male and female staff are required with individual lockers for all full-time and part-time members of staff and visitors. The following should also be provided:

- segregated shower areas affording privacy;
- WCs, hand-wash basins and wall mirrors;
- a WC and shower suitable for use by a disabled person.

### Equipment

**4.222** The following items may be included:

- lockers;
- seating;
- shoe racks;
- hand-wash basin;
- hand-towel dispensers;
- soap dispenser;
- coat rack;
- mirrors;
- hair dryer;
- toilet-roll holders;
- laundry bag holders;
- foot-operated waste bin;
- towel rails;
- storage for staff uniforms.

**4.223** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## TRAINING ROOM

### Function

**4.224** This room may be used:

- for discussion and training;

- for reading and study;
- for meetings; and
- as the departmental library.

### Location

**4.225** The room should:

- be within the administration area of the department; but
- not adjacent to plant rooms or noisy areas.

### Key requirements

**4.226** The training room provides a quiet environment for staff training and development and should be large enough to accommodate all departmental staff.

**4.227** Fittings and furniture should permit flexible arrangement of the seating layout, which can be easily altered.

**4.228** Sufficient visual aids and computer terminal points need to be installed for the use of staff who are undertaking competence training and associated study.

### Communications

**4.229** Items for inclusion may comprise voice and telephone communications, a PA system, and an induction loop system.

### Equipment

**4.230** The following should be considered:

- computer and printer;
- visual and lecturing aids;
- tables and chairs;
- bookcases and shelving;
- computer desks;
- secure storage.

**4.231** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## GENERAL AREAS: DOMESTIC SERVICES AREA

### Function

**4.232** This area is for storing domestic cleaning equipment and supplies.

### Location

**4.233** It should be located within the department with ease of access to areas serviced.

### Key requirements

**4.234** This room supports the domestic cleaning activities for the general areas of the department excluding the IAP room and the wash room:

- Disposal of liquid waste.
- Storage for cleaning equipment and chemicals.
- Hand-washing and drying facilities.
- Facilities for keeping cleaning records.

### Equipment

**4.235** Consideration should be given to the following:

- low-level bucket sink;
- hand-wash basin;
- wall-mounted hand-towel dispenser;
- wall-mounted cartridge soap dispenser;
- foot-operated waste containers;
- stainless steel sink and drainer;
- equipment storage/hanging facilities.

**4.236** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## GENERAL WASTE DISPOSAL/LAUNDRY RETURNS

**4.237** Depending on the design and size of the unit, it may be necessary to provide an independent secure area in addition to the wash room for storage of clinical waste awaiting collection. This should be in accordance with local waste management policy.

### Function

**4.238** This area is used:

- for holding departmental clinical waste for collection and disposal;
- as a holding area for reusable textiles for laundering; and
- for holding all non-clinical waste for collection and disposal.



### Location

**4.239** It should have ease of access:

- to the hospital corridor/loading bay;
- from the contaminated returns holding area;
- from the departmental corridor.

### Key requirements

**4.240** There is a risk of fire from stored material. Design considerations should take this into account.

**4.241** The size and location of the disposal area will depend on the local policy for clinical waste, domestic waste and laundry collection, particularly the frequency of collections.

**4.242** There should be provision for traceability of clinical waste in accordance with local policy.

**4.243** The room layout should be compatible with site recycling/reuse/disposal policy.

**4.244** Returnable empties that may include detergent containers and, if used, delivery pallets will be held here to await collection.

**4.245** This area needs to be secure and access controlled. Internal access for personnel to the general waste disposal room is controlled from the contaminated returns holding area.

### Equipment

**4.246** The following should be considered for inclusion:

- containers in accordance with local policy; and
- access hatch/flap from the departmental corridor for loading waste through.

**4.247** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

## TEST EQUIPMENT AND DATA ROOM

### Function

**4.248** The test equipment and data room provides an appropriate environment to support the testing and verification of the department's decontamination equipment.

### Location

**4.249** It should be close to:

- production areas; and
- administrative offices.

### Key requirements

**4.250** The following are considered essential features:

- Security of contents.
- Storage of validation records.
- Storage of routine testing records.
- Storage of archived maintenance records.
- Storage of test equipment.
- Storage of equipment maintenance manuals.
- Analysis of data.
- Preparation of test reports.

### Communications

**4.251** There should be a means of communication to all areas of the department and external areas.

### Equipment

**4.252** Items should include the following:

- IT terminal;
- office furniture;
- hand-wash basin;
- foot-operated waste container;
- sink drainer;
- laboratory refrigerator/freezer for storage of test soils and residual protein test products;
- oven set at 110°C ( $\pm$  2°C) (optional);
- storage cupboards;
- work tops;
- shelving.

### Mechanical

**4.253** Requirements include:

- hot and cold water;
- drainage.

**4.254** (See [Table 1](#) for recommended environmental, ventilation, lighting and power specifications for this area.)

TABLE 1: RECOMMENDED ENVIRONMENTAL SPECIFICATIONS AND DESIGN OPTIONS FOR VOICE AND DATA COMMUNICATIONS

| Location rooms                 | Environmental specification |                       |           | Clean room class. | Ventilation <sup>a</sup><br>+/- with respect to (wrt)        | Lighting <sup>b</sup> |                |    | Power (IP) | IT              | Comms                                   | Optional telephone points |
|--------------------------------|-----------------------------|-----------------------|-----------|-------------------|--|-----------------------|----------------|----|------------|-----------------|---|---------------------------|
|                                | Temperature range (°C)      | Relative humidity (%) | Air-cond. |                   |  | Lux                   | Pos.           | IP |            |                 |   |                           |
| Entrance areas                 | 16–24                       | –                     | –         | –                 | (–)ve wrt all areas  | 200                   | Floor          | –  | –          | –               | To office                               | ✓                         |
| Contaminated returns           | 16–19                       | –                     | –         | –                 | (+)ve wrt all other areas<br>(–)ve wrt Wash room             | 300                   | Bench          | 54 | 55         | Tracking system | –                                       | ✓                         |
| Gowning room/area (wash room)  | 16–21                       | –                     | –         | –                 | Not (+)ve wrt surrounding areas                              | 300                   | Floor          | –  | –          | –               | ✓                                       | ✓                         |
| Wash room                      | 16–21                       | 30–60                 | ✓         | –                 | Not (+)ve wrt surrounding areas                              | 500<br>300            | Bench<br>Floor | 54 | 55         | See para 4.44   | Voice communication system              | ✓                         |
| Domestic services (wash room)  | 16–19                       | –                     | –         | –                 | (–)ve wrt surrounding areas                                  | 100                   | Bench          | –  | –          | –               | –                                       | –                         |
| Gowning room (IAP room)        | 16–21                       | –                     | –         | –                 | (–)ve wrt IAP<br>(+)ve wrt all other areas                   | 300                   | Floor          | –  | –          | –               | ✓                                       | –                         |
| IAP room                       | 16–21                       | 40–60                 | ✓         | 8                 | (+)ve wrt all  | 500<br>300            | Bench<br>Floor | 44 | 44         | See para 4.89   | Voice communication system              | ✓                         |
| Domestic services (IAP room)   | 16–21                       | –                     | –         | 8                 | (–)ve wrt IAP  | 100                   | Bench          | 54 | 55         | –               | –                                       | –                         |
| Materials transfer room        | 16–21                       | 30–60                 | ✓         | –                 | (+)ve wrt all other areas<br>(–)ve wrt IAP                   | 300                   | Floor          | 54 | 55         | ✓               | ✓                                       | ✓                         |
| Sterilizer loading area        | 16–21                       | 30–60                 | ✓         | –                 | (+)ve wrt plantroom and other areas<br>(–)ve wrt IAP         | 300                   | Bench          | 54 | 55         | See para 4.131  | See para 4.132                          | ✓                         |
| Sterilizer plantroom           | <30                         | –                     | –         | –                 | (–)ve wrt other areas  | 300                   | Floor          | 56 | 56         | ✓               | ✓                                       | ✓                         |
| Unloading/cooling area         | 16–21                       | 30–60                 | ✓         | –                 | (–)ve wrt sterilizer unloading <sup>c</sup><br>(+)ve wrt PPS | 300                   | Floor          | 54 | 55         | See para 4.151  | See para 4.152                          | ✓                         |
| Processed products store (PPS) | 16–21                       | 30–60                 | ✓         | –                 | (–)ve wrt cooling<br>(+)ve wrt despatch                      | 300                   | Floor          | –  | –          | Data point      | ✓                                       | ✓                         |
| Despatch area                  | 16–21                       | –                     | –         | –                 | (–)ve wrt processed products store                           | 200                   | Floor          | –  | –          | Data point      | Comm for access control                 | ✓                         |
| Materials store                | 16–21                       | 30–60                 | ✓         | –                 | (+)ve wrt other areas  | 500/300               | Bench<br>Floor | –  | –          | Data point      | To offices, staffed areas and suppliers | ✓                         |
| Manager's office               | 16–21                       | –                     | –         | –                 | Atmospheric  | 300                   | Desk           | –  | –          | Data point      | To all areas of dept and external       | ✓                         |
| Deputy manager's office        | 16–21                       | –                     | –         | –                 | Atmospheric  | 300                   | Desk           | –  | –          | Data point      | To all areas of dept and external       | ✓                         |
| Offices (general)              | 16–21                       | –                     | –         | –                 | Atmospheric  | 300                   | Desk           | –  | –          | See para 4.206  | See para 4.207                          | ✓                         |

(continued)

| Location rooms                   | Environmental specification |                       |           | Clean room class. | Ventilation <sup>a</sup><br>+/- with respect to (wrt) | Lighting <sup>b</sup> |            |    | Power (IP) | IT         | Comms                             | Optional telephone points |
|----------------------------------|-----------------------------|-----------------------|-----------|-------------------|---|-----------------------|------------|----|------------|------------|-----------------------------------|---------------------------|
|                                  | Temperature range (°C)      | Relative humidity (%) | Air-cond. |                   |   | Lux                   | Pos.       | IP |            |            |                                   |                           |
| Staff room                       | 16–21                       | –                     | –         | –                 | (–)ve wrt processing areas                            | 300                   | Floor      | –  | –          | –          | See para 4.216                    | –                         |
| Training room <sup>d</sup>       | 16–21                       | –                     | –         | –                 | (–)ve wrt processing areas                            | 300/500               | Floor Desk | –  | –          | ✓          | –                                 | –                         |
| Domestic services (general area) | 16–21                       | –                     | –         | –                 | (–)ve wrt processing areas                            | 100                   | Floor      | 55 | 65         | ✓          | –                                 | –                         |
| General waste disposal           | 16–19                       | –                     | –         | –                 | (–)ve wrt all   | 300                   | Floor      | 55 | 65         | –          | CCTV, access control              | –                         |
| Staff changing room              | 19–23                       | –                     | –         | –                 | (–)ve wrt all   | 300                   | Floor      | 54 | 64         | –          | –                                 | –                         |
| Test equipment and data room     | 16–21                       | 30–60                 | ✓         | –                 | (–)ve wrt processing areas                            | 300<br>Task=500       | Desk       | 52 | 54         | Data point | To all areas of dept and external | –                         |

Notes: a Mechanical ventilation should be considered if placed in deep-plan area

b Careful consideration should be given to the colour balance between artificial lighting and daylight, with particular attention to deep-plan areas. The aim should be to achieve an equal colour balance across all work areas of the department

c Depending on configuration, that is, whether sterilizer unloading is in different area to cooling area

d In the training room, due attention should be given to the potential need for cooling

## 5. General guidance

### INTRODUCTION

**5.1** This chapter contains guidance concerning aspects of function and design that are common to health buildings generally and which need to be borne in mind when designing new buildings or upgrading existing premises.

### ECONOMY

**5.2** The planning of hospital buildings requires design solutions that not only satisfy functional requirements but also ensure maximum economy in respect of both capital and running costs. Due consideration should therefore be given to the questions of space provision, maintenance (including cleaning), energy consumption and staffing requirements (see NHS Estates' 'Sustainable development in the NHS').

**5.3** Planning should ensure that spaces are used as intensively as possible and are not unnecessarily duplicated. To ensure that there is no over-provision of new accommodation, project teams should first evaluate the use of similar existing facilities in relation to their workload and staffing.

### UPGRADING OR ADAPTATION OF EXISTING BUILDINGS

**5.4** The standards set out in this guidance apply to the provision of accommodation by new building, and it is not intended that they should be applied retrospectively to existing stock. However, the principles are equally valid and should be applied, so far as is reasonably practicable, when existing accommodation is being upgraded or new accommodation is being constructed within an existing building which may previously have been used for other purposes.

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

**5.6** If a prima facie case emerges for upgrading, a thorough analysis of all functional and physical conditions of the existing building should be undertaken.

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

**5.8** A checklist of physical and other aspects of existing buildings should include:

- a. availability of space for alterations and additions;
- b. type of construction;
- c. insulation;
- d. age of the buildings, condition of fabric, for example external and internal walls, floors, roofs, doors and windows, which may be determined by a condition survey;
- e. life expectancy and adequacy of engineering services, ease of access and facility for installation of new wiring, pipework, drainage and ventilation systems;
- f. the height of ceilings (high ceilings do not necessarily call for the installation of false ceilings, which are costly and often impair natural ventilation);
- g. changes of floor levels to avoid hazards to disabled people and in the movement of trolleys (see [paragraph 3.34](#));
- h. fire safety (see [paragraphs 6.23–6.27](#));
- j. physical constraints to adaptation, such as load-bearing walls and columns.

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

**5.10** The main environmental factors which should be considered are the same as for a new building – see [paragraphs 3.11–3.25](#).

**5.11** Upgradings should conform to all legislation including current fire safety and other statutory regulations.

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

**5.13** Any upgrading work should minimise the disruption to existing services – that is, there should be a clear segregation between building activity and the ongoing delivery of services.

### DAMAGE IN HEALTH BUILDINGS

**5.14** When designing and equipping health buildings, the likely occurrence and effects of accidental damage should be considered. Damage in health buildings has increased over the years through the use of heavier mechanical equipment for the movement of patients and supplies and, to some extent, as a result of lightweight, often less robust, building materials. Most damage to doors, and to floor and wall surfaces, is caused by wheeled traffic. Measures to minimise damage should be taken in the form of protective corners, buffers and plates, and to proper continuation of floor coverings, that is, strong screeds and fully-bonded floor coverings (see [paragraphs 3.34–3.38](#)). Protective devices should be capable of being renewed as the need arises. Reference should be made to the relevant British

Standards and to the guidance contained in HBN 40: ‘Common activity spaces’. Further information is provided in HTMs 56, 58 and 61.

### SIGNPOSTING

**5.15** NHS Estates’ ‘Wayfinding’ should be consulted for general guidance.

### DISABLED PEOPLE

**5.16** It is essential to ensure that suitable access and facilities are provided for people who have problems of mobility or orientation. This includes those who have difficulty walking, and may use sticks, crutches or other assistive devices, those who have a visual or hearing impairment, as well as those who use a wheelchair. Authorities are reminded of the need to comply with the provisions of:

- a. the Disability Discrimination Act 1995;
- b. BS 8300:2001 Design of buildings and their approaches to meet the needs of disabled people. Code of practice;
- c. ‘The Building Regulations 1991. Approved Document M: Access and facilities for disabled people, 1999’.

**5.17** Project teams are encouraged to refer to HFN 14: ‘Disability access’ (NHS Estates, 1996) and HBN 40: ‘Common activity spaces’, which gives guidance and a set of ergonomic data sheets on access, space and equipment relating to disabled people in health buildings.

**5.18** If public telephones are provided in the department, the telephone equipment/handset should be fitted, for example, with an inductive coupler to assist people using a hearing aid.

## 6. Engineering services

### INTRODUCTION

**6.1** This chapter describes the engineering services contained within an SSD and, where appropriate, how they integrate with the engineering systems serving the whole site. The guidance should acquaint the engineering members of the multidisciplinary design team with the criteria and material specification needed to meet the functional requirements. Specific requirements should be formulated in discussion with both end-users and manufacturers of specialist equipment.

**6.2** The planning team should adopt a comprehensive risk management approach to the design. In this way, the planning team will be able to demonstrate an appropriate level of investment in the engineering services and infrastructure necessary to support the department. Attention to security will also be prerequisite in ensuring reliable services to patients and the public. This risk management approach extends beyond the normal requirements of the Construction (Design and Management) [CONDAM] Regulations 1994 and requires the design to be fully integrated within the control assurance framework for risk management. Clear design philosophies should be developed and agreed with the planning team, which enable the users to understand how risks are being managed within the built environment, through facilities management support and by the actions of the local team. These philosophies can be developed to refine the operational policies of the department and provide an effective briefing and monitoring mechanism throughout the design, construction, commissioning and operational phases of the department.

**6.3** A quality decontamination service needs continuity of delivery. The design of engineering and building services and choice of plant and equipment should take this into consideration. Appropriate design solutions and contingency arrangements should be incorporated. Examples of issues to be considered include:

- down-time for repair/maintenance/periodic testing;
- failure of supply or quality of services (including ventilation, steam, fuel, electricity, IT);
- response time for service, maintenance and testing;

- availability of spare parts;
- operating hours of the department; and
- opportunities for planned work, reliability.

**6.4** Requirements for individual rooms and spaces are stated in [Chapter 4](#).

### MODEL SPECIFICATIONS AND TECHNICAL MANUALS

**6.5** The National Health Service Model Engineering Specifications are sufficiently flexible to reflect local needs. Full reference should also be made to the engineering services sections of HTM 2010: ‘Sterilization’ and HTM 2030: ‘Washer-disinfectors’. For steam generation and distribution, reference should be made to HTM 2031: ‘Clean steam for sterilization’.

### ECONOMY AND VALUE MANAGEMENT

**6.6** Engineering services are a significant proportion of the capital cost and a continuing charge on revenue budgets. Value management should be carried out at the inception stage. The project design engineer should therefore ensure:

- economy in provision, consistent with meeting the functional requirements and maintaining clinical standards through effective risk management, always emphasising the safety of the patient, staff and public;
- optimum benefit from the total financial resources these services are likely to absorb during their lifetime.

**6.7** Consideration should be given to generating “life cycle costings” as part of the cost-benefit analysis for the selection of systems and equipment within a given risk management framework.

**6.8** Where various design solutions are available for a given level of risk reduction, their consequential capital and revenue costs should be compared using the discounting techniques described in, for example, the ‘Capital Investment Manual’ (Department of Health, 1994).

**6.9** Maintainability and the cost of maintenance are key factors in both business planning and the design solution evaluation process. The economic appraisal of various locations and design solutions should include the heat conversion and distribution losses to the point of use. Where buildings are remote from the development's load centre, losses can be significant. This is true of a number of departments that are sited to maximise access and control disturbance to in-patient areas.

**6.10** In providing an energy-efficient solution, account should be taken of the local environmental policy in line with energy-efficiency targets. Users will be expected to achieve ongoing improvements in the utilisation of engineering services for a given level of public service activity. As a result, the design of the building management system and metering arrangements should enable areas for performance improvement in the use of fossil fuels to be identified.

**6.11** Energy management should be part of the site building management system (BMS), and this should also include metering of all services where practical. If a site BMS is not available, the energy management for this department should be stand-alone. It should also be suitable for subsequent integration with a future BMS. Further detailed guidance is contained in HTM 2005: 'Building management systems' (NHS Estates, 1996).

**6.12** The project team should consider the environmental benefits and economic viability of heat recovery and combined heat and power systems (CHPs). Further guidance on CHPs can be found in 'A strategic guide to combined heat and power' (NHS Estates, 1993).

## SERVICE REQUIREMENTS

**6.13** For (a) equipment to be available at any time and (b) to meet the throughput calculations, service requirements and provision should be based on maximum simultaneous demand; that is, no diversity is to be applied. Service requirements for possible future expansion in department workload should also be considered at the initial design stage.

**6.14** The estimated maximum demand and storage requirement (where appropriate) for each engineering service will need to be assessed individually to take account of the size and shape, geographical location, operational policies and intensity of use of the department.

## SPACE FOR PLANT AND SERVICES

**6.15** Enough space should be provided for plant and services within the department. The amount of space

will depend on the engineering solution chosen but will include space not only for decontamination plant and equipment but also for the following:

- clean steam generation;
- reverse osmosis water generation and water treatment; and
- ventilation and air-conditioning;
- hot water generation.

**6.16** Space for plant and services should provide:

- a. easy and safe means of access, protected as far as possible from unauthorised entry (note: this access should not be from within the IAP room);
- b. space for frequent inspections and maintenance;
- c. for eventual removal and replacement of major plant and equipment.

**6.17** There should be enough space to access equipment and undertake tube withdrawal within ventilation plant for cleaning or replacement. Good access should be provided around all units for inspection or opening of access doors. Access doors should be in suitable positions to inspect fire dampers and plant. It may be advisable to site ventilation plant in a separate room dedicated to air handling etc. Access doors should be provided throughout.

**6.18** Mechanical and electrical services within IAP rooms, and wherever possible in other working areas, should be concealed in walls and above ceilings.

## ACCESS TO CONTROL AND ISOLATION DEVICES

**6.19** Primary engineering distribution control and isolation devices should be:

- located in circulation rather than working areas and not in the IAP room;
- protected against unauthorised operation (for example, switchgear and fuse-boards should be housed in secure cupboards);
- easily accessible for staff to operate where appropriate.

## ACTIVITY DATA

**6.20** Environmental and engineering technical data and equipment details are described in the relevant Activity DataBase department information for SSDs. They should be referred to for space, temperatures, lighting levels, outlets for power, telephones, equipment details, security arrangements etc.

**6.21** It is the designer's responsibility to ensure that the planning team is aware of and approves the engineering service provision included within the Activity Data sheets. This information should reflect the design philosophies and operational policies for all of the activity areas and meet the risk management strategy agreed with the users. Where variations to the agreed philosophy or strategy are requested by the users, the designers should ensure that the implications of such variations (in clinical and organisational terms) are understood and accepted by the planning team. Risk considerations will often be paramount.

## SAFETY

**6.22** Section 6 of the Health and Safety at Work etc Act 1974, as partly amended by the Consumer Protection Act 1987, together with the Management of Health and Safety at Work Regulations 1999, the Workplace (Health, Safety and Welfare) Regulations 1992 and the Provision and Use of Work Equipment Regulations 1998, impose statutory duties on employers and designers to minimise any risks arising from the use, cleaning or maintenance of engineering systems. One of the requirements of this legislation is to ensure, so far as is reasonably practicable, that design and construction is such that articles and equipment will be safe and without risks to health at all times when they are being set, used, tested, cleaned or maintained by a person at work.

## FIRE PRECAUTIONS

**6.23** It is essential that project teams familiarise themselves with the guidance contained in the Firecode suite of documents, which contains Department of Health policy and technical guidance on fire precautions in hospitals and other NHS premises. In particular, the need for structural fire precautions and means of escape from the whole accommodation should be taken into account as early as possible. The key document for these aspects in hospitals is HTM 81: 'Firecode: Fire precautions in new hospitals' (NHS Estates, 1996).

**6.24** In addition, the Department of Health Fire Safety Policy (issued in June 2001: see Firecode subsection in the References chapter) sets out the key policy requirements.

**6.25** Management guidance is contained in the Firecode 'Policy and principles' document. Other Firecode documents include the HTM 80 series, which gives technical guidance on various building, engineering and equipment issues, and the Fire Practice Notes series, which covers various specialist aspects of fire precautions.

**6.26** It is important to establish during the design stage those aspects of fire safety strategy that affect the

design, configuration and structure of the SSD. The architect and engineer should discuss and verify their proposals with the Building Control Authority or Approved Inspector, and ensure that the project team and all other design staff are fully acquainted with the fire safety strategy for the design in terms of operation (staff responsibilities, equipment provision and building and engineering layouts). The following NHS Estates guidance documents give detailed information on the selection of fire-resisting components and fire signs:

- HTM 56: 'Partitions';
- HTM 57: 'Internal glazing';
- HTM 58: 'Internal doorsets';
- HTM 59: 'Ironmongery';
- HTM 60: 'Ceilings'; and
- 'Wayfinding'.

**6.27** The principles of fire safety apply equally to new projects and to alterations and upgrading of existing buildings.

## NOISE AND SPEECH PRIVACY

**6.28** Excessive noise and vibration from engineering services, whether generated internally or externally and transmitted to individual areas, or noise from other sources (for example, speech which can be transmitted by the ventilation system) can adversely affect the operational efficiency of the department and cause discomfort.

**6.29** In addition to designing for control of noise levels, there may be a need to ensure speech privacy, so that confidential conversations are unintelligible in adjoining rooms or spaces. This will be important in office areas. The use of induction loop facilities for those with hearing impairment should be considered, but the need for privacy in conversations conveyed by such means should equal that for able-bodied persons.

## ENGINEERING COMMISSIONING

**6.30** At the time of commissioning, the planning team should assess the ability of the engineering services and systems as installed to meet the agreed design philosophies and risk management strategies. Where variations occur against agreed performance parameters, the designer should ensure that the implications of such variations (in clinical and organisational terms) are understood and accepted by the planning team and users.

**6.31** The engineering services should be commissioned in accordance with the validation and verification methods identified in the current versions of each HTM.



Engineering services for which a specific HTM is not currently available should be commissioned in accordance with 'Guidance to engineering commissioning' (Institute of Healthcare Engineering and Estate Management, 1995).

**6.32** Flow measurement and proportional balancing of air and water systems require adequate test facilities to be incorporated at the design stage. Guidance is also contained in commissioning codes A (1996) and W (1994) published by the Chartered Institute of Building Services Engineers.

### EQUIPMENT VALIDATION

**6.33** Decontamination equipment should be validated fully in accordance with the relevant protocol in HTMs 2010, 2030 or 2031.

### MECHANICAL SERVICES

#### Heating

**6.34** The controlled environments (IAP room and wash room) should be heated by the mechanical ventilation system. Elsewhere, space heating requirements may be met by low-pressure hot-water radiators. They should be located under windows or against exposed walls. There should be enough space below to allow cleaning machinery to be used. Where a radiator is located on an external wall, back-insulation should be provided to reduce the rate of heat transmission through the building fabric.

#### Temperature controls

**6.35** Heating systems should be time-controlled to provide "optimum start" in the morning and a "set back" space temperature of approximately 12–15°C outside working hours.

**6.36** Facilities should be provided to override the control system on those occasions when the department needs to operate outside "normal" working hours.

**6.37** All radiators should be fitted with thermostatic radiator valves (TRVs). These should be of robust construction and selected to match the temperature and pressure characteristics of the heating system. The thermostatic head, incorporating a tamper-proof facility for presetting the maximum room temperature, should be controlled via a sensor located integrally or remotely as appropriate. To provide frost protection at its minimum setting, the valve should not remain closed below a fixed temperature. The system should have a bypass with pressure relief in the event of all TRVs being closed.

**6.38** The choice of controls should take account of the extent to which they can be linked to, or provided by, a

building management system serving the SSD, whether the unit is an independent building or part of a hospital.

**6.39** Consideration should also be given to modulating the flow temperature to the heating appliances in accordance with the external ambient temperature.

### Ventilation (see also HTM 2025: 'Ventilation in healthcare premises')

#### General

**6.40** The following factors determine the ventilation needs within the various spaces of an SSD:

- Those associated with the functional requirements or process within the space, for example, particulate contaminants within the IAP room.
- Those associated with staff comfort and safety; for example, the provision of fresh air, the control of temperature and the removal of odours, hazardous vapours/gases etc.
- Maintenance of pressure differentials to provide controlled environmental requirements.

**6.41** Individual spaces should be naturally ventilated where possible and mechanical ventilation should be minimised by ensuring that, wherever practicable, core areas are reserved for:

- rooms that require mechanical ventilation for functional reasons, irrespective of whether their location is internal or peripheral, for example sanitary facilities;
- spaces which are only used fleetingly and therefore require little or no mechanical ventilation, for example circulation and some storage areas.

**6.42** Air movement induced by mechanical ventilation should be from relatively clean to dirty areas where these can be defined. The design should allow for an adequate flow of air into any space having only mechanical extract ventilation via transfer grilles in doors or walls. Such arrangements, however, should not introduce untempered air and should not compromise fire safety. The defined pressure differentials shall be maintained continually. Intumescent grilles are not to be used in fire-resistant walls or doors.

**6.43** Fresh air should be introduced via a low velocity system and should be tempered and filtered before being distributed. Diffusers and grilles should be placed to achieve uniform air distribution within the space without causing discomfort to staff.

**6.44** The design should remove heat, vapours, aerosols and gases at source. Consideration should be given to the impact of discharge of hot products from washer-

disinfectors and sterilizers; manual cleaning and testing of products; and plant rooms, in particular the sterilizer plant room. Washer-disinfectors are likely to require dedicated extract systems.

**6.45** Local Exhaust Ventilation (LEV) will be required where chemical agents that are subject to an occupational exposure limit (OEL) are used (Control of Substances Hazardous to Health Regulations 2002). Good general ventilation should also be provided.

**6.46** Ventilation supply plant should include a pre-filter to BS EN 779: 2002 grade G3 and a secondary filter of F6 grade. In urban or other areas of high atmospheric pollution, the costs of having a higher standard of filtration to reduce the level of staining to internal finishes may be warranted. Filters should be readily accessible for replacement and should be provided with a pressure differential indicator.

**6.47** A separate extract system will be required for sanitary facilities. A dual-motor fan unit with an automatic changeover facility should be provided.

**6.48** External discharge arrangements for extract systems should be protected against back pressure from adverse wind effects and should be located to avoid reintroduction of exhausted air into the building through air intakes and windows. Extract ventilation from washer-disinfectors should be self-contained, dedicated to the equipment and be independent of the general department extract system. Reference should be made to HTM 2030: 'Washer-disinfectors – design considerations' (Chapter 6); and MES C30: 'Washer-disinfectors for surgical instruments' (Clause C30.03.38 'Ventilation systems and ductwork').

### **The IAP room**

**6.49** The positive air pressure differential (see [paragraph 3.23](#)) that must be maintained within the IAP room can be compromised by all openings such as transfer facilities and doors (including those around washer-disinfectors). This should be taken into account when designing the ventilation system. Consideration should also be given to heat gains from all sources, including process equipment and processed goods entering the IAP room from washer-disinfectors (see also paragraphs 6.55–6.56).

**6.50** The mechanical-ventilation system should be designed to ensure that, when the space is tested in accordance with BS EN ISO 14644 in the "unmanned condition", the particulate count and air pressure difference are to the standard specified for ISO Class 8 of BS EN ISO 14644 (see definition of "Class 8 standard" in the [Glossary](#)).

**6.51** To prevent outside air entering the IAP room, it will need to have non-openable windows and a sealed

ceiling. Consequently, the spaces which communicate with the IAP room may need to be mechanically ventilated. The entry to and exit from these spaces should be controlled to ensure that communicating doors will not open simultaneously. The rooms requiring interlocking doors are shown diagrammatically in [Figures 1 and 2](#). Doors on transfer facilities and hatches should be interlocking.

**6.52** Where small, open hatches are required to accommodate conveyor systems between the IAP room and wash room, for example, they should have purpose-designed close-fitting flaps to minimise air exfiltration, air change rates and consequently, energy consumption.

**6.53** All air supplied to the IAP room should be allowed to exfiltrate to adjacent spaces and via pressure relief dampers to:

- a. the materials transfer room; and
- b. the gowning room.

**6.54** The system should run continuously. During out-of-hours periods, it should be designed to operate in the supply mode only at 10–20% of the normal supply rate. The ventilation plant should be separate from plant serving other areas and should be supplied with a spare motor and alarm to indicate failure in either input or extract.

### ***Air cooling (design principles)***

**6.55** The wash room and other areas subject to high heat gains may need mechanical cooling to provide a comfortable environment for staff and to ensure satisfactory operation of equipment.

**6.56** Generally, air cooling should be included where calculations show that, without an excessive number of air changes, internal temperatures are likely to exceed the external shade temperature by more than 3°C. In these circumstances, cooling should start when the internal space temperature exceeds 25°C.

### ***Ventilation controls***

**6.57** Supply and extract ventilation systems should include controls and indicated control panels in the plant room to confirm the operational status of each system. This should include pressure indicators for air supplies. Alarms should be repeated in the manager's office. Controls will usually include those for temperature/time switching functions and should be selected to take account of the extent to which they can be linked to, or provided by, a building management system serving the whole site. Indication and alarm of status of ventilation system should be provided in the IAP room.

### Hot, cold and drinking water services

**6.58** Guidance on the design and installation of hot and cold water supply and distribution systems is contained in HTM 2027: 'Hot and cold water supply, storage and mains services' (NHS Estates, 1995). All installations must comply with the Water Regulations 1999.

**6.59** The requirements for the control of legionellae bacteria in hot and cold water systems are set out in HTM 2040: 'The control of legionellae in health care premises – a code of practice' (NHS Estates, 1994; now under revision).

**6.60** The hot water should be supplied at an outflow temperature of  $60^{\circ}\text{C} \pm 2.5^{\circ}\text{C}$ , and distributed to all outlets so that the return temperature at the calorifier is not less than  $50^{\circ}\text{C}$ . It should be boosted locally where necessary for washer-disinfectors and other equipment. The design solution should take account of requirements for *Legionella* control.

### Equipment

**6.61** Energy-efficient equipment should be chosen where possible. Such equipment also reduces the load on ventilation systems. Washer-disinfectors, sterilizers and items of equipment which tend to have high surface temperatures should be insulated where possible in every practical way to prevent heat emission to the space.

### Piped medical gases

**6.62** The provision of piped medical gas systems will depend on the engineering solution chosen. Air from a compressor or cylinder which can come into contact with medical devices either in a piece of decontamination equipment or for testing the free-passage of lumens should be of medical air quality. Medical air should not be used for equipment control purposes. Further guidance is included in HTM 2022: 'Medical gas pipeline systems'.

### Compressed air (industrial)

**6.63** Where a separate compressed air supply is required for the equipment's pneumatic controls, it may be supplied from the site's pneumatic control system or duplicate compressors located near the sterilizers. Further guidance is contained in HTMs 2010 and 2030.

### Steam

**6.64** Steam should be supplied in compliance with the requirements of HTM 2031 when measured at the entrance to the sterilizer chamber. Before choosing the design solution, steam available from a central supply should be tested in accordance with Table 2a of HTM 2031 to identify steam-generation needs. If this is not

available from a central source, localised generation or process steam/clean steam conversion facilities should be provided. Further guidance is given in HTMs 2010, 2030 and 2031.

### Decontamination equipment

**6.65** Guidance on choice, procurement, installation, validation and verification of sterilizers and washer-disinfectors is contained in HTM 2010: 'Sterilization'; HTM 2030: 'Washer-disinfectors'; MES C14: 'Sterilizers'; and MES C30: 'Washer-disinfectors for surgical instruments'.

### Gas fuel supply

**6.66** Where a gas fuel supply is available and used for heating, hot water or steam generation, the supply should terminate in a well-ventilated meter room which is accessible from outside.

### Vacuum cleaning system

**6.67** Consideration should be given to the provision of a centralised vacuum cleaning system throughout the department.

## ELECTRICAL SERVICES

### Electrical installation

**6.68** Electrical installation should comply with BS 7671: 2001 – 'Requirements for Electrical Installations'; IEE Wiring Regulations 16th Edition (and subsequent amendments).

**6.69** The point of entry for the electrical supply will be a switch-cupboard housing the main isolators and distribution equipment. This space will also be the distribution centre for subsidiary electrical services. Supplies should be metered and, whenever possible, equipment should be mounted at a height that gives easy access from a standing position. Switchgear should be lockable in the "off" position.

**6.70** The electrical installation in occupied areas should be concealed using thermoplastic-insulated cables and screwed steel conduit or trunking (in certain circumstances, mineral-insulated, metal-sheathed or other cable with resistance to extreme temperatures and physical damage may be used depending on requirements). External installations should also use thermoplastic-insulated cables in galvanised screwed steel conduit with waterproof fittings.

### Electrical interference

**6.71** Care should be taken to avoid mains-borne interference, electrical radio frequency and telephone interference affecting computers and other electronic equipment used here or elsewhere on the hospital site.

**6.72** Electrical products, systems and installations should not cause, or be unduly affected by, electromagnetic interference. This requirement is in the form of an EC Directive on Electromagnetic Compatibility (89/336/EEC as amended by 91/263/EEC and 92/31/EEC). This Directive has been implemented in UK law by the Electromagnetic Compatibility Regulations 1992.

**6.73** Advice on the avoidance and abatement of electrical interference is contained in HTM 2014: 'Abatement of electrical interference' (NHS Estates, 1993).

**6.74** Fluorescent luminaires should comply with BS EN 55015.

### Lighting

**6.75** Practical methods of lighting the various functional spaces are contained in the Chartered Institute of Building Services Engineers (CIBSE) Lighting Guide LG2, 'Hospitals and healthcare buildings'.

**6.76** Colour finishes and lighting throughout circulation areas should be coordinated to create a calm and welcoming atmosphere.

**6.77** The lighting solution should meet the Health and Safety (Display Screen Equipment) Regulations 1992. Further guidance is contained in the CIBSE Lighting Guide LG3.

**6.78** Architects and engineers should collaborate with artists and landscape designers to ensure that decorative finishes are compatible with the colour-rendering properties of the lamp and that the spectral distribution of the light source is not adversely affected.

**6.79** Luminaires should be manufactured and tested in accordance with the requirements specified in the relevant sections of BS 4533. Their location should afford ready access for lamp changing and maintenance, but with the overriding requirement that the recommended standard of illuminance be provided to the task area. Wherever possible, luminaires should incorporate a fused terminal block that permits safe isolation of the luminaires for maintenance/lamp changing, without the inconvenience of prolonged loss of light from isolating a complete lighting circuit.

**6.80** Energy-efficient luminaires should be used whenever possible. Intermittently and infrequently used luminaires may be fitted with compact source fluorescent or incandescent lamps.

**6.81** The number and location of luminaires connected to a circuit and the number of switches and circuits provided should allow flexibility in the general and local level of illumination, particularly in areas away from

windows where daylight can vary significantly. Some areas of the facility that may be unoccupied for long periods may also be suited to automatic/presence switching.

**6.82** For lighting circuits, designers should consider the impact that isolation of individual lighting circuits will have on an operational department. These proposals should be agreed with the planning team and estates manager to ensure that the design properly reflects maintenance and local operational policies.

**6.83** The lighting of corridors, stairways and other circulation areas (which generally are areas not covered by Activity DataBase sheets) should be in accordance with the guidance contained in HBN 40 – 'Common activity spaces, Vol 4: Circulation areas' (NHS Estates, 1995).

**6.84** Safety lighting should be provided on primary escape routes in accordance with HTM 2011: 'Emergency electrical services' (NHS Estates, 1993) and BS 5266. Emergency lighting of control rooms should be arranged in accordance with the requirements of users and the guidance in HTM 2011.

**6.85** The designers and planning team should ensure that emergency lighting and alternative equipment (torches etc) conform to the emergency procedures and contingency planning processes developed to enable a safe level of care to be provided at all times. Light fittings in the IAP room and wash room need to be compatible with the control of the environment.

### Socket-outlets and power connections

**6.86** Consideration should be given to the provision of devices to protect the integrity of electronic data held within microprocessor-based equipment.

**6.87** Sufficient 13-amp switched and shuttered socket-outlets, connected to ring circuits, should be provided to supply all portable appliances, other than medical equipment, likely to be used simultaneously. Designers should ensure that they have access to a complete schedule of the equipment that requires electrical supplies and a clear understanding of the operational policies regarding the use of all equipment. Twin outlets should be considered where activities take place in adjoining spaces.

**6.88** Switched socket-outlets should be provided in corridors and in individual rooms to enable domestic cleaning appliances with flexible leads (9 m long) to operate over the whole facility.

**6.89** Appliances requiring a three-phase supply or those rated in excess of 13-amp single phase should be permanently connected to separate fused sub-circuits. The sub-circuits should be fed from the distribution

board and terminate at a local isolator. Designers should agree on the location, type (flush or surface-mounted), form of indication, IP rating, construction, type of cable outlet, facilities for locking of isolator in the off position, and labelling of such isolators with the planning team. Fixed appliances, less than 13-amp rating, should be permanently connected to a double-pole switched 13-amp fused connection unit. The fused connection unit should contain an indicating light, where appropriate, and a suitable fuse.

**6.90** The selection of faceplate material (metal or plastic) and manufacturer should reflect the whole-hospital policies on electrical outlet provision.

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

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

**6.93** Depending on local circumstances, consideration may need to be given to the quality of the electrical supply to computer and other equipment. Much equipment has over-voltage and surge protection built in, but susceptibility to harmonics and other supply distortion should be discussed with the manufacturer to establish the parameters required. Additional power-factor correction should be built in as required. Advice should be sought from manufacturers and suppliers at an early opportunity.

**6.94** Socket-outlets should be connected to essential circuits in accordance with the advice contained in HTM 2011: 'Emergency electrical services' (NHS Estates, 1993).

**6.95** Isolation switches should be provided adjacent to all engineering plant and equipment for use by maintenance staff. The location, type and facilities provided on the isolation of switches should be agreed with the Authorised Person (Low Voltage) to ensure that the fixed installation enables whole-hospital policies on low-voltage operations (see HTM 2020: 'Electrical safety code for low voltage systems') to be maintained in the SSD area.

### Emergency electrical supplies

**6.96** Guidance on emergency electricity supplies is contained in HTM 2011: 'Emergency electrical services' (NHS Estates, 1993).

**6.97** Requirements for connection of individual circuits and items of equipment to UPS and/or standby

generation systems should be discussed with users and with equipment suppliers. Designers should undertake a risk assessment with the planning team to identify the operational impact when an electrical supply is not available. The risk assessment should identify how risk can be reduced using the fixed installation, business continuity and contingency planning elements of the agreed operational policies.

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

### Internal/external communications

**6.99** Central telephone facilities for internal and external calls should be extended to serve this department.

**6.100** Facilities for communication between separate rooms and areas should also be provided.

### Electronic data gathering

**6.101** Wireways for data links should be provided between rooms and areas for the following purposes:

- decontamination-process verification data;
- product release;
- patient-record traceability;
- instrument stock/inventory;
- instrument trackability.

**6.102** Process verification data should be provided for washer-disinfectors and sterilizers and should both be traceable from patient records. Product release data should be presented to equipment operators at the unloading side of the machines.

### Electric clocks

**6.103** Clocks should operate in conjunction with a master impulse clock system.

**6.104** A circuit terminating in a fused-spur outlet should be provided in a circulation space near to the entrance to supply a time-recording clock which will be used by hourly-paid staff.

### Lightning protection

**6.105** Protection against lightning should be provided in accordance with HTM 2007: 'Electrical services supply and distribution', and BS 6651.

### INTERNAL DRAINAGE

**6.106** The main objective is to provide an internal drainage system which:

- safely and effectively carries waste fluids away to the local water authority sewer;
- uses the minimum of pipework;
- remains water- and air-tight at joints and connections;
- is sufficiently ventilated to retain the integrity of water seals.

### Design parameters

**6.107** The design of internal drainage should comply with the relevant British Standards and Codes of Practice, including BS EN 12056-2, and the current building regulations. Recommendations for spatial and access requirements for public health engineering services are contained in HTM 2023: 'Access and accommodation for engineering services' (NHS Estates, 1995) and CIBSE Guide G, 'Public health engineering'.

**6.108** The drains from steam sterilizers and washer-disinfectors should comply with local water regulations. Further advice is provided in HTM 2030: Design considerations, Chapter 6.

**6.109** The gradient of branch drains should be uniform and adequate to convey the maximum discharge to the

stack without blockage. Practical considerations such as available angles of bends/junctions and their assembly, as well as space considerations, usually limit the minimum gradient to about 1:50 (20 mm/m). For larger pipes, for example those of 100 mm diameter, the gradient may be less but will require workmanship of a high standard if adequate self-cleansing flow is to be maintained.

### Operational considerations

**6.110** Consideration should be given to the fitting of meters to accurately monitor services, for example steam, fuel and water, for efficiency or charging purposes.

**6.111** Service ducts should be designed so that services can be easily accessed away from the IAP room. Reference should be made to HTM 2023: 'Access and accommodation for engineering services'.

**6.112** There should be a clear controls philosophy for the department provided by the principal contractor.

**6.113** On each operator-side of the sterilizer and washer-disinfector fascia panelling, 13-amp switched socket outlets – RCD-protected and splash-proof – should be provided.

# 7. Cost information

## INTRODUCTION

**7.1** For all types of health building, it is important that building costs and revenue expenditure are kept as low as possible and consistent with acceptable standards. In applying the guidance in this document to determine a detailed design, the need for economy should always be of prime concern, and the activities should be carefully considered so that, where appropriate, space can be shared for similar activities which are programmed to take place at different times. The solution should not be detrimental to the proper functioning of the spaces involved nor to the needs of the users. Within this general context, this series of documents provides a synopsis of accommodation for health buildings which the Department of Health recommends for the provision of a given service.

## DEPARTMENTAL COST ALLOWANCE GUIDES

**7.2** Departmental Cost Allowance Guides (DCAGs) related to this HBN are officially notified in 'Quarterly Briefing', published by NHS Estates. A full listing of all DCAGs is published in the 'Healthcare Capital Investment' document – a hard copy of which can be obtained from NHS Estates; copies can also be downloaded from <http://www.nhsestates.gov.uk>. Further information on this can be obtained from NHS Estates, telephone 0113 254 7000.

**7.3** The attention of the project team is drawn to guidance given in the 'Capital Investment Manual' (Business Case Guide) published by The Stationery Office. This publication seeks to reflect the important changes that have taken place over recent years, both with the introduction of the NHS reforms and with the changing patterns of healthcare delivery. This new process is intended to reduce unnecessary and often expensive planning work that may subsequently prove to be abortive, and emphasises the necessity for a sound business case in support of both the capital and the revenue expenditure involved. The 'Capital Investment Manual' also states that the capital works estimate of the intended scheme must be based, wherever applicable, on industry norms such as the DCAGs plus a percentage to cover for on-costs.

**7.4** The DCAGs for this HBN reflect the total building and engineering requirements and accommodation that

the sterile services department will require when incorporated into an acute general hospital where the common use of services will be available. Costs are based on a typical two-storey new-build unit, on a greenfield site with no planning constraints.

**7.5** DCAGs are exclusive of VAT, Building and Planning Fees and all Local Authority charges, and are based on a Location Factor of 1.

## ON-COSTS

**7.6** It is important to bear in mind that an allowance for on-costs should be added to the DCAGs for all units, this element being for external works, external engineering services and abnormalities etc. The abnormalities will largely be determined by the characteristics of the site, such as an inner-city location or poor ground conditions, or the condition and type of the existing building if refurbishment is the only option.

**7.7** It is important that project teams should assess at the earliest opportunity all the likely on-cost implications of individual sites and schemes.

## LOCATIONAL FACTORS

**7.8** Locational factor adjustments may be applied to the Works Costs (that is, the total of the DCAGs plus established on-costs) to take into account the local market conditions. For further information regarding these, please refer to the latest Regional Location factors in 'Quarterly Briefing', published by NHS Estates.

## SCHEDULES OF ACCOMMODATION

**7.9** The schedules are split into two distinct elements, as follows.

### The schedule of room/space types

**7.10** This lists all room/space types and major options covered by the document, giving a range of provision, when appropriate, together with a nominal area. These are grouped by the functional use of the spaces.

### Departmental examples

**7.11** These schedules show example notional whole department accommodation to highlight the scope for

sharing accommodation. **The examples are not to be taken as ideal provision for any particular project.**

**7.12** The examples included are as follows:

Example 1: Department comprising:

- 2 single chamber (10 Din baskets) washer-disinfectors;
- 2 packing stations;
- 2 x 0.6 m<sup>3</sup> sterilizers.

Example 2: Department comprising:

- 2 multi-chamber (3 x 10 Din baskets) washer-disinfectors;
- 10 packing stations;
- 3 x 0.6 m<sup>3</sup> sterilizers.

Example 3: Department comprising:

- 7 multi-chamber (3 x 10 Din baskets) washer-disinfectors;
- 30 packing stations;
- 9 x 0.6 m<sup>3</sup> sterilizers.

## DIMENSIONS AND AREAS

**7.13** In determining spatial requirements, the essential factor is not the total area provided but the critical dimensions, that is, those dimensions critical to the efficient functioning of the activities which are to be carried out. To assist project teams in preparing detailed design solutions for the rooms and spaces, studies have been carried out to establish dimensional requirements in the form of critical dimensions.

**7.14** For development planning and at the earliest stage of a design, it may be convenient for designers to have data available which will enable them to make an approximate assessment of the sizes involved. For this reason, the areas prepared for the purpose of establishing the cost allowances are listed in the schedules of accommodation found at the end of this chapter.

**7.15** It is emphasised that the areas published do not represent recommended sizes, nor are they to be regarded in any way as specific individual entitlements.

**7.16** Planning of the building efficiently may also necessitate variation of areas, for instance, in the refurbishment or conversion of older property:

a. rooms tend to be larger than the recommended area;

b. some rooms may be too small or in the wrong location for efficient use;

c. circulation space tends to form a larger than normal proportion of the total area.

## CIRCULATION

**7.17** Space for circulation, that is, all internal corridors, small vertical ducts and spaces occupied by partitions and walls, is included.

**7.18** Provision is also made for a 5% planning zone and a 3% addition for an engineering zone adjacent to the external walls. These areas are all included and therefore costed in the DCAGs.

**7.19** It is also important to remember that the circulation figures included in the DCAGs for this type of accommodation are those anticipated for new purpose-built premises with no constraints. Where constraints are encountered, for example in refurbishment or conversion of older types of property, this circulation figure would be likely to increase accordingly, and therefore some adjustment may be necessary to the circulation figure.

## COMMUNICATIONS

**7.20** Staircases and lifts are not included in the DCAGs relevant to this department. Costs related to these elements, along with a suitable space allowance, should be made in the on-costs.

## LAND COSTS

**7.21** As is the norm for DCAGs, costs are exclusive of all land costs and associated fees. However, the project team's attention is drawn to the fact that costs associated with these should be included in the Business Case submission, all as detailed in the 'Capital Investment Manual', and could therefore be an important part of the overall cost viability of the scheme.

## ENGINEERING SERVICES

**7.22** The following engineering services, as described in chapter 6 and exemplified in the Activity Data, are included in the cost allowances. Primary engineering services are assumed to be conveniently available at the boundary of the department.

### Mechanical services

- Heating – low pressure hot water system.
- Ventilation – mechanical supply and extract to areas requiring extract due to type of room, that is, WCs, showers etc. Ventilation plant – that is, air handling units/extract fans – is not included in the cost allowances.



- Cold water service – centrally supplied to service points including drinking water. Storage tanks are excluded.
- Hot water service – supplied from a central system, storage and generation is excluded.
- Piped medical gases oxygen, medical compressed air and vacuum. An emergency 2 x 1 oxygen manifold is included in the cost allowances; medical compressed air and vacuum plant are excluded.
- Steam (including plant).

### **Electrical services**

- Departmental distribution boards.
- General lighting as required by task.
- Examination lighting (examination lamps).
- Emergency luminaires as appropriate.
- Socket-outlets and other power outlets for fixed and portable equipment.
- Supplementary equipotential earth bonding.
- UPS supplies and equipment.
- Fire alarm system.
- TV/radio wireways only.
- Telephone internal cabling distribution and outlets – handsets are excluded.
- Data wireways only included.

### **Equipment (Group 1)**

- Washer-disinfectors.
- Washer-dryers.
- Drying cabinets.
- Sterilizers.
- Water boiler in staff room.

## STERILE SERVICES DEPARTMENT: ROOM/SPACE TYPE SCHEDULE

| Activity Space  | Area   | Para Ref      | Notes  |
|---|--------|---------------|--|
| <b>Entrance &amp; reception facilities</b>  |        |               |  |
| Entrance area (Staff & visitors)  | –      | Para 4.4, 4.5 | Circulation allowance  |
| Entrance area (Supplies)  | –      | Para 4.4, 4.5 | Circulation allowance  |
| Reception/waiting area  | 9.0    | Para 4.6      | Visitor waiting associated with entrance   |
| <b>Contaminated returns facilities</b>  |        |               |  |
| Contaminated returns lobby: 4 trolleys  | 8.0    | Para 4.10     | See Note a   |
| Contaminated returns lobby: 9 trolleys  | 18.0   | Para 4.10     | See Note a   |
| Contaminated returns lobby: 35 trolleys   | 70.0   | Para 4.10     | See Note a   |
| Contaminated returns holding area: 4 trolleys   | 8.0    | Para 4.15     | See Note a   |
| Contaminated returns holding area: 6 trolleys   | 12.0   | Para 4.15     | See Note a   |
| Contaminated returns holding area: 8 trolleys   | 16.0   | Para 4.15     | See Note a   |
| <b>Equipment/instrument cleaning, disinfecting &amp; drying facilities</b>                      |        |               |  |
| Wash room: 2 single chamber (10 Din baskets) washer/disinfectors                                | 54.0   | Para 4.30     | See Note b   |
| Wash room: 2 multi-chamber (3 x 10 Din baskets) washer/disinfectors                             | 76.5   | Para 4.30     | See Note c   |
| Wash room: 7 multi-chamber (3 x 10 Din baskets) washer/disinfectors                             | 200.00 | Para 4.30     | See Note d   |
| Wash room: 7 multi-chamber (3 x 10 Din baskets) washer/disinfectors & automated handling system | 259.0  | Para 4.30     | See Note e   |
| Trolley pass-through wash area (single trolley): 2 washers                                      | 15.0   | Para 4.46     | Min. two trolley washers required to allow for down-time   |
| Trolley pass-through wash area (single trolley): 4 washers                                      | 30.0   | Para 4.46     | See Note f   |
| <b>Equipment/instrument inspection, assembly &amp; packing facilities</b>                       |        |               |  |
| Inspection, assembly and packing room: 2 workstations   | 54.0   | Para 4.69     | Served by 2 single chamber (10 Din baskets) See Note g   |
| Inspection, assembly and packing room: 10 workstations  | 104.0  | Para 4.69     | Served by 2 multi-chamber (3 x 10 Din baskets) See Note h  |
| Inspection, assembly and packing room: 30 workstations  | 238.0  | Para 4.69     | Served by 7 multi-chamber (3 x 10 Din baskets) See Note i.   |
| Inspection, assembly and packing room: 30 workstations with automated handling                  | 254.0  | Para 4.69     | Served by 7 multi-chamber (3 x 10 Din baskets) washer/disinfectors with automated handling system (See Note j) |
| Materials transfer room   | 9.0    | Para 4.105    | Based upon divided room with dual access   |
| Packed product transfer facility  | 9.0    | Para 4.115    | Area allows for pass-through hatch and access to both sides  |
| <b>Equipment/instrument sterilizing facilities</b>  |        |               |  |
| Sterilizer loading/unloading area: 2 x 0.6 m <sup>3</sup> sterilizers                           | 29.5   | Para 4.120    | See Note k   |
| Sterilizer loading/unloading area: 3 x 0.6 m <sup>3</sup> sterilizers                           | 38.0   | Para 4.120    | See Note k   |
| Sterilizer loading/unloading area: 9 x 0.6 m <sup>3</sup> sterilizers                           | 99.0   | Para 4.120    | See Note k   |
| Sterilizer plant room: 2 x 0.6 m <sup>3</sup> sterilizers                                       | 17.0   | Para 4.134    | See Note l   |
| Sterilizer plant room: 3 x 0.6 m <sup>3</sup> sterilizers                                       | 22.5   | Para 4.134    | See Note l   |
| Sterilizer plant room: 9 x 0.6 m <sup>3</sup> sterilizers                                       | 67.5   | Para 4.134    | See Note l   |
| Sterilizer cooling area: 2 bays   | 13.0   | Para 4.145    | See Note m   |
| Sterilizer cooling area: 3 bays   | 14.5   | Para 4.145    | See Note m   |
| Sterilizer cooling area: 9 bays   | 43.5   | Para 4.145    | See Note m   |

| Activity Space  | Area | Para Ref        | Notes   |
|---|------|-----------------|---|
| <b>Staff support facilities: Offices</b>                                  |      |                 |   |
| Manager's office  | 10.5 | Para 4.188      |   |
| Deputy manager's office   | 10.5 | Para 4.194      | Operations manager/QA manager, etc  |
| Administrative staff office: 4 places                                     | 24.0 | Para 4.200      |   |
| Administrative staff office: 5 places                                     | 30.0 | Para 4.200      |   |
| <b>Staff support facilities: Staff rooms</b>                              |      |                 |   |
| Staff rest room with beverage bay: 5 places                               | 11.0 | Para 4.210      |   |
| Staff rest room with beverage bay: 10 places                              | 18.0 | Para 4.210      |   |
| Staff rest room with beverage bay: 30 places                              | 45.0 | Para 4.210      |   |
| <b>Staff support facilities: Sanitary/changing</b>                        |      |                 |   |
| Gowning room: 2/3 places (wash room)                                      | 8.0  | Para 4.20       | See Note n  |
| Gowning room: 4/6 places (wash room)                                      | 12.0 | Para 4.20       | See Note n  |
| Gowning room: 7/9 places (wash room)                                      | 16.0 | Para 4.20       | See Note n  |
| Gowning room: 2/3 places (IAP room)                                       | 10.0 | Para 4.55       | See Note o  |
| Gowning room: 4/6 places (IAP room)                                       | 14.0 | Para 4.55       | See Note o  |
| Gowning room: 7/9 places (IAP room)                                       | 18.0 | Para 4.55       | See Note o  |
| Gowning room: 10/12 places (IAP room)                                     | 22.0 | Para 4.55       | See Note o  |
| Gowning room: 13/15 places (IAP room)                                     | 26.0 | Para 4.55       | See Note o  |
| Gowning room: 16/18 places (IAP room)                                     | 30.0 | Para 4.55       | See Note o  |
| Staff changing facilities: 5 places                                       | 5.5  | Para 4.219      | Appropriate spaces to be designated Male or Female depending upon staff mix |
| Staff changing facilities: 10 places                                      | 8.0  | Para 4.219      |   |
| Staff changing facilities: 15 places                                      | 10.0 | Para 4.219      |   |
| Staff changing facilities: 20 places                                      | 11.5 | Para 4.219      |   |
| Staff changing facilities: 60 places                                      | 30.0 | Para 4.219      |   |
| Staff WC  | 2.0  | Para 4.219      | See Note p  |
| Staff & visitors wheelchair accessible WC                                 | 4.5  | Para 4.7, 4.219 |   |
| Staff shower  | 2.5  | Para 4.219      | See Note q  |
| Staff wheelchair accessible shower  | 4.5  | Para 4.221      |   |
| Staff wheelchair accessible WC & shower                                   | 6.0  | Para 4.221      |   |
| <b>Staff support facilities: Educational</b>                              |      |                 |   |
| Seminar/training/library room: 5 places                                   | 14.0 | Para 4.224      |   |
| Seminar/training/library room: 10 places                                  | 20.0 | Para 4.224      |   |
| Seminar/training/library room: 20 places                                  | 37.5 | Para 4.224      |   |
| <b>Support facilities: Holding/storage</b>                                |      |                 |   |
| Raw materials store: Serving 2 x 0.6 m <sup>3</sup> sterilizer units      | 20.0 | Para 4.171      | See Note r  |
| Raw materials store: Serving 3 x 0.6 m <sup>3</sup> sterilizer units      | 30.0 | Para 4.171      | See Note r  |
| Raw materials store: Serving 9 x 0.6 m <sup>3</sup> sterilizer units      | 90.0 | Para 4.171      | See Note r  |
| Processed products store: Serving 2 x 0.6 m <sup>3</sup> sterilizer units | 20.0 | Para 4.154      | See Note s  |

| Activity Space  | Area | Para Ref                   | Notes  |
|---|------|----------------------------|--|
| <b>Support facilities: Holding/storage (contd)</b>                        |      |                            |  |
| Processed products store: Serving 3 x 0.6 m <sup>3</sup> sterilizer units | 30.0 | <a href="#">Para 4.154</a> | <a href="#">See Note s</a>                           |
| Processed products store: Serving 9 x 0.6 m <sup>3</sup> sterilizer units | 90.0 | <a href="#">Para 4.154</a> | <a href="#">See Note s</a>                           |
| Despatch area (4 trolleys & 2 tugs)                                       | 27.0 | <a href="#">Para 4.162</a> | <a href="#">See Note t</a>                           |
| Despatch area (9 trolleys & 2 tugs)                                       | 35.0 | <a href="#">Para 4.162</a> | <a href="#">See Note t</a>                           |
| Despatch area (35 trolleys & 4 tugs)                                      | 80.0 | <a href="#">Para 4.162</a> | <a href="#">See Note t</a>                           |
| Lobby   | –    | <a href="#">Para 4.164</a> | Optional for off-site service, circulation allowance |
| Canopy  | –    | <a href="#">Para 4.164</a> | Optional for off-site service, external allowance    |
| Loading bay   | –    | <a href="#">Para 4.164</a> | Optional for off-site service, external allowance    |
| Support facilities: Miscellaneous   |      |                            |  |
| Housekeeping room (General area domestic services)                        | 7.0  | <a href="#">Para 4.232</a> |  |
| Housekeeping room (Wash room domestic services)                           | 7.0  | <a href="#">Para 4.48</a>  | En-suite to Wash room                                |
| Housekeeping room (IAP room domestic services)                            | 7.0  | <a href="#">Para 4.94</a>  | En-suite to IAP room                                 |
| General waste disposal/laundry returns                                    | 10.0 | <a href="#">Para 4.237</a> |  |
| General waste disposal/laundry returns                                    | 15.0 | <a href="#">Para 4.237</a> |  |
| Test equipment and data room  | 15.0 | <a href="#">Para 4.248</a> |  |
| Support facilities: Engineering   |      |                            |  |
| Plant room/switchgear room  | –    | <a href="#">Para 6.15</a>  | Area project-specific                                |
| Computer hub room   | 9.0  | <a href="#">Para 4.206</a> |  |

## STERILE SERVICES DEPARTMENT: EXAMPLE SCHEDULES

| Department comprising  | 2 single chamber<br>(10 Din baskets)<br>washer/disinfectors<br>2 packing stations<br>2 x 0.6 m <sup>3</sup> sterilizers |      |            | 2 multi-chamber<br>(3 x Din baskets)<br>washer/disinfectors<br>10 packing stations<br>3 x 0.6 m <sup>3</sup> sterilizers |       |            | 7 multi-chamber<br>(3 x Din baskets)<br>washer-disinfectors<br>30 packing stations<br>9 x 0.6 m <sup>3</sup> sterilizers |       |            |
|--|---|------|------------|--|-------|------------|--|-------|------------|
|  | Qty   | Area | Total Area | Qty  | Area  | Total Area | Qty  | Area  | Total Area |
| <b>Entrance &amp; reception facilities</b>   |   |      |            |  |       |            |  |       |            |
| Entrance area (Staff & visitors)   | 1   | –    | –          | 1  | –     | –          | 1  | –     | –          |
| Entrance area (Supplies)   | 1   | –    | –          | 1  | –     | –          | 1  | –     | –          |
| Reception/waiting area   | 1   | 9.0  | 9.0        | 1  | 9.0   | 9.0        | 1  | 9.0   | 9.0        |
| <b>Contaminated returns facilities</b>   |   |      |            |  |       |            |  |       |            |
| Contaminated returns lobby: 4 trolleys   | 1   | 8.0  | 8.0        | –  | –     | –          | –  | –     | –          |
| Contaminated returns lobby: 9 trolleys   | –   | –    | –          | 1  | 18.0  | 18.0       | –  | –     | –          |
| Contaminated returns lobby: 35 trolleys  | –   | –    | –          | –  | –     | –          | 1  | 70.0  | 70.0       |
| Contaminated returns holding area: 4 trolleys  | 1   | 8.0  | 8.0        | 1  | 8.0   | 8.0        | –  | –     | –          |
| Contaminated returns holding area: 6 trolleys  | –   | –    | –          | –  | –     | –          | 1  | 12.0  | 12.0       |
| <b>Equipment/instrument cleaning, disinfecting &amp; drying facilities</b>                       |   |      |            |  |       |            |  |       |            |
| Gowning room: 2/3 places (wash room)   | 1   | 8.0  | 8.0        | 1  | 8.0   | 8.0        | –  | –     | –          |
| Gowning room: 7/9 places (wash room)   | –   | –    | –          | –  | –     | –          | 1  | 16.0  | 16.0       |
| Wash room: 2 single chamber (10 Din baskets) washer/disinfectors                                 | 1   | 54.0 | 54.0       | –  | –     | –          | –  | –     | –          |
| Wash room: 2 multi-chamber (3 x 10 Din baskets) washer/disinfectors                              | –   | –    | –          | 1  | 76.5  | 76.5       | –  | –     | –          |
| Wash room: 7 multi-chamber (3 x 10 Din baskets) washer/disinfectors & automated handling system: | –   | –    | –          | –  | –     | –          | 1  | 259.0 | 259.0      |
| Trolley pass-through wash area (single trolley): 2 washers                                       | 1   | 15.0 | 15.0       | 1  | 15.0  | 15.0       | –  | –     | –          |
| Trolley pass-through wash area (single trolley): 4 washers                                       | –   | –    | –          | –  | –     | –          | 1  | 30.0  | 30.0       |
| Housekeeping room (Wash room domestic services)  | 1   | 7.0  | 7.0        | 1  | 7.0   | 7.0        | 1  | 7.0   | 7.0        |
| <b>Equipment/instrument inspection, assembly &amp; packing facilities</b>                        |   |      |            |  |       |            |  |       |            |
| Gowning room: 2/3 places (IAP room)  | 1   | 10.0 | 10.0       | –  | –     | –          | –  | –     | –          |
| Gowning room: 4/6 places (IAP room)  | –   | –    | –          | 1  | 14.0  | 14.0       | –  | –     | –          |
| Gowning room: 16/18 places (IAP room)  | –   | –    | –          | –  | –     | –          | 1  | 30.0  | 30.0       |
| Materials transfer room  | 1   | 9.0  | 9.0        | 1  | 9.0   | 9.0        | 1  | 9.0   | 9.0        |
| Inspection, assembly and packing room: 2 workstations  | 1   | 54.0 | 54.0       | –  | –     | –          | –  | –     | –          |
| Inspection, assembly and packing room: 10 workstations   | –   | –    | –          | 1  | 104.0 | 104.0      | –  | –     | –          |
| Inspection, assembly and packing room: 30 workstations with automated handling system            | –   | –    | –          | –  | –     | –          | 1  | 254.0 | 254.0      |
| Housekeeping room (IAP room domestic services)   | 1   | 7.0  | 7.0        | 1  | 7.0   | 7.0        | 1  | 7.0   | 7.0        |

| Department comprising   | 2 single chamber<br>(10 Din baskets)<br>washer/disinfectors<br>2 packing stations<br>2 x 0.6 m <sup>3</sup> sterilizers |      |            | 2 multi-chamber<br>(3 x Din baskets)<br>washer/disinfectors<br>10 packing stations<br>3 x 0.6 m <sup>3</sup> sterilizers |      |            | 7 multi-chamber<br>(3 x Din baskets)<br>washer-disinfectors<br>30 packing stations<br>9 x 0.6 m <sup>3</sup> sterilizers |      |            |
|---|---|------|------------|--|------|------------|--|------|------------|
|   | Qty   | Area | Total Area | Qty  | Area | Total Area | Qty  | Area | Total Area |
| <b>Equipment/instrument sterilizing facilities</b>                    |   |      |            |  |      |            |  |      |            |
| Packed product transfer facility                                      | 1   | 9.0  | 9.0        | 1  | 9.0  | 9.0        | 1  | 9.0  | 9.0        |
| Sterilizer loading/unloading area: 2 x 0.6 m <sup>3</sup> sterilizers | 1   | 29.5 | 29.5       | –  | –    | –          | –  | –    | –          |
| Sterilizer loading/unloading area: 3 x 0.6 m <sup>3</sup> sterilizers | –   | –    | –          | 1  | 38.0 | 38.0       | –  | –    | –          |
| Sterilizer loading/unloading area: 9 x 0.6 m <sup>3</sup> sterilizers | –   | –    | –          | –  | –    | –          | 1  | 99.0 | 99.0       |
| Sterilizer plant room: 2 x 0.6 m <sup>3</sup> sterilizers             | 1   | 17.0 | 17.0       | –  | –    | –          | –  | –    | –          |
| Sterilizer plant room: 3 x 0.6 m <sup>3</sup> sterilizers             | –   | –    | –          | 1  | 22.5 | 22.5       | –  | –    | –          |
| Sterilizer plant room: 9 x 0.6 m <sup>3</sup> sterilizers             | –   | –    | –          | –  | –    | –          | 1  | 67.5 | 67.5       |
| Sterilizer cooling area: 2 bays                                       | 1   | 13.0 | 13.0       | –  | –    | –          | –  | –    | –          |
| Sterilizer cooling area: 3 bays                                       | –   | –    | –          | 1  | 14.5 | 14.5       | –  | –    | –          |
| Sterilizer cooling area: 9 bays                                       | –   | –    | –          | –  | –    | –          | 1  | 43.5 | 43.5       |
| <b>Staff support facilities</b>                                       |   |      |            |  |      |            |  |      |            |
| Manager's office  | 1   | 10.5 | 10.5       | 1  | 10.5 | 10.5       | 1  | 10.5 | 10.5       |
| Deputy manager's office   | 1   | 10.5 | 10.5       | 1  | 10.5 | 10.5       | 3  | 10.5 | 31.5       |
| Administrative staff office: 4 places                                 | 1   | 24.0 | 24.0       | 1  | 24.0 | 24.0       | –  | –    | –          |
| Administrative staff office: 5 places                                 | –   | –    | –          | –  | –    | –          | 1  | 30.0 | 30.0       |
| Staff rest room with beverage bay: 5 places                           | 1   | 11.0 | 11.0       | –  | –    | –          | –  | –    | –          |
| Staff rest room with beverage bay: 10 places                          | –   | –    | –          | 1  | 18.0 | 18.0       | –  | –    | –          |
| Staff rest room with beverage bay: 30 places                          | –   | –    | –          | –  | –    | –          | 1  | 45.0 | 45.0       |
| Male staff changing facilities: 5 places                              | 1   | 5.5  | 5.5        | –  | –    | –          | –  | –    | –          |
| Female staff changing facilities: 10 places                           | 1   | 8.0  | 8.0        | –  | –    | –          | –  | –    | –          |
| Male staff changing facilities: 15 places                             | –   | –    | –          | 1  | 10.0 | 10.0       | –  | –    | –          |
| Female staff changing facilities: 20 places                           | –   | –    | –          | 1  | 11.5 | 11.5       | –  | –    | –          |
| Male staff changing facilities: 60 places                             | –   | –    | –          | –  | –    | –          | 1  | 30.0 | 30.0       |
| Female staff changing facilities: 60 places                           | –   | –    | –          | –  | –    | –          | 2  | 30.0 | 60.0       |
| Staff WC  | 2   | 2.0  | 4.0        | 2  | 2.0  | 4.0        | 6  | 2.0  | 12.0       |
| Staff & visitors wheelchair accessible WC                             | –   | –    | –          | –  | –    | –          | 1  | 4.5  | 4.5        |
| Staff wheelchair accessible shower                                    | –   | –    | –          | –  | –    | –          | 1  | 4.5  | 4.5        |
| Staff & visitors wheelchair accessible WC & shower                    | 1   | 6.0  | 6.0        | 1  | 6.0  | 6.0        | –  | –    | –          |
| Staff shower  | 2   | 2.5  | 5.0        | 2  | 2.5  | 5.0        | 3  | 2.5  | 7.5        |
| Seminar/training/library room: 5 places                               | 1   | 14.0 | 14.0       | –  | –    | –          | –  | –    | –          |
| Seminar/training/library room: 10 places                              | –   | –    | –          | 1  | 20.0 | 20.0       | –  | –    | –          |
| Seminar/training/library room: 20 places                              | –   | –    | –          | –  | –    | –          | 1  | 37.5 | 37.5       |
| <b>Support facilities</b>   |   |      |            |  |      |            |  |      |            |
| Raw materials store: Serving 2 x 0.6 m <sup>3</sup> sterilizer units  | 1   | 20.0 | 20.0       | –  | –    | –          | –  | –    | –          |
| Raw materials store: Serving 3 x 0.6 m <sup>3</sup> sterilizer units  | –   | –    | –          | 1  | 30.0 | 30.0       | –  | –    | –          |
| Raw materials store: Serving 9 x 0.6 m <sup>3</sup> sterilizer units  | –   | –    | –          | –  | –    | –          | 1  | 90.0 | 90.0       |

Option to below  
Option to below  
Option to above

| Department comprising   | 2 single chamber<br>(10 Din baskets)<br>washer/disinfectors<br>2 packing stations<br>2 x 0.6 m <sup>3</sup> sterilizers |              |                | 2 multi-chamber<br>(3 x Din baskets)<br>washer/disinfectors<br>10 packing stations<br>3 x 0.6 m <sup>3</sup> sterilizers |                |               | 7 multi-chamber<br>(3 x Din baskets)<br>washer-disinfectors<br>30 packing stations<br>9 x 0.6 m <sup>3</sup> sterilizers |      |                |
|---|---|--------------|----------------|--|----------------|---------------|--|------|----------------|
|   | Activity Space  | Qty          | AreaTotal Area | Qty  | AreaTotal Area | Qty           | AreaTotal Area   | Qty  | AreaTotal Area |
| <b>Support facilities (contd)</b>   |   |              |                |  |                |               |  |      |                |
| Processed products store: Serving 2 x 0.6 m <sup>3</sup> sterilizer units | 1   | 20.0         | 20.0           | –  | –              | –             | –  | –    | –              |
| Processed products store: Serving 3 x 0.6 m <sup>3</sup> sterilizer units | –   | –            | –              | 1  | 30.0           | 30.0          | –  | –    | –              |
| Processed products store: Serving 9 x 0.6 m <sup>3</sup> sterilizer units | –   | –            | –              | –  | –              | –             | 1  | 90.0 | 90.0           |
| Despatch area (4 trolleys & 2 tugs)                                       | 1   | 27.0         | 27.0           | –  | –              | –             | –  | –    | –              |
| Despatch area (9 trolleys & 2 tugs)                                       | –   | –            | –              | 1  | 35.0           | 35.0          | –  | –    | –              |
| Despatch area (35 trolleys & 4 tugs)                                      | –   | –            | –              | –  | –              | –             | 1  | 80.0 | 80.0           |
| Lobby (off-site delivery)   | –   | –            | –              | –  | –              | –             | 1  | –    | –              |
| Canopy  | –   | –            | –              | –  | –              | –             | 1  | –    | –              |
| Loading bay   | –   | –            | –              | –  | –              | –             | 1  | –    | –              |
| Housekeeping room (General area domestic services)                        | 1   | 7.0          | 7.0            | 1  | 7.0            | 7.0           | 1  | 7.0  | 7.0            |
| General waste disposal/laundry returns                                    | 1   | 10.0         | 10.0           | 1  | 10.0           | 10.0          | –  | –    | –              |
| General waste disposal/laundry returns                                    | –   | –            | –              | –  | –              | –             | 1  | 15.0 | 15.0           |
| Test equipment and data room  | 1   | 15.0         | 15.0           | 1  | 15.0           | 15.0          | 1  | 15.0 | 15.0           |
| Plant room/switchgear room  | 1   | –            | –              | 1  | –              | –             | 1  | –    | –              |
| Computer hub room   | –   | –            | –              | –  | –              | –             | 1  | 9.0  | 9.0            |
| <b>Net Allowance</b>  |   |              |                |  |                |               |  |      |                |
|   |   | 455.0        |                | 606.0  |                | 1501.0        |  |      |                |
| 5% Planning Allowance   |   | 23.0         |                | 30.5   |                | 75.0          |  |      |                |
| <b>Total</b>  |   | <b>478.0</b> |                | <b>636.5</b>   |                | <b>1576.0</b> |  |      |                |
| 3% Engineering Allowance  |   | 14.5         |                | 19.0   |                | 47.5          |  |      |                |
| 25% Circulation Allowance   |   | 119.5        |                | 159.0  |                | 394.0         |  |      |                |
| <b>Total Allowance</b>  |   | <b>612.0</b> |                | <b>814.5</b>   |                | <b>2017.5</b> |  |      |                |

#### Optional accommodation

| Activity Space  | Qty | Area  | Gross Area | Para Ref        | Notes  |
|---|-----|-------|------------|-----------------|--|
| Lobby (off-site delivery)   | 1   | –     | –          | Para 4.164      |  |
| Canopy  | 1   | –     | –          | Para 4.164      |  |
| Loading bay   | 1   | –     | –          | Para 4.164      |  |
| Computer hub room   | 1   | 9.0   | 12.0       | –               |  |
| Staff & visitors wheelchair accessible wc                           | 1   | 4.5   | 4.5        | Para 4.7, 4.219 | Optional separate provision                        |
| Staff wheelchair accessible shower                                  | 1   | 4.5   | 4.5        | Para 4.219      | Optional separate provision                        |
| Staff & visitors wheelchair accessible wc & shower                  | 1   | 6.0   | 6.0        | Para 4.219      | Optional combined provision                        |
| Wash room: 7 multi-chamber (3 x 10 Din baskets) washer/disinfectors | 1   | 200.0 | 270.0      | Para 4.30       | Option to provision with automated handling system |
| Inspection, assembly and packing room: 30 workstations              | 1   | 238.0 | 321.5      | Para 4.69       | Option to provision with automated handling system |

**NOTES**

a. 2 m<sup>2</sup> per trolley space including trolley 0.5 m<sup>2</sup> manoeuvring space

|                                    |  |
|------------------------------------|--|
| b. Manual sorting workstations     | 2 x 3.0 m <sup>2</sup> per place = 6.0 m <sup>2</sup>  |
| Manual washing workstation         | 1 x 4.5 m <sup>2</sup> per place = 4.5 m <sup>2</sup>  |
| Single chamber washer/disinfectors | 2 x 6.0 m <sup>2</sup> per place = 12.0 m <sup>2</sup> |
| Handling systems                   | 3 x 4.0 m <sup>2</sup> = 12.0 m <sup>2</sup>           |
| Net Total                          | = 34.5 m <sup>2</sup>                                  |
| Circulation within space & support | 40% = 14.0 m <sup>2</sup>                              |
| Storage                            | 6 m <sup>2</sup> = 6.0 m <sup>2</sup>                  |
| Gross Total                        | = 54.5 m <sup>2</sup>                                  |

|                                    |  |
|------------------------------------|--|
| c. Manual sorting workstations     | 3 x 3.0 m <sup>2</sup> per place = 9.0 m <sup>2</sup>  |
| Manual washing workstations        | 2 x 4.5 m <sup>2</sup> per place = 9.0 m <sup>2</sup>  |
| Multi chamber washer/disinfectors  | 2 x 8.0 m <sup>2</sup> per place = 16.0 m <sup>2</sup> |
| Handling space                     | 3 x 4.0 m <sup>2</sup> = 12.0 m <sup>2</sup>           |
| Net Total                          | = 46.0 m <sup>2</sup>                                  |
| Circulation within space & support | 40% = 18.5 m <sup>2</sup>                              |
| Storage                            | 12.0 m <sup>2</sup> = 12.0 m <sup>2</sup>              |
| Gross Total                        | = 76.5 m <sup>2</sup>                                  |

|                                    |  |
|------------------------------------|--|
| d. Manual sorting workstations     | 8 x 3.0 m <sup>2</sup> per place = 24.0 m <sup>2</sup> |
| Manual washing workstations        | 4 x 4.5 m <sup>2</sup> per place = 18.0 m <sup>2</sup> |
| Multi chamber washer/disinfectors  | 7 x 8.0 m <sup>2</sup> per place = 56.0 m <sup>2</sup> |
| Handling space                     | 7 x 4.0 m <sup>2</sup> = 28.0 m <sup>2</sup>           |
| Net Total                          | = 126.0 m <sup>2</sup>                                 |
| Circulation within space & support | 40% = 50.5 m <sup>2</sup>                              |
| Storage                            | 24.0 m <sup>2</sup> = 24.0 m <sup>2</sup>              |
| Gross Total                        | = 200.5 m <sup>2</sup>                                 |

|                                    |  |
|------------------------------------|--|
| e. Manual sorting workstations     | 8 x 3.0 m <sup>2</sup> per place = 24.0 m <sup>2</sup> |
| Manual washing workstations        | 4 x 4.5 m <sup>2</sup> per place = 18.0 m <sup>2</sup> |
| Multi chamber washer/disinfectors  | 7 x 8.0 m <sup>2</sup> per place = 56.0 m <sup>2</sup> |
| Handling space                     | 7 x 4.0 m <sup>2</sup> = 28.0 m <sup>2</sup>           |
| Automated handling system          | 50% of last 2 items) = 42.0 m <sup>2</sup>             |
| Net Total                          | = 168.0 m <sup>2</sup>                                 |
| Circulation within space & support | Plus 40% = 67.0 m <sup>2</sup>                         |
| Storage                            | 24.0 m <sup>2</sup> = 24.0 m <sup>2</sup>              |
| Gross Total                        | = 259.0 m <sup>2</sup>                                 |

f. Based upon 7.5 m<sup>2</sup> per trolley washer incl. access space etc

|   |  |
|---|--|
| g. General space for support activities etc | = 20.0 m <sup>2</sup>                                  |
| Workstations                                | 2 x 5.0 m <sup>2</sup> per place = 10.0 m <sup>2</sup> |
| Single chamber washer/disinfectors exit     | 2 x 2.0 m <sup>2</sup> per place = 4.0 m <sup>2</sup>  |
| Handling system                             | 3 x 2.0 m <sup>2</sup> per place = 6.0 m <sup>2</sup>  |
| Storage                                     | = 14.0 m <sup>2</sup>                                  |
| Gross Total                                 | = 54.0 m <sup>2</sup>                                  |

|   |   |
|---|---|
| h. General space for support activities etc | = 20.0 m <sup>2</sup>                                   |
| Workstations                                | 10 x 5.0 m <sup>2</sup> per place = 50.0 m <sup>2</sup> |
| Multi-chamber washer/disinfectors exit      | 2 x 2.0 m <sup>2</sup> per place = 4.0 m <sup>2</sup>   |
| Handling system                             | 3 x 2.0 m <sup>2</sup> per place = 6.0 m <sup>2</sup>   |
| Storage                                     | = 24.0 m <sup>2</sup>                                   |
| Gross Total                                 | = 104.0 m <sup>2</sup>                                  |

|   |  |
|---|--|
| i. General space for support activities etc | = 20.0 m <sup>2</sup>                                    |
| Workstations                                | 30 x 5.0 m <sup>2</sup> per place = 150.0 m <sup>2</sup> |
| Multi-chamber washer/disinfectors exit      | 7 x 2.0 m <sup>2</sup> per place = 14.0 m <sup>2</sup>   |
| Handling system                             | 9 x 2.0 m <sup>2</sup> per place = 18.0 m <sup>2</sup>   |
| Storage                                     | = 36.0 m <sup>2</sup>                                    |
| Gross Total                                 | = 238.0 m <sup>2</sup>                                   |

|   |  |
|---|--|
| j. General space for support activities etc | = 20.0 m <sup>2</sup>                                    |
| Workstations                                | 30 x 5.0 m <sup>2</sup> per place = 150.0 m <sup>2</sup> |
| Multi-chamber washer/disinfectors exit      | 7 x 2.0 m <sup>2</sup> per place = 14.0 m <sup>2</sup>   |
| Handling system                             | 9 x 2.0 m <sup>2</sup> per place = 18.0 m <sup>2</sup>   |
| Automated handling system                   | (50% of last 2 items) = 16.0 m <sup>2</sup>              |
| Storage                                     | = 36.0 m <sup>2</sup>                                    |
| Gross Total                                 | = 254.0 m <sup>2</sup>                                   |

k. Area based upon 8.5 m<sup>2</sup> per sterilizer incl. carriage parking plus 2.5 m<sup>2</sup> for administration functions etc.

Test pack conditioning space – 10 m<sup>2</sup> for testing 1 sterilizer at any one time; 20 m<sup>2</sup> for testing 2 sterilizers at any one time



- l. Based upon 5.5 m<sup>2</sup> per sterilizer (equipment & access) plus 6 m<sup>2</sup> per 3 sterilizers for space access & support activities. Additional plant will require additional project specific area allowance
- 
- m. Based upon one carriage parking bay per sterilizer. 1.5 m<sup>2</sup> per sterilizer carriage parking bay plus 10 m<sup>2</sup> per 3 bays for manoeuvring etc.
- 
- n. Based upon 8 m<sup>2</sup> for 2/3 persons using space at any one time with an extra 4 m<sup>2</sup> for each additional 2/3 persons gowning
- 
- o. Based upon 10 m<sup>2</sup> for 2/3 persons using space at any one time with an extra 4 m<sup>2</sup> for each additional 2/3 persons gowning
- 
- p. Number required based upon 1 per 15 staff per sex on duty min 2 (1 male 1 female)
- 
- q. Number required based upon 1 per staff change plus additional for numbers of staff over 30
- 
- r. Area dependent upon collection/work profile. Allowance 10 m<sup>2</sup> per sterilizer
- 
- s. Area dependent upon collection/work profile & storage system. Area based upon mainly short term storage only. Allowance 10 m<sup>2</sup> per sterilizer
- 
- t. Based upon parking trolley approx size 1500 x 750 (1.5 m<sup>2</sup> per trolley space). Plus 15 m<sup>2</sup> for holding distribution boxes, loading & manoeuvring trolleys. Additional area for tug(s) 3.0 m<sup>2</sup> per tug Garaging/battery charging for battery powered vehicles
-

# Appendix 1 – Environmental needs

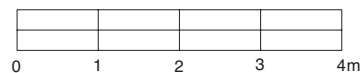
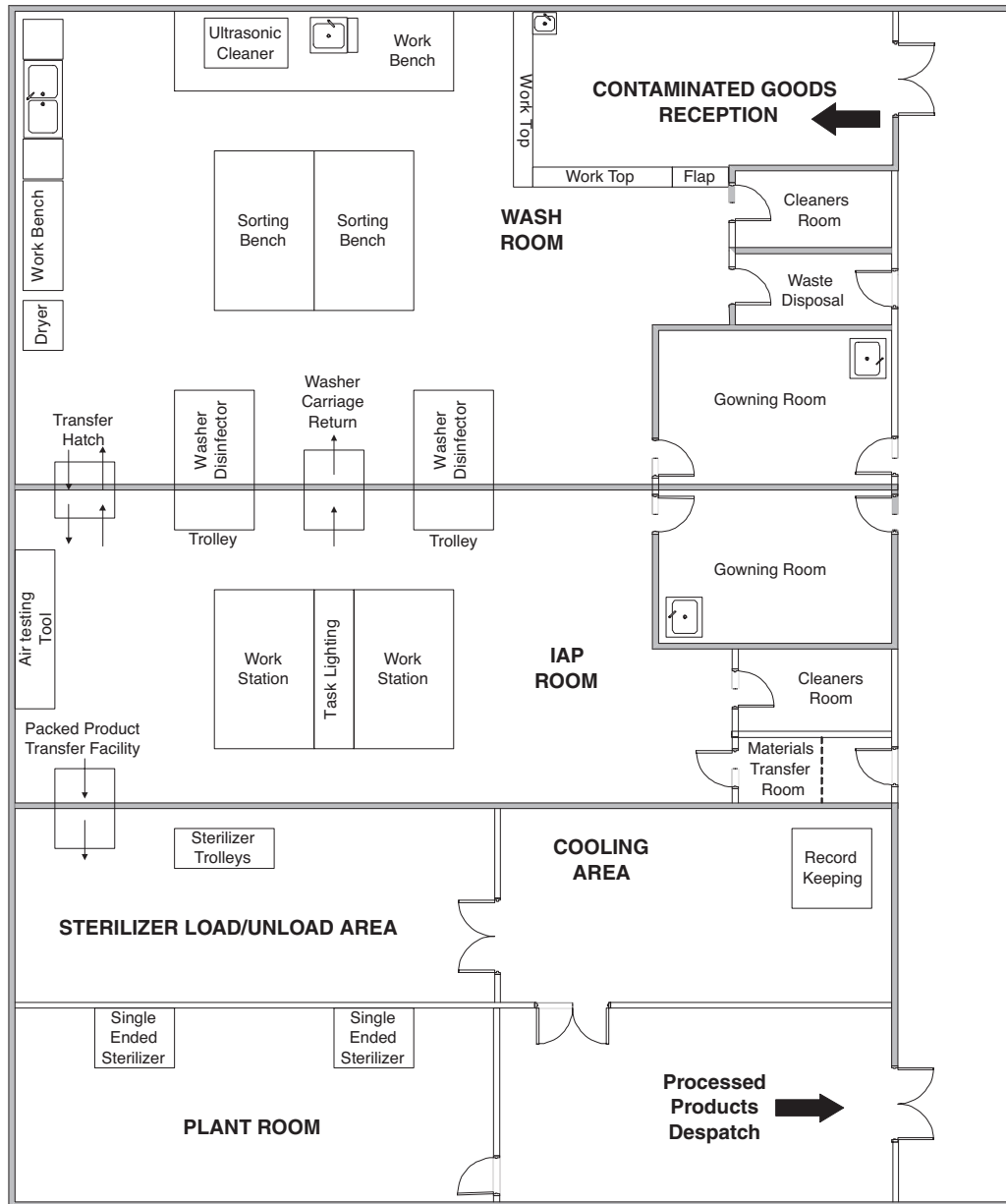
---

- 1.** The table opposite shows the likely minimum requirement for mechanical ventilation, windows, task lighting, and wall and door protection. Individual buildings may need these in other spaces, according to the building design (for example, when a room which would normally be naturally ventilated has no external wall, mechanical ventilation may be required).
- 2.** Mechanical ventilation is recommended in spaces where openable windows are unacceptable or for extraction of steam and heat from machines.
- 3.** The need for windows is greater in some spaces than others. Also, windows are a disadvantage in certain spaces. Recommendations are given where windows are not admissible. Unopenable windows must be completely sealed and airtight. Window frames without ledges and joints, where dust could collect, are mandatory in clean-rooms, and are preferable wherever unopenable windows are provided.

|  | Windows                 |           |               |                 |                            |                                 |                        |
|--|-------------------------|-----------|---------------|-----------------|----------------------------|---------------------------------|------------------------|
|  | Need for windows        |           |               |                 |                            | Other needs                     |                        |
|  | Essential and with view | Desirable | Not essential | Not recommended | If provided must be sealed | Wall & door protection required | Task lighting required |
| Entrance area                          |                         | ✓         | ✓             |                 |                            | ✓                               |                        |
| Contaminated returns lobby             |                         |           | ✓             |                 | ✓                          | ✓                               |                        |
| Contaminated returns holding area      |                         | ✓         | ✓             |                 | ✓                          | ✓                               |                        |
| Wash room: gowning area                |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| Wash room                              | ✓                       | ✓         |               |                 | ✓                          | ✓                               | ✓                      |
| Wash room: domestic services room      |                         |           | ✓             |                 | ✓                          | ✓                               |                        |
| IAP gowning room                       |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| IAP room                               | ✓                       | ✓         |               |                 | ✓                          | ✓                               | ✓                      |
| IAP domestic services room             |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| Materials transfer room                |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| Packed product transfer facility       |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| Sterilizer loading area                |                         | ✓         | ✓             |                 | ✓                          | ✓                               |                        |
| Sterilizer plant room                  |                         | ✓         | ✓             |                 |                            | ✓                               |                        |
| Unloading/cooling area                 |                         | ✓         | ✓             |                 | ✓                          | ✓                               |                        |
| Processed products store               |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| Despatch area                          |                         | ✓         | ✓             |                 |                            | ✓                               |                        |
| Materials store                        |                         | ✓         | ✓             |                 | ✓                          | ✓                               | ✓                      |
| Manager's office                       |                         | ✓         | ✓             |                 |                            |                                 |                        |
| Deputy manager's office                |                         | ✓         | ✓             |                 |                            |                                 |                        |
| Office(s): general                     |                         | ✓         | ✓             |                 |                            |                                 |                        |
| Staff room                             |                         | ✓         | ✓             |                 |                            |                                 |                        |
| Staff changing/WC/shower room          |                         |           |               | ✓               |                            | ✓                               | ✓                      |
| Training room                          |                         | ✓         | ✓             |                 |                            |                                 | ✓                      |
| General areas: domestic services room  |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| General waste disposal/laundry returns |                         |           |               | ✓               | ✓                          | ✓                               |                        |
| Test equipment and data room           |                         | ✓         | ✓             |                 | ✓                          | ✓                               | ✓                      |

# Appendix 2 – Layout diagrams

## SMALL DECONTAMINATION FACILITY



The above diagram/footprint provides a potential layout for a small decontamination facility. No sizes have been suggested for the washer disinfectors nor the sterilizers, as these are required to be determined by the workload to be reprocessed within the unit. The Capacity Planning Tool, issued on a CD-Rom with this Health Building Note, will assist in determining the most appropriate size of decontamination equipment for the throughput.

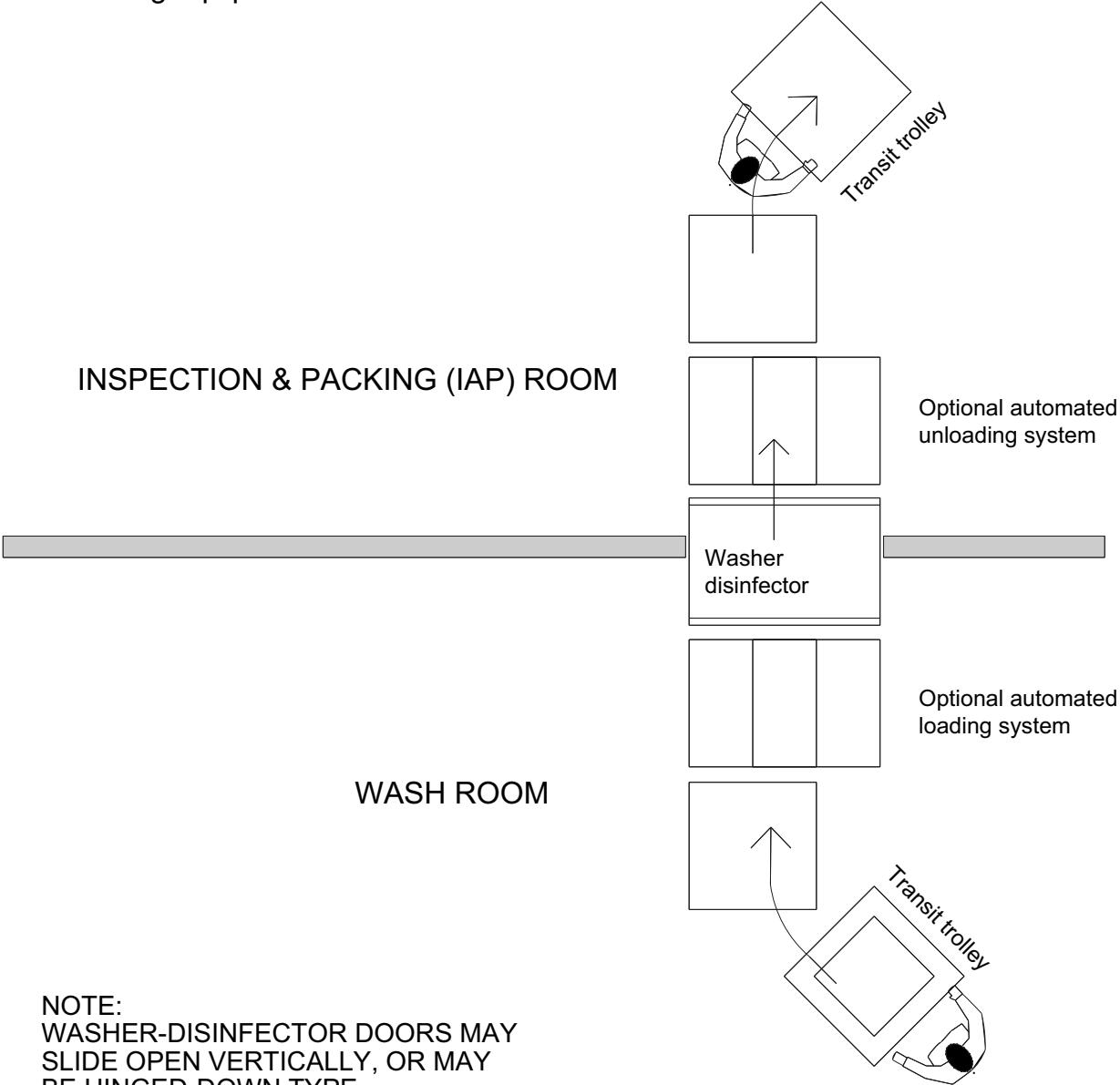
It is not intended that this unit be built as a stand-alone facility, but seen as part of a larger building design. The layout shows the main production areas, which need to be supported by adjoining facilities for staff changing, bulk store for raw materials and office accommodation as required.

The layout has adhered to the standard footprint of a stand-alone Sterile Services Department (SSD) detailed in this Health Building Note, with similar room relationships (with the exception of those identified above), clean and dirty flows, etc. All other functional and design requirements should be applied to its construction.

NOTE: Air tool testing, shown in the above diagram as being located in the IAP room, could alternatively be located in the wash room.

**TYPE I WASHER-DISINFECTOR**

Through-wall installation; with associated load-handling equipment

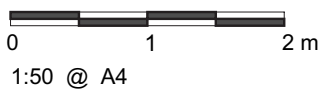
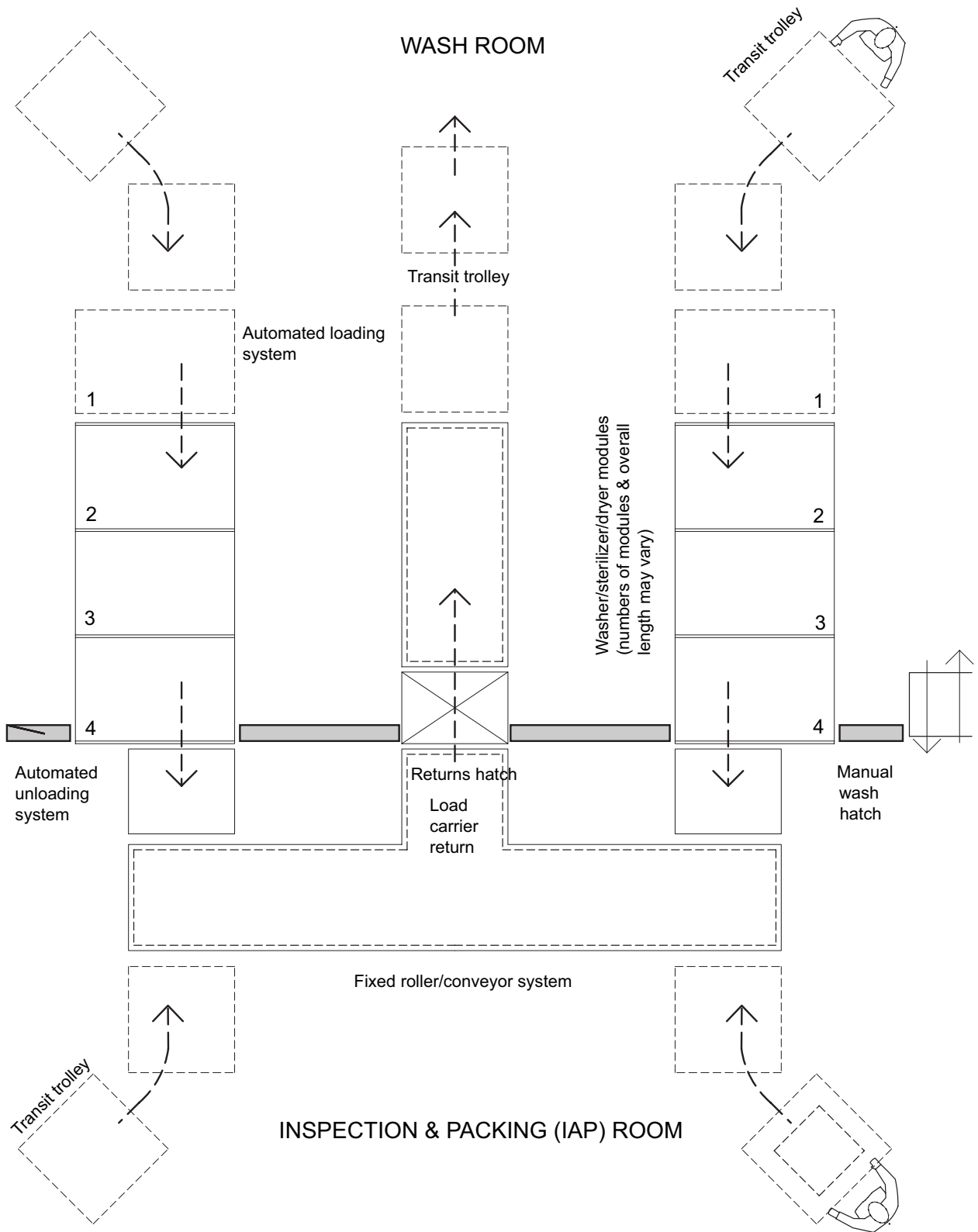


NOTE:  
WASHER-DISINFECTOR DOORS MAY  
SLIDE OPEN VERTICALLY, OR MAY  
BE HINGED-DOWN TYPE



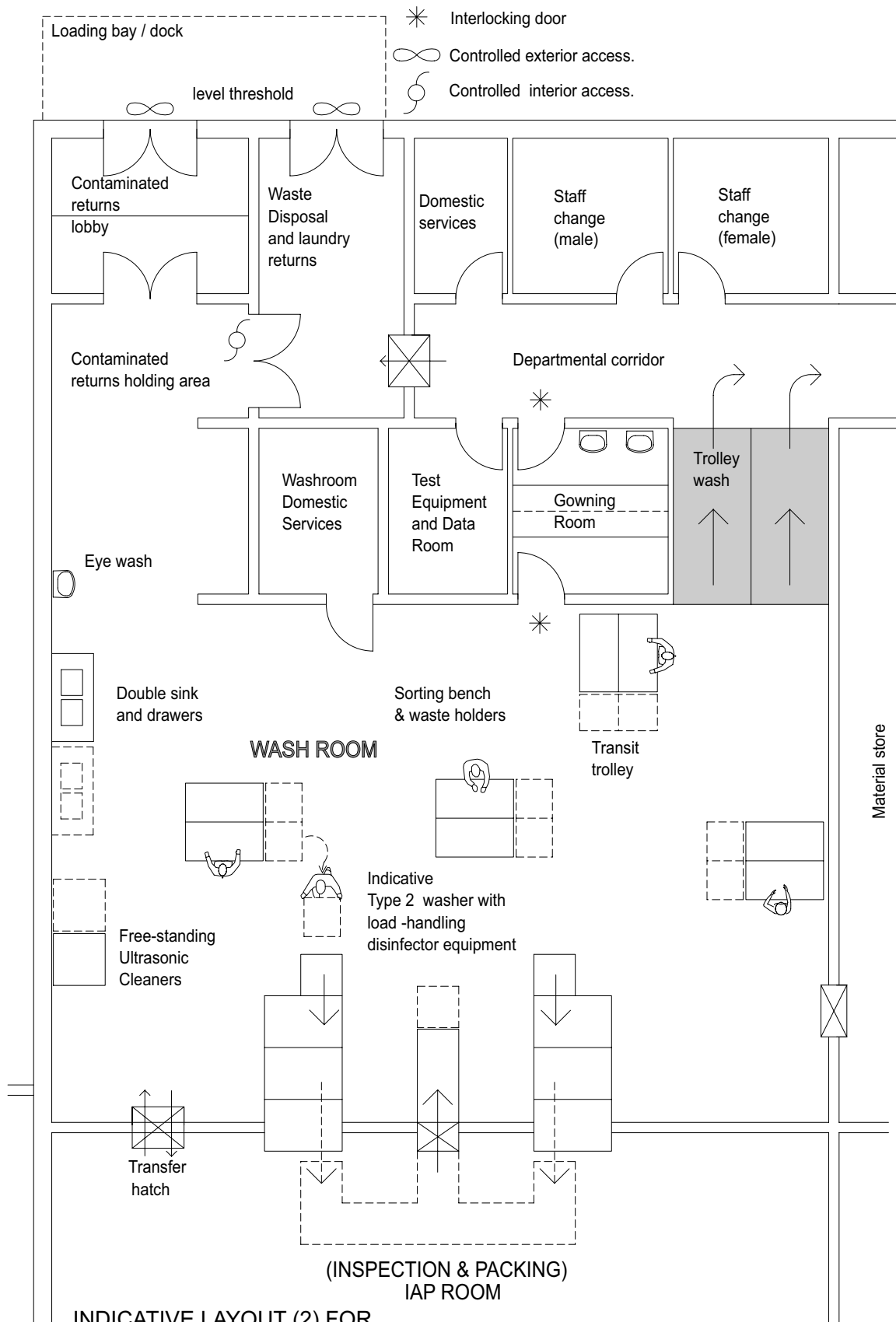
1:50 @ A4

**TYPE II WASHER-DISINFECTOR**

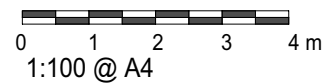


Indicative arrangement showing paired washer/ disinfector/dryer assemblies, with associated load-handling systems

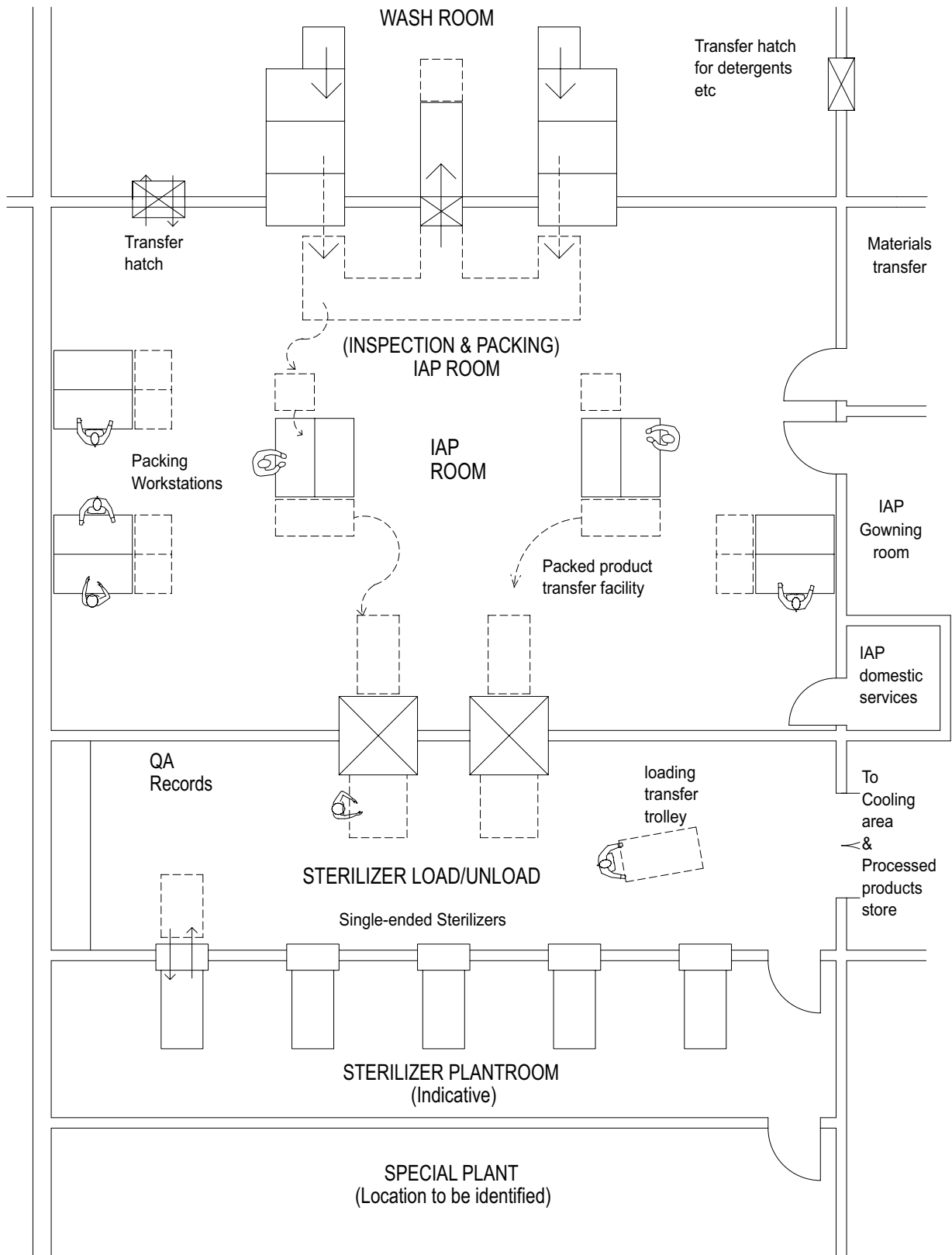
**WASH ROOM AND ADJACENT AREAS**



**INDICATIVE LAYOUT (2) FOR WASH ROOM & ADJACENT AREAS:**  
 showing Type 2 washer-disinfectant



**IAP ROOM AND STERILIZER LOADING/UNLOADING AREA**



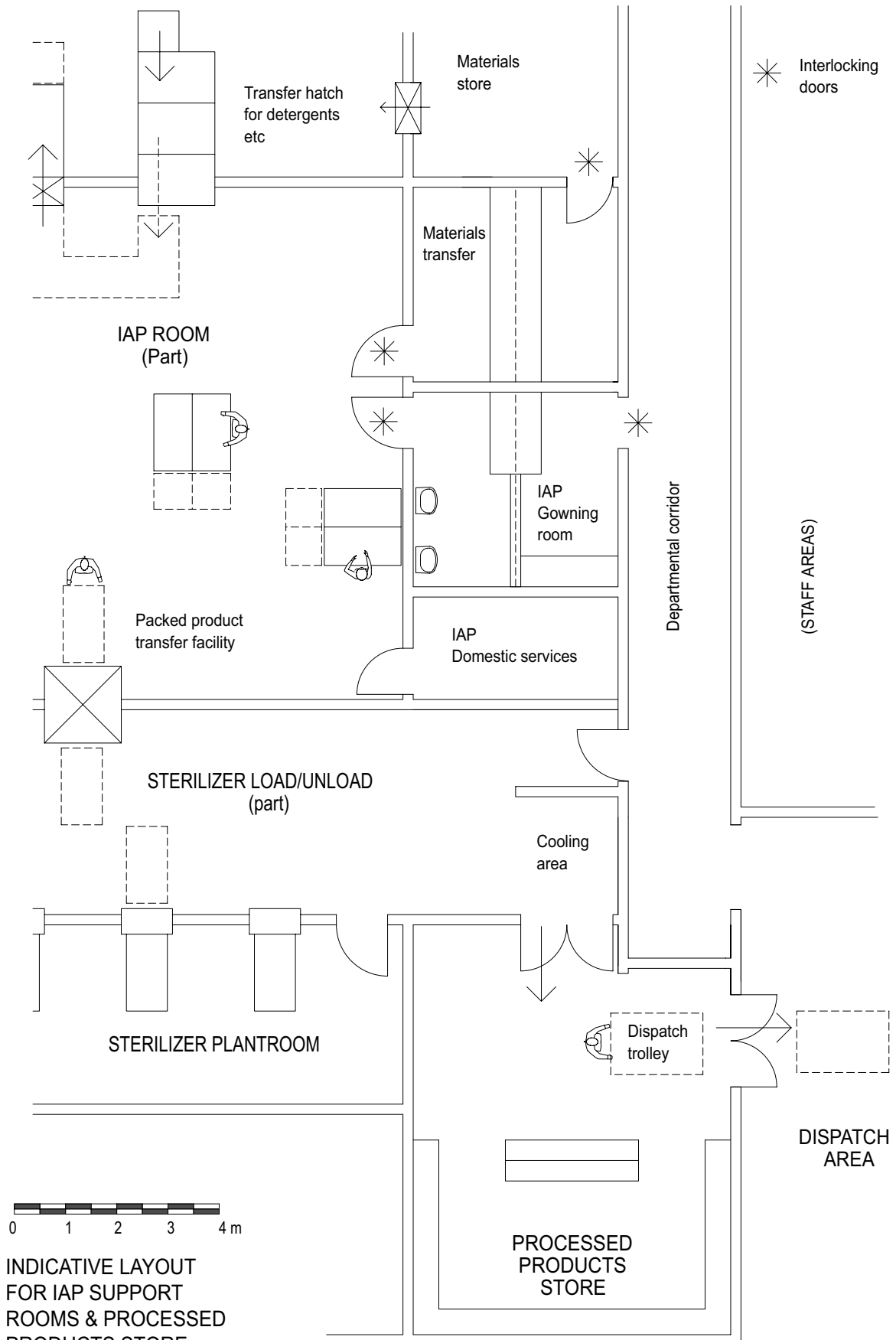
INDICATIVE LAYOUT FOR IAP ROOM & STERILIZER LOAD/UNLOAD showing single-ended sterilizers



1:100 @ A4



**IAP SUPPORT ROOMS AND PROCESSED PRODUCTS STORE**



INDICATIVE LAYOUT  
FOR IAP SUPPORT  
ROOMS & PROCESSED  
PRODUCTS STORE  
1:100 @ A4

## Appendix 3 – Recommended finishes

| Schedule of recommended finishes       | Floors               |                      |                  | Walls                |                      |                  | Ceilings             |                      |                  |
|--|----------------------|----------------------|------------------|----------------------|----------------------|------------------|----------------------|----------------------|------------------|
|  | Recommended finishes | Performance category | Cleaning routine | Recommended finishes | Performance category | Cleaning routine | Recommended finishes | Performance category | Cleaning routine |
| Entrance areas and corridors           | SW                   | 3                    | C                | EM/ES                | 5                    | C                | M                    | 4                    | C                |
| Contaminated returns lobby             | ESR                  | 4                    | B                | SEV                  | 2                    | B                | I                    | 2                    | B                |
| Contaminated returns holding area      | ESR                  | 4                    | B                | SEV                  | 2                    | B                | I                    | 2                    | B                |
| Wash room: gowning area                | SW                   | 3                    | D                | SEV/ES               | 5                    | C                | 1                    | 3                    | C                |
| Wash room                              | ESR                  | 4                    | B                | SEV                  | 2                    | B                | I                    | 2                    | B                |
| Wash room: domestic services room      | SW                   | 2                    | C                | ES                   | 5                    | B                | MP                   | 3                    | C                |
| IAP gowning room                       | SW                   | 3                    | D                | SEV/ES               | 5                    | C                | 1                    | 3                    | C                |
| IAP room                               | SW/IS                | 2                    | *                | SEV                  | 3                    | *                | Special              | 1                    | *                |
| IAP domestic services room             | SW                   | 2                    | C                | ES                   | 5                    | B                | MP                   | 3                    | C                |
| Materials transfer room                | SW                   | 3                    | D                | ES/OE                | 5                    | C                | MP                   | 3                    | C                |
| Sterilizer loading area                | SW/IS                | 3                    | D                | SEV/ES               | 5                    | C                | I/MP                 | 3                    | C                |
| Sterilizer plant room                  | SW/IS                | 3                    | D                | OE                   | 5                    | D                | –                    | –                    | D                |
| Unloading/cooling area                 | SW/IS                | 3                    | D                | SEV/ES               | 5                    | C                | I/MP                 | 3                    | C                |
| Processed products store               | SW                   | 3                    | D                | ES/OE                | 5                    | C                | MP                   | 3                    | C                |
| Despatch area                          | SW/IS                | 3                    | D                | SEV/ES               | 5                    | C                | I/MP                 | 3                    | C                |
| Materials store                        | SW                   | 3                    | D                | ES/OE                | 5                    | C                | MP                   | 3                    | C                |
| Manager's office                       | T4                   | 6                    | E                | EM/WS                | 6                    | D                | M                    | 6                    | D                |
| Deputy manager's office                | T4                   | 6                    | E                | EM/WS                | 6                    | D                | M                    | 6                    | D                |
| Office(s): general                     | T4                   | 6                    | E                | EM/WS                | 6                    | D                | M                    | 6                    | D                |
| Staff room                             | T4                   | 6                    | E                | EM/WS                | 6                    | D                | M                    | 6                    | D                |
| Staff changing                         | SW/T4                | 5/6                  | C/E              | ES                   | 5                    | C                | MP                   | 5                    | C                |
| Lockers                                | SW                   | 3                    | C                | ES                   | 5                    | C                | M                    | 4                    | C                |
| Shower/disabled WC                     | ESR                  | 4                    | B                | OE/SEV               | 4                    | C                | MP                   | 2                    | C                |
| Training room                          | T4                   | 6                    | E                | EM/WS                | 6                    | D                | M                    | 6                    | D                |
| General areas: domestic services room  | SW                   | 2                    | C                | ES                   | 5                    | B                | MP                   | 5                    | C                |
| General waste disposal/laundry returns | SW                   | 2                    | C                | OE                   | 3                    | B                | M                    | 5                    | C                |
| Test equipment and data room           | SW                   | 3                    | D                | ES/OE                | 5                    | C                | MP                   | 3                    | C                |

A selection of finishes suitable for use in a sterile services department is shown in the table above. These should be read in conjunction with NHS Estates' HTM 61: 'Flooring' (for floor finishes); HTM 56: 'Partitions' (for wall finishes); and HTM 60: 'Ceilings' (for ceiling finishes). These documents propose performance categories for finishes and set out cleaning routines for which the

finishes are suitable. Suggested performance categories and cleaning routines are listed for each space. An asterisk shows that cleaning schedules are to be determined locally.

**Notes:**

*Floor finishes:*

SW = pvc sheet with welded joints

IS = *in situ* – resin-bonded flooring (see HTM 61 paragraphs 3.13 and 3.34)

ESR = slip resistant pvc sheet with welded joints or slip-resistant resin-based flooring (see paragraphs 3.13 and 3.34)

T4 = Textile (that is, carpet) heavy domestic/general contract grade

**Note:** other finishes shown in HTM 61 within these categories may not be suitable.

Resin-bonded floor finishes are recommended for use on rigid floor slabs but not on floor slabs which deflect when loaded.

Skirtings should be coved and integral with or welded to the floor finish, except where textile floor finishes are used, when a wood skirting is appropriate.

## Appendix 4 – Glossary of terms

**Adventitious contamination:** The accidental introduction of environmental micro-organisms onto a medical device or product.

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

**Class 8 standard:** Inspection, assembly and packaging (IAP) rooms are classified by the cleanliness of their air. This is done according to BS EN ISO 14644-1. The maximum permitted airborne concentration of particles, that is the class limit, can be calculated for any given particle size. Shown in the table below are the classes selected by ISO 14644-1 to illustrate class limits. IAP rooms shall be to ISO Class 8.

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

**Medical device:** Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; and control of conception: and

| ISO Classification number | Maximum concentration limits (particles/m <sup>3</sup> of air) for particles equal to and larger than the considered sizes shown below |          |          |            |           |          |
|---------------------------|--|----------|----------|------------|-----------|----------|
|                           | = 0.1 µm   | = 0.2 µm | = 0.3 µm | = 0.5 µm   | = 1 µm    | = 5.0 µm |
| ISO Class 1               | 10   | 2        |          |            |           |          |
| ISO Class 2               | 100  | 24       | 10       | 4          |           |          |
| ISO Class 3               | 1000   | 237      | 102      | 35         | 8         |          |
| ISO Class 4               | 10,000   | 2370     | 1020     | 352        | 83        |          |
| ISO Class 5               | 100,000  | 23,700   | 10,200   | 3520       | 832       | 29       |
| ISO Class 6               | 1,000,000  | 237,000  | 102,000  | 35,200     | 8320      | 293      |
| ISO Class 7               |  |          |          | 352,000    | 83,200    | 2930     |
| ISO Class 8               |  |          |          | 3,520,000  | 832,000   | 29,300   |
| ISO Class 9               |  |          |          | 35,200,000 | 8,320,000 | 293,000  |

In the case of Class 8, the particle counts are not to be exceeded when measured at rest in the “unmanned condition”. To achieve a Class 8 environment, it is not envisaged that a HEPA filter (see paragraph 6.42) would be required.

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

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

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

which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC)

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

**Particulate:** Minute portions of matter which may cause contamination.

**Phaco:** Ultrasonic instrument used in ophthalmology.

**Porous-load steam sterilizer:** A clinical sterilizer designed to process, by exposure to high temperature steam under pressure, porous items such as towels, gowns and dressings, and also medical devices that are wrapped in porous materials such as paper or fabrics.

**Sterile:** Free from viable micro-organisms, including bacterial spores and viruses.

**Sterilization:** A process undertaken to render a load sterile.

**Sterilizer:** An apparatus designed to achieve sterilization. (See also **Porous-load sterilizer**.)

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

**Validation:** A documented procedure for gathering and interpreting data to show that the machine (that is sterilizer, washer-disinfector) complies with the manufacturer's specification and that it is capable of processing a product consistently, when used according to the manufacturer's instructions.

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

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

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**Factories Act 1961**, HMSO, London.

**Factories Act (Northern Ireland) 1965** (1965 c.20 (NI)).

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**Health & Safety at Work (Northern Ireland) Order 1978**.

**Health and Safety (Display Screen Equipment) Regulations 1992**, SI 1992 No 2792, HMSO, 1992.  
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[http://www.hmso.gov.uk/si/si1992/Uksi\\_19923004\\_en\\_1.htm](http://www.hmso.gov.uk/si/si1992/Uksi_19923004_en_1.htm)

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## BRITISH STANDARDS

### BS 4533

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

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