NHS National Services Scotland

Scottish Health Planning Note 13 Part 1

Decontamination Facilities:

Central Decontamination Unit

Health Facilities Scotland
Engineering and Environment

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Contents

Executive summary

This Planning Note provides guidance to help plan and design a new or an upgrade to a Central Decontamination Unit (CDU) in a controlled manner as required by the quality management system standard BS EN ISO 13485.

Within this Planning Note there are Sections covering general considerations (including CDU operational policies), general functional and design requirements and engineering services. Appendix 1 contains Room Data Sheets (RDS) and Appendix 2 is a Glossary of Terms.

The document provides clear, user friendly guidance to multi-disciplined professionals operating within a design team. Hence the majority of the guidance is presented within room data sheets. The Glossary of Terms provides a full explanation of the terms or processes described in this Executive Summary.

The Planning Note presents a CDU model described by 39 room data sheets and a single site data sheet. When a new build is proposed the CDU model is applicable; when an upgrade is proposed, the room data sheets are applied to the existing or modified facility layout.

Each of the room data sheets comprises guidance including specifications on design, finishes, mechanical and electrical and equipment/furniture/fittings.

The design page of each room data sheet takes the reader through a number of questions to provide further information to inform the design. This is intended to help generate a complete set of site specific room data sheets which will be required as part of the Validation Master Plan (VMP) process.

Input from other documents, such as the User Requirement Brief (URB) within the business case, is required in order that the rooms described by their RDS can be scaled to meet the specified production throughput.

Ultimately the size of the CDU model for a new build or the modified facility layout for an upgrade and their site is dependent on the design production capacity.

1. Introduction

1.1 This Scottish Health Planning Note (SHPN) provides information to assist individuals and organisations to make informed decisions about the provision of sterile services from a Central Decontamination Unit (CDU). It replaces Scottish Hospital Planning Note 13: 'Sterile services departments' published in 1994. A survey carried out by Health Facilities Scotland indicated that in 2010 over 50 million instruments were processed through healthboard managed CDUs.

All new build and upgrading of CDUs will require to be validated in accordance with the requirements of the quality management system BS EN ISO 13485. There should be a Validation Master Plan (VMP) for the project which will define the qualification exercises required for the design, installation, operation and performance of the facility. The design qualification requires input by way of a clear User Requirement Brief that is prepared during the Business Case development. Ensuring compliance with the VMP, which is generated and approved by the design team, is critical to the delivery of a CDU that is fit for its intended purpose. The requirement for a VMP and the resulting resources required should be made clear to those responsible for producing the business case. Refer to the Scottish Capital Investment Manual (SCIM) Business Case Guide which is now available online. It should be noted that this Planning Note (SHPN 13 part 1) sets the design quality objectives for the CDU. A risk assessment should be carried out to inform the CDU design which will include the consideration of the need for duplex systems. At an early stage in this exercise the design team should review the report 'Central Decontamination Unit-Risks and Contingency Arrangements' 2007 available from Health Facilities Scotland. The assembly of a competent design team with a clear understanding of their individual and collective responsibility in producing a CDU fit for purpose is key to the overall project delivery.

Note: How to use this document. When planning a new build - with the CDU model layout (Figure 1), the site layout (Figure 2), the Site Data Sheet and the Room Data Sheets the members of the project design team are prompted to seek and provide information. When planning an upgrade (see glossary of terms for definition) – the Room Data Sheets are applied by the project design team to the existing or modified facility layout. This is in order that the rooms can be scaled and the associated equipment/furniture/fittings specified to deliver a CDU that meets their specified production throughput requirements as per their business case rationale. Each Room Data Sheet has a unique reference number which corresponds with that in the CDU model layout (Figure 1). The Room Data Sheets provide guidance on Design, Finishes, Mechanical & Electrical and Equipment/Furniture/Fittings. General considerations are covered in Sections 2 and 3 with engineering services in Section 4.

1.2 The Sterile Services Provision Review Group report - 'The Glennie Report', published under cover of HDL(2001)66 in August 2001 set out a framework for change, specifically related to the technical and operational requirements for

decontamination of reusable medical devices. The Technical Requirements for re-processing of devices were based on the potential risk for transmission of CJD for the particular tissue with which a device is in contact during use. This risk was categorised at three risk levels (high, medium and low). The decontamination of devices categorised as 'high' or 'medium' risk must be undertaken in an accredited central decontamination unit (CDU). It is also a specific requirement that the decontamination of reusable medical devices used in clinical procedures undertaken in all acute hospitals, dental hospitals/schools/institutes must be undertaken in an accredited CDU.

Local Decontamination Units, which can only reprocess devices categorised as 'low' CJD transmission risk, and Endoscopy Decontamination Units, which reprocess heat labile endoscopes, are dealt with in Parts 2 and 3 of SHPN 13.

Surgical instruments and their accessories are classified as medical devices* under the Medical Devices Directive (93/42/EEC) and amendments. Included within the essential requirements are the undernoted:

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

* **Medical Device:** "Any instrument, apparatus, appliance or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of or compensation for and injury or handicap; investigation, replacement of part of the anatomy or a physiological process; and control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means". *Ref*: *Abbreviated from the Medical Device Regulations 2002*.

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

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

  - outwith the hospital complex; or
- obtain services from a third party.

Note: Local authority planners and building control agencies will consider most CDUs as a 'Factory' therefore location zoning will have significant influence over planning approval applications. Upgrades of existing facilities may require use of other accommodation whilst refurbishment works are in progress.

1.4 This guidance does not indicate the space requirements for a CDU to deliver a specified production throughput. The Room Data Sheets provide guidance to consider when designing the decontamination unit to meet production requirements. The model CDU layout shown in this guidance requires to be scaled to meet individual production throughput requirements. The model layout describes a stand alone facility; this could be on a separate dedicated site or within hospital grounds.

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

A risk assessment should be carried out to inform the CDU design. This will include the consideration of the need for duplex systems. For all practical design intent whether the CDU is to be located within or external to a hospital complex it should be designed to exist and function as a self reliant facility. At an early stage in this exercise the design team should review the report 'Central Decontamination Unit-Risks and Contingency Arrangements' 2007. An estimate of the intended workload covering trauma/urgent surgery, elective/non-urgent surgery, maternity, primary care, private sector and wards/clinics should be detailed in the design rationale. This will inform the design rationale when considering the impact of production downtime. The report details reasons why CDUs have had to make use of contingency arrangements with other CDUs. These have included utilities failure, Reverse Osmosis (RO) plant failure, upgrading of CDU, staffing problems, breakdown of sterilizer or washer disinfector, steam problems, waiting times initiatives, capacity issues and clean steam generator problems.

The principle of designing in duplex systems and back-up systems for critical plant/services to minimise production downtime should be considered. This should include water, RO water, steam, clean steam, electricity/gas, compressed air, HVAC, decontamination equipment and IT systems. Note, systems have been sold as 'duplex' but still share common elements, e.g. control panels or storage tanks. The health organisation needs to carefully evaluate and risk assess not only the security of supplies but also capacity, condition and remaining life of the hospital services infrastructure. Existing hospital services may be unable to satisfy or cope with the demands of modern CDU facilities. The design team and those responsible for the business case should be clear that an accurate specification of the production throughput is

critical to ensuring an underprovision or overprovision is avoided. The size of the CDU facility, i.e. the building and its site, the engineering services and the equipment required in both capital and revenue terms will be considerable.

Note: Planning and design should include input from relevant experts including those involved in decontamination, engineering, building and design (including cleanroom design), service users and suppliers of specialised equipment. Capacity planning and the option appraisal exercises have not been addressed in detail in this document. Throughput calculations taking account of any future needs will be required in order that the size of the facility can be determined.

Accommodation schedule

1.6 The following areas within the CDU, along with a Site Data Sheet, are described in this Planning Note.

Reference number (as used in the Room Data Sheets and the model layout in Figure 1)	Room/ Area Description
1	Cart Wash Load Area
2	Cart Wash Plant Area
3	Cart Wash Unload Area
4	CDU Manager's Office
5	Contaminated Returns Lobby
6	Cooling Area
7	Communications Room
8	Deputy CDU Manager's Office
9	Dispatch
10	Entrance Staff/Visitors
11	Estate Manager's Office
12	First Aid Room
13	General/Clinical Waste Disposal Area
14	General Corridor
15	General Areas Domestic Services Room
16	General Plant Room
17	Inspection, Assembly and Packing (IAP) Room
18	IAP Room: Gowning Room
19	IAP Room: Domestic Services Room
20	IAP Materials Transfer Room
21	Maintenance Manager's Office
22	Materials Store
23	Office

Reference number (as used in the Room Data Sheets and the model layout in Figure 1.)	Room/ Area Description
24	Processed Products Store
25	Quality Manager's Office
26	Wash Room: Gowning Room
27	Wash Room
28	Wash Room: Domestic Services Room
29	Sterilizer Plant Room
30	Sterilizer Unload Area
*30A	Sterilizer Load and Unload Area
31	Staff Changing Room(s)
32	Staff Room
33	Technicians Room
34	Test Equipment Room
35	Training Room
36	Vehicle Loading Bay
37	Vehicle Wash Area
38	Wash Room Materials Transfer Room
39	WC

* this room (30A) is not applicable to the CDU model in Figure 1.

CDU activities

1.7 The primary production activities undertaken by a CDU may include:

- disassembly, cleaning and disinfection of instruments, trays, utensils, containers and other items able to be reprocessed which have been used in clinical procedures carried out in operating theatres, treatment rooms, etc;
- inspection, assembly, functionality testing and packaging of supplementary instruments, instrument trays and packs;
- sterilization of supplementary instruments, instrument trays and packs;
- product release including disinfected devices where this is the required level of decontamination and sterile products;
- storage of raw materials/components prior to assembly into instrument trays/packs;
- storage of goods processed in the department until they are ready for transfer to point of use;
- collection of used items and distribution of sterile products;

- storage of single use products as emergency stock in the event of significant production downtime. Given a fixed shelf life for these products a risk assessment is required to determine if the investment is worthwhile.

Support activities could include:

- management of waste including recycling;
- traffic management on site.

Capital Investment/Business Case

1.8 This SHPN provides information to assist individuals and organisations make informed decisions on the provision of decontamination services from a CDU. The Scottish Capital Investment Manual (SCIM) has been prepared by the Scottish Government Health Directorate. This investment manual creates a framework within which NHS Boards can plan, develop, procure and manage their infrastructure projects effectively and efficiently. The guidance within the manual is mandatory (as stated in letter CEL 19(2009)) and must be followed by all NHSScotland bodies. The SCIM is now only available online. The healthcare organisation is required to complete and submit for approval to the government, full and robust scheme proposals that will outline the project planning strategy together with probable and actual costs projections from project inception to completion. The client body will therefore have the responsibility for creating the briefing information and resources to prepare the scoping outline, the management strategy required for the actions, personnel and funding to enable the Outline Business Case (OBC) to be prepared. Healthcare organisations may engage the services of external consultants to assist with the feasibility studies and provide probable costs associated with the formation of the CDU. It should be noted that this initial exercise will be considered as independent from the procurement process associated with building a design team. The Outline Business Case will need to identify, cost and evaluate a number of options within the option appraisal exercise. Typical options that can feature include:

- do nothing;
- new-build within an existing healthcare site;
- refurbishment within an existing healthcare site;
- new build outwith a healthcare environment;
- refurbishment of existing building outwith healthcare environment;
- long term lease hire 20/25 years of an existing factory building for adaption;
- contract the services of a third party.

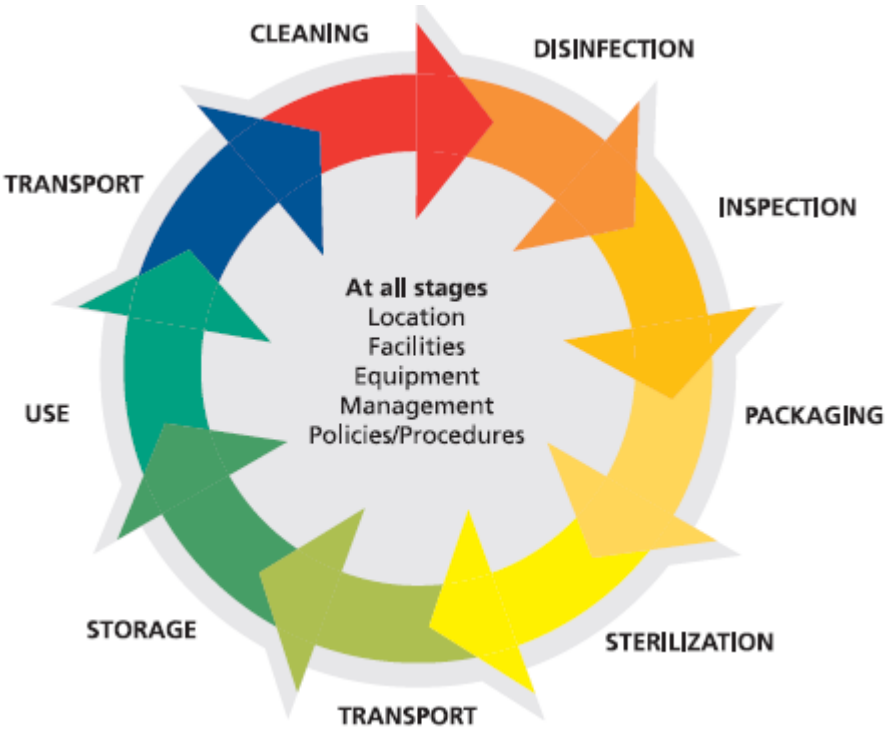
1.9 As required by quality management system BS EN ISO 13485, suppliers such as architects, builders and other consultants required for the new build or upgrade shall be evaluated and selected based on their ability to supply a product/service in accordance with the CDU management requirements.

2. General considerations

Introduction

2.1 The decontamination life cycle (see below) includes each stage of the medical device decontamination process. For effective decontamination, the required standards need to be achieved for 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 and engineering services;
- policies and procedures;
- training of personnel.



Decontamination life cycle

2.2 A number of principles have been identified which help to achieve the highest standards for reprocessing of surgical instruments. The decontamination requirements for reprocessing of reusable medical devices (specifically referring to surgical instruments, endoscopes and their reusable components/accessories) are currently known as the 'Glennie technical requirements'.

Standards, regulations and guidance

2.3 Within Scotland, decontamination of medical devices is covered by the Medical Devices Directive 93/42/EEC and amendments and the Medical Devices Regulations 2002.

2.4 It is a government requirement that management of decontamination in a CDU is compliant and accredited to the quality management system, BS EN ISO 13485.

Guidance from National Institute for Health and Clinical Excellence (NICE) suggests that separate batches be considered for instruments exposed to high CJD risk tissues. It is considered that this guidance will not impact on the facility design but will have operational implications.

NICE guidance Feb 2007

The main recommendations affecting CDUs are:

- steps should be taken to ensure that instruments in contact with high-risk tissues do not move from one instrument set to another;
- supplementary instruments that come into contact with high-risk tissues remain with the set to which they have been introduced;
- rigid rather than flexible neuroendoscopes should be used wherever possible;
- all accessories used through neuroendoscopes for interventions such as for biopsies should be single use;
- a special separate pool of reusable surgical instruments and new neuroendoscopes for high-risk procedures should be used for children born after 1st January 1997;
- apart from neuroendoscope accessories, the guidance does not advocate a wholesale move to single use instruments and specifically advises that single use instruments should only be used if they are of equivalent quality to reusable instruments.

It is a mandatory requirement (Chief Medical Officer (CMO) letter 8th July 2003) that single use instruments are used for routine tonsillectomy procedures.

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

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

2.7 There are four main sources of contamination of a device before it is sterilized:

- materials/products used during the processing;
- personnel;
- the manufacturing environment;
- process equipment.

2.8 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.

2.9 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 CDU's quality control manual. The standard for environmental control is BS EN ISO 14644-1 which specifies airborne particle concentration levels. The Inspection, Assembly and Packing (IAP) Room (17) and its DSR (19) require to be compliant with ISO Class 8 (ISO 14644) in the 'operational' occupancy state. The IAP Room Gowning Room (18) and the IAP Materials Transfer Room (20) require to be compliant with ISO Class 9 (ISO 14644) in the 'operational' occupancy state. Microbial contamination levels should be routinely monitored and maintained within defined levels. The standard on biocontamination control is BS EN ISO 14698 Parts 1 and 2.

Service strategy considerations

2.10 Current service strategies have evolved in response to differing local service policies and demands and, consequently, vary considerably throughout the country. The decontamination of devices categorised as 'high' or 'medium' CJD risk must be undertaken in an accredited central decontamination unit (CDU). It is also a specific requirement that the decontamination of reusable medical devices used in clinical procedures undertaken in all acute hospitals, dental hospitals/schools/institutes must be undertaken in an accredited CDU.

2.11 Existing operational 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.

2.12 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.

2.13 The size of a CDU will be influenced by:

- the Health Board's sterile services policy;
- production throughput, including external supply to potential third parties and contingency arrangements with other CDUs;
- the quantity of duplex systems/plant;
- potential future demand, for example servicing primary care settings;
- impact of changes in legislative, mandatory or best practice requirements.

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.

Upgrading or adaptation of existing buildings/services

2.14 When considering an upgrade the Room Data Sheets are applied to the existing or modified facility layout. There will be elements of the Room Data Sheets that may not be valid, e.g. adjacencies. It is anticipated that the quality of finishes and M&E specifications detailed in the Room Data Sheets could still be delivered in an upgrade. It is likely that some of the room names as specified for each Room Data Sheet would not be the same as that which are currently in use across the various healthboards. Review of the content within the function

and activities section in the design page of each Room Data Sheet should ensure the correct sheet is applied.

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.

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

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.

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

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

- planning consent for change of use or for listed building status;
- Disability Discrimination Act requirements.

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.

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

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

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

Any upgrading work should minimise the disruption to existing services – that is, there should be a clear segregation between building activity and the ongoing delivery of services. Refer to the HFS publication 'SHFN 30: Infection control in the built environment' for the specification of suitable control measures. Traffic impact studies should be considered given that a CDU may generate significant use of vehicles. Waste handling will present additional challenges for site managers. Access for large commercial vehicles with drop-off, load/unload, turning etc may cause considerable disruption within a hospital site. Road/footpath and surface water drainage may suffer damage as a result of construction related traffic.

Service objectives

2.15 To appreciate the special requirements needed for producing sterile products, it is necessary to identify the basic service objectives in the form of an operational policy. By establishing the principles, the process flow of the CDU can more easily be justified and understood by those involved in the design and construction.

Key objectives which the Quality Management System (QMS) should define will include:

- decontaminate to the level required for the intended use of the product;
- minimise adventitious contamination through control of the environment, personnel and materials;

- batch records;
- decontaminate products in such a way as to safeguard patients and staff;
- provide products in a timely manner;
- ensure the location and facilities provide a high quality and cost-effective service;
- provide adequate labeling and instructions for safe use;
- ensure decontamination environment equipment, facilities and processes are validated;
- hold appropriate documentation/records to demonstrate compliance with required standards.

2.16 The workload demand on a CDU will depend on the healthboard's 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 theatres, out-patient departments etc. The policy therefore needs to be determined as early as possible, allowing for foreseeable future requirements to be identified.

2.17 It is important that the design rationale for the CDU should consider growth in capacity, for example the need for additional washer disinfectors/sterilizers/packing tables as well as plant such as boilers etc.

Capacity of a CDU

Note: Capacity planning has not been addressed in detail in this version of the document. Throughput calculations taking account of current and any future needs will be required in order that the size of the facility can be determined. This information should be contained within the User Requirement Brief generated during the development of the Business Case.

2.18 It is essential to specify the department's required production throughput when determining the physical size of a new-build CDU. This allows planners and designers to:

- calculate the optimum capacity of a CDU before bottlenecks start occurring;
- model the overall installed production capability of a CDU;
- assess the potential effects on throughputs and turn-round times (both for fast track and normal deliveries) due to:
  - changes in the number and size of processing equipment;
  - downtime for planned inspection/servicing plant;
  - downtime for breakdown of plant/equipment;
  - changes in number of staff;
  - requirements for instrument streaming.

Design solutions need to satisfy functional requirements but also ensure maximum efficiency in respect of both capital and revenue. Due consideration should therefore be given to the questions of space provision, maintenance (including cleaning), energy consumption and staffing requirements.

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 design teams should review feedback from the use of similar existing facilities in relation to their workload and staffing levels.

Location of the CDU

2.19 When choosing the location of a CDU, consideration should be given to the long-term strategy for the service, CDU location, space required for the new service, and the size and condition of the building (if applicable). Regard should also be paid to the orientation and the aspect of the building. See Figure 2 in Appendix 1 for an example of a site layout. In addition, the following issues may be taken into consideration when determining the location:

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

- Transport vehicle purchase and driver training.

2.20 Other aspects that project teams should consider include the following:

- fire precaution requirements: if the CDU is to be built within a hospital complex it is essential to locate it away from patient areas and to ensure good access for the Fire Service;
- daylight with a pleasant outlook, particularly for the Staff Room and those operational areas occupied by staff throughout the daytime, for example, the Wash Room and the IAP Room. It should be noted that windows in an IAP Room (17) with inadequate cooling/heating capacity can cause excess heat in summer and condensation in the winter, both of which may result in increased contamination risk and/or staff discomfort. The layout model shown in Figure 1 has no natural lighting as the Wash Room (27) and the IAP Room (17) are built without an external wall. Suitable building solutions that allow natural light to enter via the ceiling are often difficult and costly.

Operational policies

Used instrument/equipment - Contaminated returns

2.21 Single use devices should be disposed of at point of use and not be returned to the CDU. Screws, plates and implants should be purchased sterile single use. Contaminated instruments and equipment should be delivered to the CDU in sealed containers conforming to UN3291. This area/room, the Contaminated Returns Lobby (5), will connect directly to the Wash Room (27) and be clearly segregated. The doors into the Contaminated Returns Lobby (5) should be secured against unauthorised access.

Cleaning and disinfection

2.22 All reprocessable items returned to the department should be treated as contaminated and be subjected to standard precautions. In addition those devices contacting high CJD transmission risk tissues require additional consideration and management as recommended in the NICE guidance February 2007. These devices should be quarantined at point of use and not returned to the CDU.

2.23 Cleaning followed by thermal disinfection minimises the infection risk to staff.

2.24 It is recommended that cleaning, disinfection and drying processes are automated, and should in all cases be controlled and validated as required by the quality management system (QMS) BS EN ISO 13485.

2.25 All items should be cleaned and thermally disinfected in a validated washer-disinfector conforming to SHTM 2030: 'Washer disinfectors', MES C30: 'Washer-disinfectors for surgical instruments' and the relevant European and International standard BS EN ISO 15883 Parts 1 and 2'. In some cases the

device manufacturer may recommend manual cleaning and mechanical drying and compliant facilities/equipment for this will be required.

2.26 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. The original design rationale should consider this and if applicable blanked-off service connections should be installed.

2.27 Consideration should be given to the advantages of having washer-disinfectors with interchangeable load handling equipment. Washer-disinfectors shall be of a pass-through design as required by the model layout in Figure 1.

2.28 At the end of the process, clean, disinfected and dry devices should not be compromised by being exposed unnecessarily to further handling.

2.29 The air pressure in the Wash Room (27) relative to other areas is specified to minimise the risk of dispersal of infective aerosols.

2.30 The Wash Room Gowning Room (26) is designated for hand hygiene and staff changing into and out of personal protective equipment required for Wash Room (27) activities.

2.31 A dedicated domestic services room, the Wash Room: Domestic Services Room (28) needs to have direct access from the Wash Room.

Inspection, assembly and packing

2.32 The IAP Room (17) will receive goods from the Wash Room (27) and materials from the IAP Materials Transfer Room (20). These will then be inspected and assembled onto trays and into procedure packs in preparation for sterilization. Adventitious contamination should be minimised by all practicable means. The IAP Room (17) should be an ISO Class 8 cleanroom in the 'operational' occupancy state with a pressure differential higher than adjoining areas as specified in its Room Data Sheet. Cleanroom discipline should be followed by all staff.

2.33 A room directly connected to the IAP Room, i.e. the IAP Gowning Room (18), should be an ISO Class 9 cleanroom in the 'operational' occupancy state. The room should be designated for staff changing into cleanroom clothing before they enter the IAP Room.

2.34 A dedicated domestic services room, i.e. the IAP Domestic Services Room (19) should be an ISO Class 8 cleanroom in the 'operational' occupancy state. This room shall have direct access only from the IAP Room (17).

2.35 Controlled entry and exit of personnel and materials via separate dedicated air locks/transfer hatches should be incorporated to maintain the integrity of the IAP Room (17). Staff shall not be able to leave or enter the IAP Room other than via the IAP Room: Gowning Room (18), unless in an emergency. The Fire

Safety Officer should be consulted at the design stage to specify suitable evacuation procedures. Raw materials enter the IAP Room (17) via the IAP Materials Transfer Room (20). Trolleys shall not pass into or out of the IAP Room (17) unless the procedure has been validated to ensure acceptable levels of contamination are not exceeded.

2.36 All wet processes including hand-washing should take place outwith the IAP Room (17). This will help to minimise the contamination of devices during production. Inspection activities should be approved and minimize the generation of contamination within the room.

Sterilization

2.37 Most items processed in the IAP Room (17) will be sterilized by steam. However, a CDU may require access, to an alternative process for sterilizing those items that cannot withstand porous-load steam sterilization, for example, thermo-labile items.

2.38 The choice, purchase, installation, operation, testing and maintenance of porous-load steam sterilizers should conform to the requirements given in SHTM 2010: 'Sterilization', SHTM 2031: 'Clean steam for sterilization', MES C14: 'Sterilizers' and relevant, European and international standards. Alternative sterilization processes are not within the scope of this planning note.

2.39 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. Sufficient sterilizers should be installed to maintain production, and their regular servicing and maintenance should be ensured without disruption to production.

It is important to locate sterilizers as per the design qualification to facilitate the installation of additional machines should this be specified in the design rationale. If additional sterilizers are planned to be installed after the facility is in production, the additional valved service header connections for sterilizers (and washer disinfectors) together with drainage connection ports should be provided as part of the initial installation work for the new CDU.

2.40 In the example model CDU in Figure 1 pass-through sterilizers are shown. This reduces the possibility of non-processed loads being released in error. Before considering sterilizer sizes and configurations, issues such as, frequency of use, working practices, load types and mass should be addressed to ensure performance requirements will be consistently met. In upgrade projects where single door sterilizers are in use a specific room data sheet is presented namely the Sterilizer Load and Unload Area (30A).

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

Staff changing

2.42 Staff will require to change from outdoor clothing to working dress. Full changing facilities including showers for male and female staff should be provided within the CDU. Refer to the Staff Changing Rooms (31).

2.43 The number of staff employed and provision for contractors/ visitors will dictate the number of lockers specified in the design.

2.44 When entering the CDU production areas, staff and visitors will need appropriate clothing, and may only enter the IAP Room (17) via its gowning room (18). The type and specification for the required clothing will be determined by the area to be visited.

2.45 Where staff are required to wear special protective clothing over their normal working dress, for example PPE, this additional protection is put on in the Wash Room: Gowning Room (26).

2.46 WCs with wash hand basins should be within the Staff Changing Rooms (31). 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

2.47 A Training Room (35) should be provided within the CDU. It should be separate from the production area, providing a space where teaching material and work samples will be secure.

Floor management system

2.48 Floor Management Systems 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 the system. The merits of available systems need to be assessed and the system of choice agreed at the planning stage making allowances for contingency arrangements. IT servers are contained in the Communications' Rooms (7).

Staff rest

2.49 A Staff Room (32) is required, outwith the production area, for staff rest including preparation and consumption of food. (Eating and drinking should not be allowed in production areas).

Domestic services

2.50 High standards of cleanliness are essential in all areas of the CDU. Therefore, a minimum of 3 Domestic Services Rooms (DSRs) are required so that cleaning equipment used can be segregated to the specific areas of use, i.e. Wash

Room DSR (28), IAP Room DSR (19) and the General Areas DSR (15). This is intended to minimise the risk of contamination moving from dirty to clean areas. The room data sheet for each DSR will define the areas to be cleaned from that DSR. Where the CDU design has rooms on an upper floor additional DSRs may be required to accommodate this.

Waste management

2.51 The arrangements for the handling and temporary storage of waste awaiting collection should be specified within the CDU's waste management programme and should conform to current legislation and guidance. This should be capable of managing the large volumes of waste cardboard packaging, pallets, shrink wrap, polythene containers in addition to the domestic waste. All waste containers that have lids should be hands free operated. Consideration should be given to the need for fire resistance properties of the waste containers. Provision is required for the storage of both clinical and general waste, i.e. within the General/Clinical Waste Disposal Area (13). Management of waste materials recycling should also be carried out.

Storage

2.52 Only production materials and those items that are to be processed as defined in the CDU procedures should be stored in or passed through the CDU.

2.53 Sufficient stock levels of raw materials are important for a CDU to operate smoothly. It is essential that adequate storage space is considered and specified in the design. This should also consider space requirements for pallet and fork lift truck movement.

2.54 A significant number of storage spaces are required within the CDU. Each Room Data Sheet requires an assessment by the design team of the storage requirements for each room. Examples include:

- a store for raw materials- the Materials Store (22);
- a store for process chemicals(this could be in the General Plant Room 16);
- a processed products area- the Processed Products Store (24);
- documentation storage – this could be in multiple rooms. Rationale as regards archiving records needs to be clearly specified by the design team;
- storage for spare parts for decontamination equipment and plant could be within the Technicians Room (33) and in the General Plant Room (16). Spare parts can be used for both clean and dirty maintenance work. The location of the spare parts storage should give consideration to this. The level of storage should reflect the fact that CDUs are intended to be stand-alone units providing a contracted level of service to its customers.

An assessment of the compatibility of materials planned to be stored in the same area should be carried out. Short term storage of certain materials will be

required in the Wash Room Materials Transfer Room (38) and the IAP Materials Transfer Room (20).

Records storage may be contained within the Office (23). Longer term archiving of records may be required offsite.

2.55 The Materials Store (22) contains those items used in the production process. Control of Substances Hazardous to Health Regulations 2002 need to be considered when storing chemicals. Manual handling regulations should also be considered.

The Processed Products Store (24) should be used as a holding area for items awaiting distribution to users via Dispatch (9).

Storage spaces external to the CDU could include that required for compaction units with containers, skips, bulk storage vehicles. Site layout design should specify adequate space to allow movement of the vehicles associated with these items. See Figure 2 and the external site data sheet.

Trolleys and internal transportation

2.56 Trolleys containing used items should not enter the General Corridor (14). A designated area, the Contaminated Returns Lobby (5), should be provided next to the Wash Room (27) for receipt of trolleys/transit containers holding used items. An area and facilities, the Cart Wash Load Area (1) should be provided for decontamination of trolleys and transit containers. This should be carried out by an automated process (cart/trolley washer). It should be noted that these units will require routine testing and maintenance. Different types of trolley may be used for:

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

2.57 If different trolleys are required for different functions, the choice of model will rest with the design team and should take into account manual handling issues. Where the customer is some distance from the CDU, vehicular trolleys will be required.

Trolleys used for several stages of the process must be fully compatible with all relevant process equipment, e.g. sterilization trolleys used for subsequent transport need to allow effective steam penetration, condensate removal and drying, while ensuring secure transportation, i.e. there use should be validated.

2.58 Trolleys, transport containers, product packaging and vehicular transport design and arrangements should be validated to ensure that the condition and sterility of processed goods is not compromised and that contaminated returns do not pose a risk of transfer of contamination during transportation.

2.59 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. Where motorised vehicles are used, the usable dimensions of both vehicles and loading/delivery bays need to be incorporated into the overall design of the CDU. The siting of bumper rails to protect the building fabric from potential damage from trolley movements will be influenced by the trolley dimensions. Consideration of any further restrictions to trolley dimension presented by the customers delivery and collection points should be undertaken, e.g. theatre areas.

2.60 Where battery-powered vehicles or floor trolleys 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 where appropriate. (refer to the Materials Store room data sheet 22). If extended distances and frequent use of these vehicles is required consideration should be given to LPG powered vehicles. The gas cylinders would be stored externally in a secure cage. (Refer to Figure 2 and the external site data sheet).

Offsite transportation

2.61 Offsite transport vehicles will require to be cleaned internally as well as externally. A Vehicle Wash Area (37) may be provided (see Figure 2). Handling of spillages within the vehicles involving soiled devices should be described within the waste management policy.

3. General functional and design requirements

Introduction

3.1 This Section provides design guidance based on the general considerations outlined in Section 2. It includes discussion on a range of topics that should be taken into account when designing a CDU.

There should be a validation master plan (VMP) for the build project with qualification exercises for the design, installation, operation and performance of the facility. This will require a design team to be assembled and managed. This will require considerable resources. The design team can typically consist of a dozen members who will have to commit to attend regular meetings and comment/approve significant amounts of validation documentation over the project duration. A project manager will require to be appointed to control the process. There may be multiple contracts in place over the project duration. The overall control of the project will fall within the CDU quality management system. It is through the quality management that documented evidence is presented to demonstrate the operational CDU is fit for its intended purpose.

Each room data sheet has a list containing equipment/furniture and fittings to be considered. These items can be managed in a number of ways:

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

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

Note: Specific functional and design requirements for each room/ area are given in the form of Room Data Sheets.

Workflow

3.2 Two classifications of goods will be received at the CDU, 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. Figure 1 illustrates the layout of the CDU model. The General Corridor (14) shown in the layout is not exposed to trolleys containing used items.

3.4 The activities within each room/area are given in the Room Data Sheets.

3.5 A single CDU layout has been identified for new builds to enable compliance with current technical requirements for decontamination. This model utilises double door sterilizers loaded from within the IAP Room (17). For certain upgrade projects this configuration may not be possible. In this case refer to Room Data Sheet (30A).

Capacity planning (also refer to paragraph 2.18)

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

3.7 Capacity provision should be specified to inform the design rationale. This information should be contained within the User Requirement Brief generated during the development of the Business Case.

3.8 The standards set out in this guidance are equally applicable to the upgrade or extension of existing buildings. During upgrade work, the production environment should not be compromised (refer to 'Protection of sensitive areas' in SHFN 30 and BS EN ISO 14644-4).

3.9 Consideration should be given to the long-term strategy for the service, CDU 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.

3.10 Service continuity arrangements and decant costs should be included.

3.11 Planning and design should include input from relevant experts including those involved in decontamination, engineering, building and design (including cleanroom design) and service users. These individuals will require to be 'approved suppliers' as stated in the quality management system BS EN 13485.

Access and facilities for disabled people

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

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

Project teams are encouraged to refer to SHFN 14: 'Disability access' and SHPN 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.

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

Environment

Natural lighting (refer to Scottish Health Technical Memorandum 55)

3.12 Natural lighting has a positive effect on staff morale. If this option is considered the facility design must be qualified to verify that the ventilation systems can deliver the specified room conditions (as per Room Data Sheets) throughout the year. Light pipes may be one of a number of suitable design solutions.

3.13 Windows should be considered in Offices (where privacy is not an issue), the Staff Room (32) and the Training Room (35). Opaque glass may be suitable in some circumstances. 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.

3.14 Light levels and the level of protection (Index of protection rating) for the fitting/enclosure are specified for each room within its Room Data Sheet.

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. Curtains are not acceptable in production areas (see also SHFN 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 as specified in the Room Data Sheets. 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 a consistent colour balance across all work areas of the CDU.

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. Task lighting should be kept to a minimum in the IAP Room (17). The room design should be such that the light levels required (as specified in the Room Data Sheets) from ceiling lighting provides the required light level at each workstation. 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. Light levels are specified in each Room data Sheet.

Ventilation (also see paragraph 4.38)

3.19 Production areas will require mechanical ventilation. Design of air ventilation systems must be such that they can meet the specifications for room conditions as defined in each Room Data Sheet.

3.20 Consideration of the ventilation requirements at the Design Qualification (DQ) stage should include the ability of the air handling unit(s) to deliver the specified conditions if increasing production throughput by increasing the number of washer disinfectors or sterilizers. Duplex air conditioning plant would be required to maintain the production environment while maintenance duties are performed on offline plant.

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. 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. Therefore the ventilation planning calculations should take this into account. To conserve energy and minimise operating costs, heat recovery from ventilation systems should be incorporated where appropriate. Note: the Room Data Sheets specify where there should be no recirculation of extract air.

3.22 The IAP Room (17) and the IAP Domestic Services Room (19) should be cleanroom standard, designed, constructed, operated and maintained to be compliant with airborne particle classification ISO Class 8 in the 'operational' occupancy state as defined in BS EN ISO 14644-1. The IAP Gowning Room

(18) and the IAP Materials Transfer Room (20) should be a designed, constructed, operated and maintained to be compliant with airborne particle classification ISO Class 9 in the 'operational' occupancy state as defined in BS EN ISO 14644-1. The Room Data Sheets specify the required pressure differential cascade system in the CDU. Pressure differential indicators, visible from outside the IAP Room (17), 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 (17) should indicate this.

3.23 Where washer disinfectors, drying cabinets, sterilizers or transfer hatches are fitted into IAP Room (17) walls, these should be effectively sealed to maintain the IAP Room environment and pressure differentials as specified in the Room Data Sheets.

Noise (also see **paragraph 4.26**)

3.24 Careful consideration should be given to the choice of surface finishes (as specified in the Room Data Sheets) especially in the Wash Room (27), IAP Room (17), Sterilizer unload Area (30), Cart Wash Load Area (1) and Cart Wash Unload Area (3) to achieve sound absorption while meeting cleaning and microbiological requirements (SHTM 2045: 'Acoustics'). Equipment such as the Sterilizers may require to be sound-proofed.

3.25 Noise Limits are specified in the Room Data Sheets in line with the Noise at Work Regulations 2005.

Maintenance

3.26 Building and engineering maintenance/testing can compromise the integrity of the product or the production environment. Maintenance and testing which compromises the integrity of the IAP Room (17) and/or environment cannot be undertaken within the IAP Room (17) at times when goods are being produced or processed. Design solutions can and should minimise the effects of these activities. Where the design solution cannot meet this requirement, e.g. ceiling hatches in the IAP Room (17), the impact of downtime and recertification of the area prior to production start up should be both understood and documented.

3.27 Test and maintenance equipment, tools etc brought into the IAP Room (17) 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 (17), a suitable dedicated storage location accessible only from the IAP Room should be provided, i.e. the IAP Domestic Services Room (19).

3.28 Materials and finishes requiring minimal maintenance should be chosen as specified in the Room Data Sheets. Building finishes requiring frequent redecoration or which are difficult to clean should be avoided. Note that spray finishes that may appear a satisfactory application method during construction of a new facility will likely cause significant production downtime on subsequent

reapplication. Floor finishes should be appropriate in heavy traffic areas. Floors finishes that shrink, lift or develop cracks in joints present significant maintenance problems and associated production downtime.

3.29 Locating the plant areas of the CDU on an outside wall at ground-floor level as Figure 1 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 taking account of the finishes specified in the Room Data Sheets and the environmental cleanliness required in each area. An environmental monitoring programme should be in place to verify the effectiveness of the cleaning activities.

Finishes

3.31 In processing areas, all finishes including floors, walls and ceilings should be suitable for frequent cleaning, tolerant to surface-cleaning agents and constructed from moisture-resistant non-shedding materials. Joints and uneven surfaces should be avoided as they can hold moisture, encouraging the growth of organisms and prevent effective cleaning. 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 (17), it is advisable that workstations and storage units should be on wheels. See each Room Data Sheet for the required category of finish for walls, ceiling and floors in each area in line with the HFS SHTM Building Component Series.

3.32 Ledges trap dust particles and should be avoided. This is particularly important in the IAP Room (17), which requires finishes that are minimize contamination levels, are easily cleaned and low in maintenance.

3.33 In areas where heavily loaded trolleys are in use the floor and wall (and door) finish should be protected against accidental damage as specified in the Room Data Sheets. Most damage to doors, and to floor and wall surfaces, is caused by wheeled traffic. Measures to minimise damage would include protective corners, buffers and plates, and proper continuation of floor coverings, that is, strong screeds and fully-bonded floor coverings. Protective devices should be capable of being renewed as the need arises. Where heavy traffic is expected, e.g. transport carts, door protection should include protective plates and buffer rails mounted vertically at door edges. Vision panels in doors will help reduce damage. Auto sensor door opening devices where permittable will also help reduce impact damage.

Floors – see Room Data Sheets for individual rooms

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:

- continuous with the floor;
- 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 floor finish should be hard-wearing, non-slip, easy to clean and, in the IAP Room (17) should minimise the generation of contamination during cleaning. Floor finishes and design, particularly in the Wash Room (27) and the General Plant Room (16), should protect against damage and disfigurement caused by malfunctioning equipment and should facilitate maintenance.

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

3.37 Floor finishes suitable for offices, staff rest room and training room are given in the Room Data Sheets.

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 (17).

Walls – see Room Data Sheets for individual rooms

3.39 In storage and processing areas in particular, hollow-wall constructions pose an infestation risk and may be more susceptible to trolley damage – careful choice of materials and construction should eliminate these risks. Solid walls should be rendered to a finish as defined in the Room Data Sheets.

3.40 Where hollow walls, partitioning or boxing is used, consideration should be given to means of access and inspection. The design qualification will determine the suitability of access/maintenance hatches in each area.

3.41 Walls should be protected as specified in the Room Data Sheets against accidental damage from wheeled traffic by buffer rails or wall protection and corner guards, which should be appropriately sited to reflect the specifications of trolleys in use. (This level of protection is not appropriate in all areas. Refer to individual Room Data Sheets).

Ceilings – see Room Data Sheets for individual rooms

3.42 Building services are regularly located above suspended ceilings and access to them can pose risks of contamination to the processing environment. Routeing of services should eliminate these risks as far as possible. Suspended ceilings using fibre ceiling tiles should be avoided in production areas where possible and are not suitable in the IAP Room (17) or rooms directly connected to it.

3.43 Ceiling design solutions should not allow access to engineering services from the IAP Room (17) or rooms accessible from the IAP Room, unless

unavoidable. The IAP Room (17) ceiling should be to cleanroom 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). Where access is from within the IAP Room (17) through ceiling panels/hatches allowance must be made for the room environment to stabilise before production recommences. This should be taken into consideration when designing the IAP Room (17) ceiling.

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 life of the building fabric. Where door interlocks are provided, for example in the IAP Room (17), the IAP Room: Gowning Room (18) and the IAP Materials Transfer Room (20), 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 (audible) of indicating they have been opened particularly in the IAP Room (17) and preferably connected to a building management system to record the event. Door seals should be checked regularly to avoid contamination ingress.

3.47 Where trolley movement occurs, protection is essential on all doors and door linings. Flush-fitting vision panels should also be provided in doors that are frequently used. Consideration should be given to fire precautions. Consult the Room Data Sheet 36 for points for the design team to consider with regard to external doors and approaches.

Windows

3.48 Windows in the Wash room (27) and IAP Room (17) 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 the Staff Room (32) provided the room conditions specified in the Room Data Sheets can be achieved.

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, security lighting 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.

Wash hand basins

3.51 Dedicated wash hand basins are required with taps, which are elbow, foot or automatic sensor–operated. The tap should be mixer or thermostatically controlled. There should be no overflow or plug; taps must not discharge directly into the drain. The trap should be remote from the wash hand basin. Pipework associated with the wash hand basin should be boxed in to allow for ease of cleaning but also allow for maintenance access. A handwash solution dispenser should be wall-mounted near the wash hand basin. The handwash solution in the dispensers should not be refillable but be of a disposable, single cartridge design. A dispenser for disposable paper hand towels should be fitted above the sink. Dispensers should be easy to clean.

Wash hand basins to be sited as per room layouts and there should be a sufficient number available for the intended workforce. The Room Data Sheets specify where hand hygiene activities take place and where a wash hand basin(s) is required.

Manual wash & rinsing sinks (Wash Room 27 only)

3.52 Dedicated rectangular stainless steel sinks with draining boards are required, one for manual washing and one for rinsing of soiled devices. Sink seals should be smooth and intact. A suitably sized waterproof splashback is required at each sink. Each sink should have single taps or a mixer tap, which is lever operated. The sinks should have no overflow and the taps should not discharge directly into the drain. The running trap should be remote from each sink. Each sink will require an upstand overflow tube plug. A spray gun may be required at the wash sink. The spray gun should be installed with suitable back flow protection that is related to the risks involved with the waste fluid generated. A means of indicating the water fill level in the wash sink should be considered. In addition consideration should be given to the need for detergent dosage pumps.

4. Engineering services

Introduction

4.1 This section describes the engineering services contained within a CDU 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 (as specified in the Room Data Sheets) needed to meet the functional requirements.

4.2 The design team should adopt a comprehensive risk management approach to the design. In this way, the team will be able to demonstrate an appropriate level of investment in the engineering services and infrastructure necessary to support the CDU. 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) [CDM] Regulations 2007 and requires the design to be fully integrated within the NHS board's risk management system. Clear design philosophies should be developed and agreed within the design 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 CDU (refer to paragraphs 2.21 to 2.61). There should be a validation master plan (VMP) for the build project with qualification exercises for the design, installation, operation and performance of the facility as required by BS EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. This VMP will include validation of engineering services.

4.3 A quality decontamination service needs continuity of delivery. The design of engineering and building services and choice of plan, equipment and the room finishes should take this into consideration. Appropriate design solutions and contingency arrangements should be incorporated and validated. Consideration should be given to duplex systems for critical engineering services. Examples of issues to be considered include:

- down-time for repair/maintenance/periodic testing of plant;
- failure of supply or quality of services (including ventilation, compressed air, steam, clean steam, fuel, electricity, IT, water, RO water, drainage);
- response time for service, maintenance and testing, consideration to as much on site support as possible;
- availability of spare parts consignment stock held on site;
- operating hours of the CDU and its customers;
- opportunities for future expansion and reliability;

- plant replacement.

The design qualification (DQ) exercise as part of the VMP should consider all of the above matters.

Technical specifications and manuals

4.4 If bespoke specifications are not required, the Health Technical Specifications may be sufficiently flexible to reflect local needs. Full reference should also be made to the engineering services sections of SHTM 2010: 'Sterilization' and SHTM 2030: 'Washer-disinfectors'. For steam generation and distribution, reference should be made to SHTM 2031: 'Clean steam for sterilization'. Consult SHTM 2025 for ventilation in healthcare premises. The Room Data Sheets within this planning note specify the required room conditions.

Economy and value management

4.5 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 design team should therefore ensure:

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

4.6 Life cycle cost analysis should be one of the criteria for the selection of systems and equipment within a given risk management framework.

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

4.8 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.

4.9 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.

4.10 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 SHTM 2005: 'Building management systems 2005'.

4.11 The design team should consider the environmental benefits and economic viability of heat recovery and combined heat and power systems (CHPs). Waste heat recovery from washer disinfector discharge must be considered.

Service requirements

4.12 For (a) equipment to be available at any time and (b) to meet the throughput calculations and service requirements the provision may be based on maximum simultaneous demand. The rationale used should be stated within the User Requirement Brief which is generated during the Business Case. Service requirements for possible future expansion in production throughput should also be considered and documented at the initial design qualification stage as required by the Validation Master Plan.

4.13 The estimated maximum demand and storage requirement (where appropriate) for each engineering service (water, electrical, steam, gas etc) 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. The sequence of operation and frequency of loading/unloading cycles need to be reviewed in order that the required boiler efficiency can be achieved. The introduction of clean steam generators that are located in-line between the boiler plant and sterilizers can be evaluated and interlock arrangements designed to meet maximum user requirements. Consideration should be given to triplex boiler configuration to maximise boiler efficiency and give flexibility for annual service etc.

Space for plant and services

4.14 Enough space should be provided for the maximum required footprint for plant and services within the CDU. The amount of space will depend on the engineering solution chosen (including duplex systems) and will include space (inside and outside on the CDU grounds) not only for decontamination plant and equipment but also for the following:

- clean steam generators (central or local to sterilizers) with associated pumps and controls;
- main boiler plant, heat recovery plant and associated services;
- water treatment, reverse osmosis water generation, and water storage of defined capacity, e.g. 12 or 24 hours supply;
- emergency back up water supply via water tanker in event of mains supply failure;

- ventilation and air-conditioning;
- hot water generation;
- fuel storage if required;
- heat recovery units;
- electricity distribution boards;
- gas meter housings;
- air compressors;
- emergency generators including fuel storage to allow a specified running time;
- sprinkler systems;
- control panels.

4.15 Space for plant and services should provide:

- 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 (17));
- space for frequent inspections and maintenance;
- for eventual removal and replacement of major plant and equipment. These areas should be adequately lit with the provision of suitable number/type of electrical sockets (as specified in Room Data Sheets) for use of portable equipment in this area;
- access routes to roof mounted plant requires to be safe and secure.

4.16 There should be enough space to access equipment and undertake maintenance such as tube withdrawal and filter replacement within ventilation plant, steam generators and calorifiers etc. Good access should be provided around all units for inspection or opening of access doors. Secure access doors should be in suitable positions to inspect fire dampers and plant. It may be advisable to site ventilation plant in a separate plant room dedicated to air handling or locate externally in a secure area (refer to External Site Data Sheet).

4.17 Mechanical and electrical services within the IAP Room (17), should be concealed in walls and above ceilings but be accessible from outwith the IAP Room for maintenance and testing, e.g. replacing lamps or terminal air filters if applicable.

4.18 In other working areas mechanical and electrical services should be contained within ducting systems with easy access for maintenance and testing. Horizontal runs should be kept to a minimum. All plant and equipment should be designed, installed and maintained in accordance with the CDM regulations. Suitable designated escape routes within plant rooms should be specified in the design qualification. Emergency lighting, alarm sounders and illuminated exit signs at fire exit doors should be specified.

Access to control and isolation devices

4.19 Primary engineering distribution control and isolation devices should be:

- located in plant rather than working areas and not in the IAP Room (17);
- protected against unauthorised operation (for example, switchgear and fuse-boards should be housed in secure plant area);
- easily accessible for staff to operate where appropriate.

Safety

4.20 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

4.21 It is essential that the design team familiarise themselves with the guidance contained in the Firecode suite of documents, which contains SGHD 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. SHTM 86 should be used as a risk assessment tool to help formulate the fire action safety policy.

4.22 In addition, the SGHD Fire Safety Policy sets out the key policy requirements.

4.23 Management guidance is contained in the Firecode 'Policy and principles' document.

4.24 It is important to establish during the design stage those aspects of fire safety strategy that affect the design, configuration and structure of the CDU. The architect and engineer should discuss and verify their proposals with the Building Control Authority, Hospital Fire Officer or Approved Inspector, and ensure that the design team are fully acquainted with the fire safety strategy for the design in terms of operation (staff responsibilities, equipment provision and building and engineering layouts). This will include the provision of portable fire extinguishers. A fire certificate will be required to enable the CDU to operate. It needs to be recognised that access to/from controlled areas with interlocked doors and potentially large travel distances present challenges in terms of escape routes for staff.

The selection, type and placement of smoke detection must also take account of contamination control issues within the controlled environments. Fire detection systems prone to false alarms can have an impact on production levels due to the time for cleanroom staff to regown after such an event as well as the recovery time of the cleanroom once it has been compromised through the use of emergency exits. Some fire detection systems require maintenance from within the cleanroom (IAP Room (17)) thereby impacting on production, while other systems, e.g. VESDA can be maintained externally from the cleanroom. The following HFS guidance documents give detailed information on the selection of fire-resisting components and fire signs:

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

The Room Data Sheets specify the performance category of material finishes.

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

Noise and speech privacy (also see paragraph 3.24)

4.26 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. Acoustic panelling can be employed in noise management matters.

4.27 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. The Room Data Sheets give specifications regarding speech privacy, privacy factor, mechanical services-noise rating (NR) level and intrusive noise NR levels.

Engineering services validation

4.28 There should be a validation master plan for the build project with qualification exercises for the design, installation, operation and performance of the facility.

4.29 This will include the engineering services that should be validated in accordance with the methods identified in the current versions of the relevant SHTM.

4.30 Flow measurement and proportional balancing of air and water systems require adequate test facilities to be incorporated at the design stage, e.g. test points either side of filters for integrity testing. Guidance is also contained in commissioning codes A (1996) and W (1994) published by the Chartered Institute of Building Services Engineers. Also BS EN ISO 14644-3 and PD 6609:2007 will be applicable if testing HEPA filters.

Equipment validation

4.31 Decontamination equipment should be validated fully in accordance with the relevant protocol in SHTMs 2010, 2030 and 2031 or in the case of special sterilization processes, according to the principles in BS EN ISO 14937: 2001.

Mechanical and electrical services

Heating

4.32 The production environment should be controlled by the mechanical ventilation system, i.e. there should be no radiators in the Wash Room (27), IAP Room (17) and associated areas such as gowning rooms (26 and 18), DSRs (19 and 28) and materials transfer rooms (20 and 38). In offices, the Training Room (35) and Staff Room (32) space heating requirements may be met by low-pressure hot-water radiators providing the room conditions specified in the Room Data Sheets are achieved. 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

4.33 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. Production areas require to be within specification (as detailed in Room Data Sheets) before production starts.

4.34 Facilities should be provided to override the control system on those occasions when the CDU needs to operate outside 'normal' working hours.

4.35 Radiators where permitted, 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.

4.36 The choice of controls should take account of the extent to which they can be linked to, or provided by, a building management system (BMS) serving the CDU, whether the unit is an independent building or part of a hospital. The validation of the BMS should include verification that it will be compatible with the automated controls and systems in use within the buildings services package.

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

Ventilation (also see paragraph 3.19)

4.38 The following factors determine the ventilation needs within the various spaces of a CDU (the ventilation needs are specified in the M&E section of the Room Data Sheets):

- those associated with the functional requirements or process within the space, for example, minimization of 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.

4.39 Air movement induced by mechanical ventilation 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 should draw air from a controlled environment and should not compromise fire safety. The defined pressure differentials (as given in the Room Data Sheets) shall be maintained continually with allowances for door openings. Grilles are not to be used in fire-resistant walls or doors.

4.40 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.

4.41 Ventilation supply plant should include a pre-filter and a secondary filter (to BS EN 779) as defined in the Room Data Sheets such that the specified room conditions are achieved. 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. For IAP Room (17) air supply, terminal HEPA filters may be considered but these are only one of a number of ways of providing the required air quality in the IAP Room and its adjoining areas. Appropriately spaced and type of air supply grills, low level extract grills and the

number of air changes per hour will significantly impact on the air quality in the IAP Room (17). Filters should be readily accessible for replacement and should be provided with a pressure differential indicator. Pressure drops for clean and dirty filters should be noted for reference.

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

4.43 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 SHTM 2030: 'Washer-disinfectors – design considerations' (Section 6); and MES C30: 'Washer disinfectors for surgical instruments' (Clause C30.03.38 'Ventilation systems and ductwork').

4.44 The mechanical-ventilation system should be designed and constructed to ensure that, when the IAP Room (17) and its DSR (18) is tested in accordance with BS EN ISO 14644-1 in the 'operational' occupancy state, i.e. during production the airborne particulate classification is compliant with ISO class 8. (See Room Data Sheets 17 and 18).

4.45 Consideration should also be given to heat gains from all sources, including process equipment and processed goods entering the IAP Room (17) via the washer-disinfectors. The Room Data Sheets specify the positive air pressure differential regime that must be maintained within the IAP Room (17) and its adjoining areas. Room air temperature and relative humidity levels are also specified.

4.46 To minimize outside air entering the IAP Room (17), it will need to have non-openable windows and a sealed ceiling. Consequently, the spaces which communicate with the IAP Room (17) 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 specified in the Room Data Sheets. Doors on transfer facilities and hatches should be interlocking.

4.47 Where small, open hatches are required to accommodate conveyor systems between the IAP Room (17) and the Wash Room (27), for example, they should be validated to confirm they do not compromise the integrity of the IAP Room (17).

4.48 The air handling system should run continuously. During out of hours periods, it may be designed to operate in the supply mode only at a lower than normal supply rate as determined during the commissioning of the system, assuming this does not raise contamination levels. This design would require qualification to determine the room environmental conditions recovery time prior to production start up. The ventilation plant for the IAP Room (17) should be separate from plant serving other areas. Duplex systems should be considered

with regard to minimizing production downtime and if selected these systems should be validated.

4.49 Any areas subject to high heat gains may need mechanical cooling to provide a comfortable environment for staff and to ensure satisfactory operation of equipment.

4.50 Air conditioning should be included where required to achieve the temperature and relative humidity limits specified for each room in the Room Data Sheets.

4.51 Supply and extract ventilation systems should include controls and indicated control panels in the General Plant Room (16) containing the air handling unit to confirm the operational status of each system. This should include pressure indicators for air supplies. Alarms should be repeated in a manager's office. This could be the CDU Manager's Office (4), the Deputy Manager's Office (8), the Quality Manager's Office (25) or other. 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 the ventilation system should be provided in the IAP Room (17). It may be necessary to relay alarms to other locations to enable timely corrective action to be taken.

Hot and cold water services

4.52 Guidance on the design and installation of hot and cold water supply and distribution systems is contained in SHTM 2027: 'Hot and cold water supply, storage and mains services'. All installations must comply with the Scottish Water Bye Laws 2004.

4.53 The requirements for the control of legionellae bacteria in hot and cold water systems are set out in SHTM 2040: 'The control of legionellae in health care premises – a code of practice'.

4.54 The hot water should be supplied at an outflow temperature of 60°C ± 2.5°C, and distributed to all outlets so that the return temperature at the calorifier is not less then 50°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. The maximum water temperature at wash hand basin outlets should be 43°C.

4.55 RO water supply system(s) may be installed to ensure the quality of final rinse water to washer disinfectors meets the requirements of SHTM 2030 and BS EN ISO15883 Parts 1 and 2. These should be designed, installed, maintained and periodically tested according to the guidance in SHTM 2030, BS EN ISO 15883 Parts 1 and 2 and manufacturer's instructions.

Equipment

4.56 Energy-efficient equipment should be chosen where possible. Such equipment also reduces the load on ventilation systems. Washer-disinfectors, cart washers, 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. Guidance on choice, procurement, installation and validation of sterilizers and washer disinfectors is contained in SHTM 2010: 'Sterilization'; SHTM 2030: 'Washer-disinfectors'; MES C14: 'Sterilizers', MES C30: 'Washer-disinfectors for surgical instruments'. Energy usage and water usage should be considered in the procurement stage.

Piped medical gases

4.57 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 SHTM 2022: 'Medical gas pipeline systems'.

Compressed air (industrial)

4.58 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 SHTMs 2010 and 2030.

Steam

4.59 Steam should be supplied in compliance with the requirements of SHTM 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 SHTM 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 SHTMs 2010, 2030 and 2031.

Gas and oil fuel supply

4.60 Where a gas fuel supply is available and used for heating, hot water or steam generation, the supply should terminate in a well-ventilated gas meter house (refer to External Site Data Sheet and Figure 2).

4.61 Duel fuel systems should be considered within the boiler design. Where oil is the alternative fuel source it may be necessary to provide separate propane gas storage (for pilot fuel storage) in a suitable secure external cage. Some oil burners do not require gas pilot ignition and light directly from electrode spark

ignition. Fuseable links are normally connected to the mains gas valve which will operate and shut-down the fuel supply in the event of fire outbreak.

Vacuum cleaning system

4.62 Consideration could be given to the provision of a centralised vacuum cleaning system. If installed within the production area the system will require to be validated.

Electrical services

Electrical installation

4.63 Electrical installation should comply with BS 7671: 2008 – 'Requirements for Electrical Installations'; IEE Wiring Regulations 17th Edition (and subsequent amendments).

4.64 The point of entry for the electrical supply will be a secure switchroom area within the General Plant Room (16) housing the main isolators and distribution equipment. This space will also be the distribution centre for subsidiary electrical services. Distribution boards may require to be located in different areas within the CDU. 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.

4.65 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

4.66 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.

4.67 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 Scotland under the Electromagnetic Compatibility Regulations 1992.

4.68 Advice on the avoidance and abatement of electrical interference is contained in SHTM 2014: 'Abatement of electrical interference'.

4.69 Fluorescent luminaires should comply with BS EN 55015.

Lighting

4.70 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'. Light levels and level of protection (index of protection) of fittings/enclosures are specified in the Room Data Sheets.

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

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

4.73 The design team may 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.

4.74 The location of luminaires should afford ready access for lamp changing and maintenance. The Room Data Sheets give specific details with regard to this and the light levels required. 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.

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

4.76 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.

4.77 For lighting circuits, designers should consider the impact that isolation of individual lighting circuits will have on the production areas. These proposals should be approved by the design team to ensure that the design properly reflects maintenance and local operational policies.

4.78 The lighting of stairways and other circulation areas should be in accordance with the guidance contained in SHBN 40: 'Common activity spaces, Vol 4: Circulation areas'.

4.79 Safety lighting should be provided on primary escape routes in accordance with SHTM 2011: 'Emergency electrical services' and BS 5266. Emergency lighting of control rooms should be arranged in accordance with the requirements of users and the guidance in SHTM 2011.

4.80 The design 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 (17) and the Wash Room (27) need to be compatible with the control of the environment. Lighting has to be configured over the ceiling, such that the delivered light level, at the surface of each work station is in line with that specified in the room data sheet for the IAP Room (17).

Socket-outlets and power connections

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

4.82 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. The Room Data Sheets specify the Index of Protection (IP) required of each socket. This covers protection regarding solids and liquids where applicable.

4.83 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.

4.84 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. Note: some pressure washers could be 16-Amp or more but would not be hard wired. The sub-circuits should be fed from the distribution board and terminate at a local isolator. The design team should approve the location, type (flush or surface-mounted), form of indication, 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.

4.85 The selection of faceplate material (metal or plastic) should be within the requirements for ‘Finishes’ as specified in each Room Data Sheet. In controlled areas the face plate should be flush fitting. The index of protection for electrical sockets in each area is specified in each Room Data Sheet.

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

4.87 The electrical supply connections to electromedical equipment should comply with BS 5724 and the relevant SHTMs.

4.88 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.

4.89 If appropriate socket-outlets should be connected to essential circuits in accordance with the advice contained in SHTM 2011: 'Emergency electrical services'.

4.90 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 SHTM 2020: 'Electrical safety code for low voltage systems') to be maintained in the CDU area.

Emergency electrical supplies

4.91 Guidance on emergency electricity supplies is contained in SHTM 2011: 'Emergency electrical services'.

4.92 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. The Design Team should undertake a risk assessment 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.

4.93 Given the importance of the sterile service provision a CDU will require an independent emergency generator. 24 hour emergency cover should be available. The full electrical load under normal conditions must be determined in order that a suitably rated generator can be specified. This would include an assessment of the "start up time" required of the generator. The requirements for generator fuel storage should be assessed and specified.

Internal/external communications

4.94 If the CDU is located within a hospital site central telephone facilities for internal and external calls should be extended to serve the CDU. If the CDU is a stand alone facility the telephone system and IT Node Cabinets should be housed in the Communications' Rooms (7).

4.95 Facilities for communication between separate rooms and areas should also be provided as specified in the Room Data Sheets. This should be of audio visual type where possible.

Electronic data gathering

4.96 Conduits, trunking and cable trays for data links should be provided between rooms and areas for the following purposes: (Wireless networking should be considered in addition to a hard wired system)

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

The positioning of the various cable containment systems need to be clearly specified by the design team and verified as satisfactory after installation. The installation programme has to be managed such that completed room finishes (walls, floors etc) are not damaged. Service ducts should be designed so that services can be easily accessed away from the IAP Room (17). Reference should be made to SHTM 2023: 'Access and accommodation for engineering services'.

4.97 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

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

4.99 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

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

Internal drainage

4.101 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;
- is constructed from a material compatible with the chemicals and temperatures of the fluids to be carried away.

4.102 The design of internal drainage should comply with the relevant 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 SHTM 2023: 'Access and accommodation for engineering services' (1995)'.

4.103 The drains from steam sterilisers, washer disinfectors and cart washers should comply with local water regulations. (Further advice is provided in SHTM 2030: Design considerations, *Section 6).* It should be noted that the volume of effluent and the discharge temperature could potentially exceed temperatures acceptable to SEPA. Cooling by waste heat recovery before discharge should be considered as part of the energy and waste management policy. A certificate from SEPA may be required as the CDU activities may be classified as an industrial process.

4.104 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. Waste pipes passing through the internal structure of the building, such as roof rain water conductors must be completely sealed with no rodding eyes within or above production areas. The Room Data Sheets identify which rooms containing wash hand basins or sinks require maintenance access to waste traps external to the room. Service ducts should be designed so that services can be easily accessed away from the IAP Room (17). Reference should be made to SHTM 2023: 'Access and accommodation for engineering services'.

Other operational considerations

4.105 Meters should be fitted to accurately monitor all incoming utility services, for example steam, fuel and water, for efficiency or charging purposes. Local meters can also be installed as considered necessary to monitor the usage and efficiency of plant and equipment.

4.106 There should be a clear controls philosophy for the CDU. This would be specified at the design stage for the integration of valves, timers, motors and

other engineering controls associated with the Building Management System (BMS) planned for the CDU.

Appendix 1: Layout diagrams

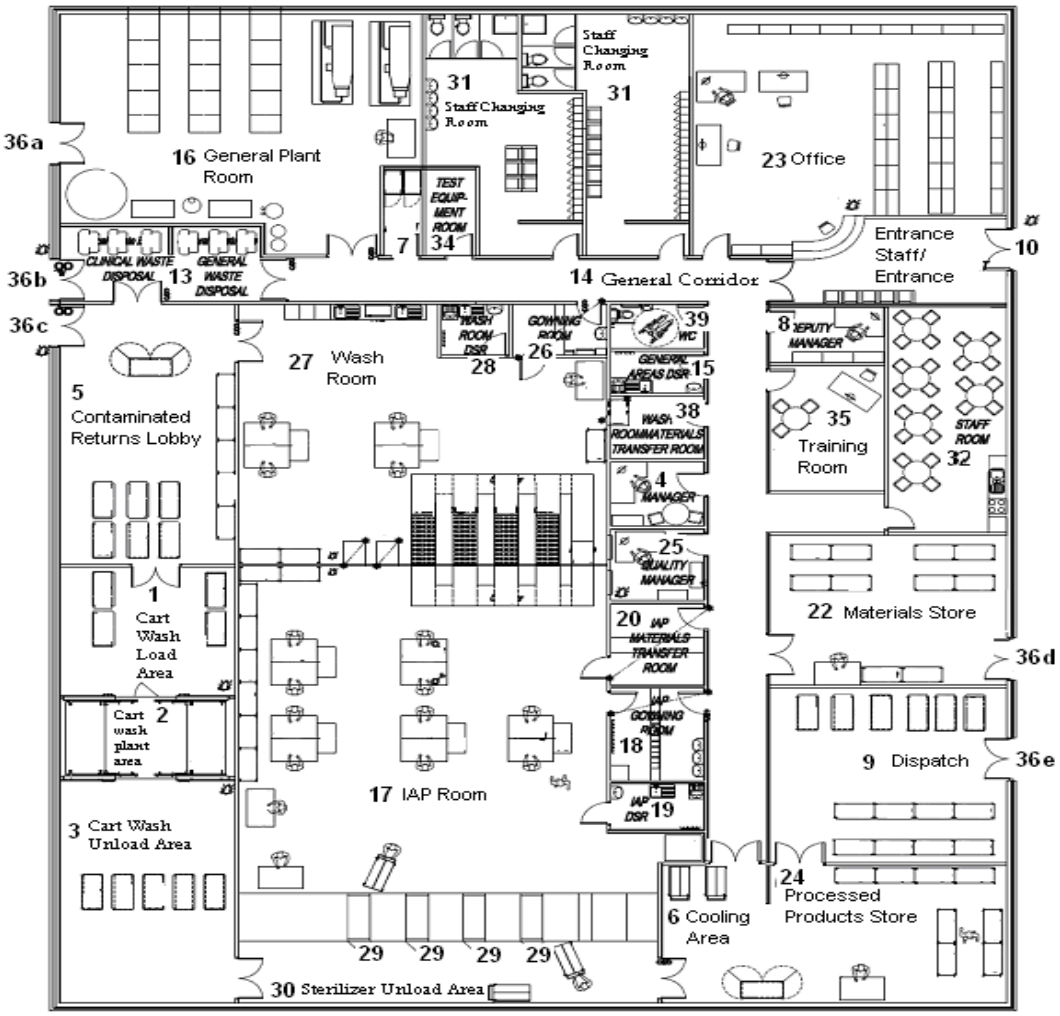


Figure 1: CDU model (Drawing not to scale)

Note: Each room within Figure 1 has a reference number which corresponds to its Room Data Sheet. Refer to paragraph 1.6 for a full list of rooms.

The size of the CDU model is dependent on the designed production capacity. The option appraisal and design qualification will determine the type and number of each type of equipment required. Other rooms, some not shown in this layout, such as the Estate Manager's Office (11), Maintenance Manager's Office (21), Technicians Room (33), First Aid Room (12), other Communications Rooms (7), and other plant areas will be required. These may be located on an upper floor. Refer to Materials Store (22) for consideration of an ante room. Fire exits are not shown in this figure. External support areas are shown in Figure 2. Vehicle movement at loading bays (36a to e) should be considered.

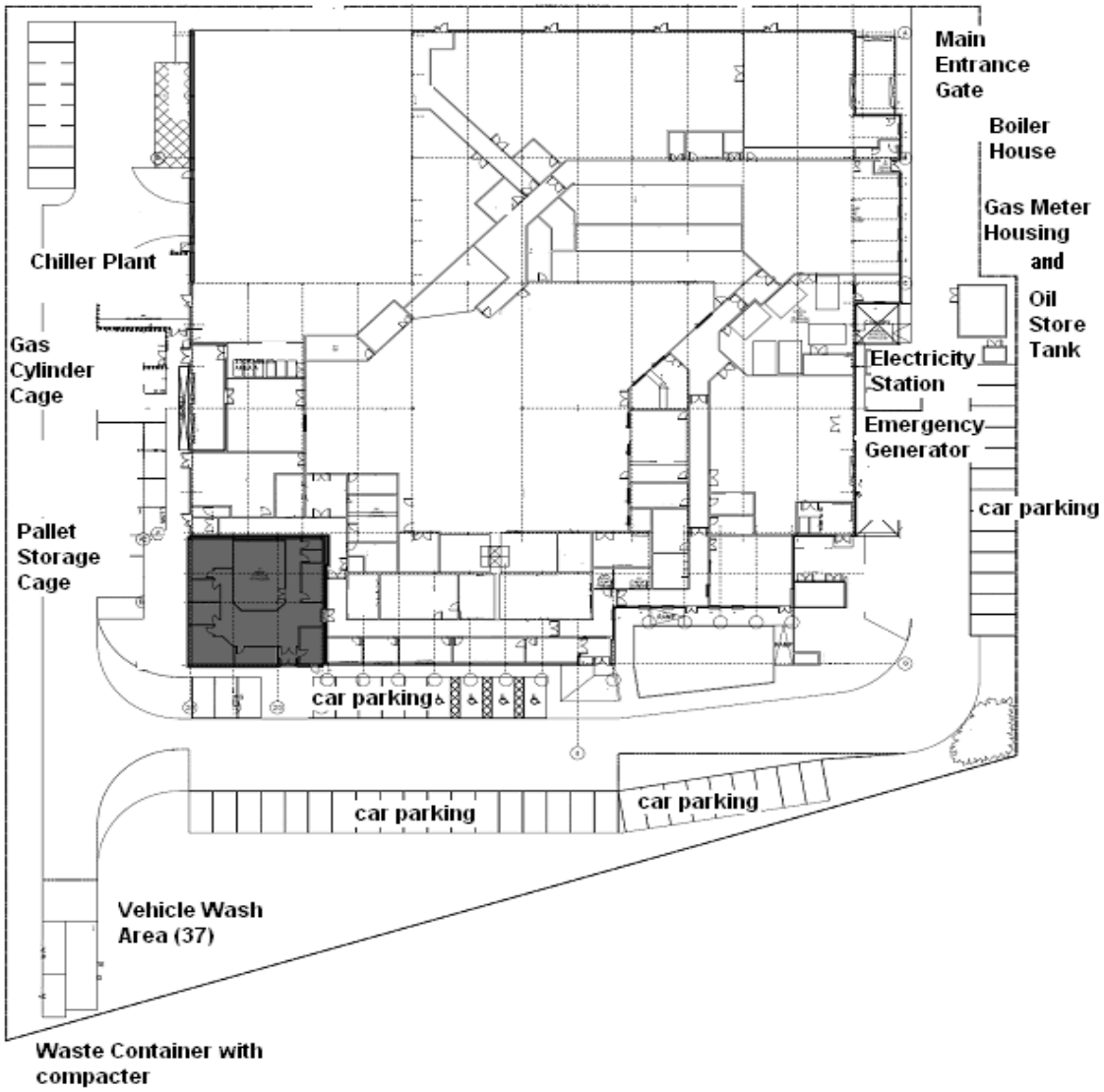


Figure 2: CDU example site layout (Drawing not to scale)

Note: This example is intended to highlight some of the external spaces that are required to support the CDU. Refer to the External Site Data Sheet.

External Site Data - Design

Function: The enclosed area around the CDU building is used to support the CDU's activities.

Occupancy	Personnel	Specify the maximum number of personnel working in the area and vehicles' movement.
Activities	CDU sterile service provision. Staff movement. Suppliers dropping off goods. Waste management. Movement of various sized vehicles such as oil tankers, emergency services, transport vehicles, waste container lorries etc.	
Design Notes	For a dedicated CDU site outwith the hospital grounds a secure perimeter fence should be place with suitable footpaths around the site. All areas should have pedestrian crossings and walkways with specified emergency areas for Fire and Ambulance. The main entrance gates should have secure access for all persons and vehicles. The road around the site should accommodate all vehicles entering the site with room to manoeuvre at all loading bays shown in Figure 1 (reference 36a to e), other drop off/pick up points for example oil deliveries, waste collection points and also meet the requirements of the emergency services. Suitable lighting should be in place around the site. Suitable signage should be in place across the site, e.g. directions at the entrance, reception, loadings bays and muster points in addition to hazard warnings. Car parking should be specified for staff/visitors and contractors with disabled spaces assigned. This may be in several locations around the site to give the best access dependent on the work to be done. Parking may also be required for transport vehicles. A range of the CDU plant and other support areas may be located externally to the building (see room data sheet 16 General Plant Room and Figure 2 in Appendix 1). These may include items such as chiller plant and emergency generator. Enclosed spaces may also be require for oil storage tanks, gas meter housing, electricity station, boiler house, waste storage areas (domestic, clinical, recycled cardboard/plastics etc), gas cylinder cages (propane and medical air) and pallet storage cages. A Vehicle Wash Area (37) may also be required. A number of staff muster points will need to be identified for use in the event of a fire. See Figure 2 for the site layout drawing.	

1	Room Data - Design	

Room: Cart Wash Load Area.

Function	This is an area used to load contaminated return containers/trolleys into the cart washer.	
Occupancy	Personnel	Specify the maximum number of personnel working in the area.
Activities	Loading of the cart washer. Operation of the cart wash cycle. Manual cleaning of carts in the event of cart washers being out of use.	
Design Notes	Specify the maximum number and dimensions of the transport carts containers required to be accommodated in this area as required to achieve the maximum specified production throughput. This should include storage of carts and space for manual cleaning in the event of cart washers being out of use. Consideration of how manually cleaned transport carts would be moved through into the Cart Wash Unload Area (3) in the event of cart washers being out of use. Electronic communication between Cart Wash Load Area (1) and Cart Wash Unload Area (3) required. Consideration should be given to the need for suitable protection of the walls/doors from potential damage from the transport containers when being moving within the room. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Controlled access is required to area.	
Adjacencies (as Figure 1)	Direct access to Contaminated Returns Lobby (5). Direct access to the Cart Wash Plant Area (2).	

1 Room Data - Finishes

Room: Cart Wash Load Area.

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 2. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), protective corners, durable materials on lower part of walls and splayed skirting. Floor finish should allow for the heavy traffic in this area. Edges where the wall meets the ceiling should be coved.	

1 Room Data – M+E

Room: Cart Wash Load Area

Air	Winter deg C	16 to 19
	Summer deg C	16 to 19
	Supply air changes per hour (ac/hr)	That required to deliver the specified room temperature limits.
	Extract ac/hr	Min 10 (with no recirculation into the room supply).
	Relative Pressure	Same pressure as the Contaminated Returns Lobby (5).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height)
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	50
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2	
Safety	Hot Surface Temperature deg C	43
	Hot Water Temperature deg C	N/a
Safety Notes	Warning note that water in cart washer is hot (potentially 80^0C during the cycle).	
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector – The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

1	Room Data – Equipment/Furniture/Fittings	

Room: Cart Wash Load Area

	Details will be required from the cart washer manufacturer. Services will include hot and cold water, drainage, electrical supply and a drainage pit. A steam extract system will be required. Waste water heat recovery systems should be considered. A stainless steel wash sink to be used for manual cleaning purposes in the event of the cart washer being out of service.
	Transport carts.
	Stainless steel storage rack.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

2 Room Data - Design

Room: Cart Wash Plant Area

Function	This is a controlled area used to support the cart washer allowing maintenance and test activities.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	Periodic Testing of cart washer. Maintenance of cart washer.	
Design Notes	A pit will be required in the plant area for each cart washer. Ventilation design to achieve the temperature specified. Adequate space and electrical outlets for maintenance and testing is required including consideration of their impact on production. Ensure the light levels in this area are appropriate at the locations where maintenance or testing is carried out. Adequate space between plant if two cart washers are installed. Will require details from the cart washer manufacturer, will require hot and cold water, drainage, electrical supply and drainage pit. Will also require a steam extract system. Given that a large volume of waste water is generated during operation of the cart washer drainage size should be specified accordingly. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	It should contain the cart washer and associated plant. Direct access from the Cart Wash Load Area (1) only.	

2 Room Data - Finishes

Room: Cart Wash Plant Area

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish stainless steel panels.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be concrete, smooth and finished.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category not defined. There may be no ceiling in this plant space.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	n/a
Internal glazing	Glazing	n/a
Ceiling Hatch	Hatch	If required to be in line with ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered. Stainless steel panels.	

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2 Room Data – M+E

Room: Cart Wash Plant Area

Air	Winter deg C	< 30
	Summer deg C	< 30
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Negative with respect to other areas.
	Final Filtration	Not specified.
	Relative Humidity%	Not specified.
Air notes	Air specification is not applicable if the plant area has no ceiling.	
Lighting	Lighting Level Normal lux	300 (bench height)
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	B
Lighting Notes	Design as SHTM 2011 (need to specify wall lighting if no ceiling is in place).	
Noise	Privacy Factor	< 70
	Mechanical Services-Noise Rating (NR) noise level	Not specified.
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector - The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

2	Room Data – Equipment/Furniture/Fittings	

Room: Cart Wash Plant Area

	Services will include hot and cold water, drainage, electrical supply and a drainage pit. A steam extract system will be required. Waste water heat recovery systems should be considered.
	Workbench.
	Smoke detector.
	Fire extinguishers.
	Socket outlet switched 13 Amp double, ac, wall mounted and IP 56 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 56 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

3 Room Data - Design

Room: Cart Wash Unload Area

Function	This is an area used to unload clean disinfected containers/trolleys from the cart washer and store until required.	
Occupancy	Personnel	Specify the maximum number of staff working in this area.
Activities	Unloading of the cart washer. Checking satisfactory cart wash cycle. Storage of containers/trolleys.	
Design Notes	Specify the maximum number and dimensions of transport carts required to be accommodated in this area as required to achieve the specified maximum production throughput. Electronic communication between Cart Wash Load Area (1) and Cart Wash Unload Area required. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Controlled access is required to area.	
Adjacencies (as Figure 1)	Direct access to Steriliser Unload Area (30). The Cart Wash Unload Area is connected to the cart washer.	
Other Notes	This area has secure and controlled access from the Sterilizer Unload Area (30).	

3 Room Data - Finishes

Room: Cart Wash Unload Area

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transport carts), protective corners, durable materials on lower part of walls and splayed skirting. Floor finish should allow for the heavy traffic in this area. Edges where the wall meets the ceiling should be coved.	

3 Room Data – M+E

Room: Cart Wash Unload Area

Air	Winter deg C	16 to 19
	Summer deg C	16 to 19
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same pressure as the Sterilizer Unload Area (30).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	50
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector - The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

3 Room Data – Equipment/Furniture/Fittings

Room: Cart Wash Unload Area

	Will require details from the cart washer manufacturer.
	Transport carts.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

4 Room Data - Design

Room: CDU Manager's Office

Function	This is an area used to provide an appropriate environment to undertake managerial duties.	
Occupancy	Personnel	Specify the maximum number of personnel in this room, i.e. the CDU manager and the maximum number of persons during a meeting.
Activities	Discussion and meetings with staff. Discussion and meetings with visitors.	
Design Notes	Define storage requirements. Consider the privacy and security of contents. Define the maximum number of people in the room. Depending on CDU manager's requirements there may be a requirement for computers displaying some elements of the building management system. These systems may be on more than one computer. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Ensure the air ventilation system design can deliver the specified room temperature limits, given the equipment planned to be in the room and the specified maximum number of people during a meeting.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Close to the Office (23).	

4 Room Data - Finishes

Room: CDU Manager's Office

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. Consult CDU manager for privacy requirements.
Internal glazing	Glazing	(SHTM 57) Not essential. Consult CDU manager for privacy requirements.
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

4 Room Data – M+E

Room: CDU Manager's Office

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not Specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

4	Room Data – Equipment/Furniture/Fittings	

Room: CDU Manager's Office

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table.
	Desk.
	Chairs.
	Filing cabinet.
	Computer & printer.
	Telephone.
	Wall mounted marker board.
	Computer(s) for floor management system and or building management system.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

5 Room Data - Design

Room: Contaminated Returns Lobby

Function	This is an area for receiving contaminated return containers/trolleys.	
Occupancy	Personnel	Specify the maximum number of staff working in this area.
Activities	Receiving & holding soiled returns. Wash Room staff collect goods. Scanning equipment trolleys. Scanning trays. Hand hygiene.	
Design Notes	Specify the maximum number and dimensions of transport carts and storage containers required to be accommodated in the lobby (allowing for contingency arrangements) as required to achieve the specified maximum production throughput. The maximum fully loaded weight of the transport trolleys should be specified as this will impact on the floor design. Interlock between Contaminated Returns Lobby (5) and the Wash Room (27) required. A hold open device on the two leaf door between these areas will be required. Electronic communication between Contaminated Returns Lobby (5) and the Wash Room (27) required. Doors should be sized to allow replacement of large decontamination equipment such as washer disinfectors which would require to pass through the Contaminated Returns Lobby. (removable transom preferred option with removable panel above doors). Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Controlled access is required to area. Refer to Vehicle Loading Bay (36) for the specification of the loading bay connected to the Contaminated Returns Lobby.	
Adjacencies (as Figure 1)	Direct access to an exterior loading bay (36c). Direct access (interlocked) to the Wash Room (27). Direct access to General/Clinical Waste Disposal (13). Direct access to Cart Wash Load Area (1).	

5 Room Data - Finishes

Room: Contaminated Returns Lobby

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 2. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts). Protective Corners, durable materials on lower part of walls and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish should allow for the heavy traffic in this area. The floor finish together with the sub floor must be capable of withstanding the heavy loads. Edges where the wall meets the ceiling should be coved.	

5 Room Data – M+E

Room: Contaminated Returns Lobby

Air	Winter deg C	16 to 19
	Summer deg C	16 to 19
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	Min 10 (with no recirculation into the room supply).
	Relative Pressure	Negative pressure with respect to the Wash Room (27).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	50
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

5 Room Data – Equipment/Furniture/Fittings

Room: Contaminated Returns Lobby

	Computer terminal point/ Data Scanner for management information system.
	Transport carts.
	Transport containers.
	Storage racking for transport containers.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Pressure differential meter, wall mounted.
	Admin workstation.
	White board
	Wash hand basin as SHTM64.
	Waste- flush, grated, metal, 32mm, no plug as SHTM64.
	Paper towel dispenser, wall mounted.
	Wall mounted dispenser of hand wash solution.
	Hands free clinical waste container.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

6 Room Data - Design

Room: Cooling Area

Function	This is an area used for:- Cooling of instrument trays, packs and supplementary items following sterilization.	
Occupancy	Personnel	Specify the maximum number of personnel working in the area.
Activities	Cooling of sterilized products. Product release. Transfer cooled released product to the Processed Products Store. Parking the sterilizer unloading trolleys.	
Design Notes	Define the maximum number and dimensions of products to be accommodated in this area including trolleys and or racking to allow the maximum specified production throughput. Heat emitted from the cooling product will impact on the design of air ventilation system required to deliver the specified room temperature and relative humidity levels. Confirm the floor structure/finish can accommodate the maximum weight of trolleys to be moved through the area. As there may be frequent movement of trolleys through the door connecting the Cooling Area and the Sterilizer Unload Area (30) door opening sensors should be considered to assist this process in addition to adequate door protection. Specify an area for quarantine of product that has failed visual inspection after sterilization. Sufficient space for manoeuvring trolleys when at maximum capacity allowing for traffic from the Cart Wash Unload Area (3). Ensure the ventilation design is capable of delivering the specified room temperature limits with the maximum design production throughput. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Controlled access is required to this area.	
Adjacencies (as Figure 1)	Direct access to the Sterilizer Unload Area (30). Direct access to the General Corridor (14), Processed Products Store (24) and Dispatch (9).	

6 Room Data - Finishes

Room: Cooling Area

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts). Protective Corners, durable materials on lower part of walls and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved.	

6 Room Data – M+E

Room: Cooling area

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Negative pressure with respect to Sterilizer Unload Area (30).
	Final Filtration	Minimum F5.
	Relative Humidity%	30-60
Air notes	Ensure the ventilation design takes account of the effect of placing the maximum production throughput of hot product into this area. Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	50
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector - The selection, type and placement of smoke detection systems must also take account of false alarms due to the introduction of bulk hot product into the area.

6 Room Data – Equipment/Furniture/Fittings

Room: Cooling Area

	Sterilizer unloading trolleys.
	Transport carts.
	Transport containers.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Stainless steel wires racking for quarantine items and cooling product.
	Desk.
	Chair.
	Filing cabinet.
	Computer.
	Data scanner.
	Telephone.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

7 Room Data - Design

Room: Communications Room

Function	This is a controlled area(s) used to site the various IT servers required to support the quality management system. It may also contain the telephone switchgear. There may be more than one Communications Room required.	
Occupancy	Personnel	Specify the maximum number of staff working in this room.
Activities	Maintenance/ test activities on IT and communication equipment.	
Design Notes	Security of access only to approved staff and supervised contractors. Node cabinets should have different electrical supplies with auto-changeover and UPS back up. Node cabinets may be required in more than one location to provide data security and back up, i.e. there may be more than one Communications Room required. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Sufficient space should be allowed around the node cabinets to carry out maintenance work. Sufficient space should be allowed around the telephone switchgear cabinet to carry out maintenance work. Storage racking should be kept to a minimum and should not interfere with the working space around the node cabinets or telephone cabinet. Ventilation design to achieve the temperature & relative humidity levels specified. Sprinkler Systems would not be recommended in this room.	
Adjacencies (as Figure 1)	Each Communications Room should be connected to the General Corridor (14).	

7 Room Data - Finishes

Room: Communications Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Doorsets	Doorsets	(SHTM 58) Compliant, no vision panel in door for security purposes.
Windows	Windows Type	(SHTM 55) Not essential.
Internal glazing	Glazing	n/a
Ceiling Hatch	Hatch	If required, to be in line with ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

7 Room Data – M+E

Room: Communications Room

Air	Winter deg C	16-21
	Summer deg C	16-21
	Supply ac/hr	That required to meet minimum fresh air requirements for IT staff.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14).
	Final Filtration	Minimum F5.
	Relative Humidity%	30-60
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70 (audible but not intrusive).
	Mechanical Services-Noise Rating (NR) noise level	35
	Intrusive noise – NR noise level	40
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

7 Room Data – Equipment/Furniture/Fittings

Room: Communications Room

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Telephone.
	Intercom to all areas.
	IT servers.
	Telephone switchgear cabinet.
	Shelving.
	Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

8 Room Data - Design

Room: Deputy CDU Manager's Office

Function	This is an area used to provide an appropriate environment to undertake managerial duties of the deputy CDU Manager.	
Occupancy	Personnel	Specify the maximum number of personnel in this room, i.e. the deputy CDU manager and the maximum number of persons during a meeting.
Activities	Discussion and meetings with staff. Discussion and meetings with visitors. Storing files and records.	
Design Notes	Define storage requirements. Privacy and security of contents. Depending on the CDU manager's requirements there may be a requirement for computers displaying some elements of the building management system. These systems may be on more than one computer. Ensure the ventilation system design can deliver the specified room temperature limits, given the equipment planned to be in the room and the maximum number of people during a meeting. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14).	

8 Room Data - Finishes

Room: Deputy CDU Manager's Office

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

8 Room Data – M+E

Room: Deputy CDU Manager's Office

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

8 Room Data – Equipment/Furniture/Fittings

Room: Deputy CDU Manager's Office

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table.
	Desk.
	Chairs.
	Filing cabinet.
	Computer.
	Telephone.
	Wall mounted marker board.
	Computer for floor management system and or building management system.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

9 Room Data - Design

Room: Dispatch

Function	This is an area used for :- Assembling batches of processed products for distribution.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	Loading transportation containers and trolleys. Parking decontaminated distribution trolleys and transport containers waiting to be loaded. Placing trays/packs into transport trolleys. Short term storage of sterile trays & packs. Selecting trays/packs for transferring to Hospitals.	
Design Notes	Define the maximum number and dimensions of products to be accommodated in this area including transport trolleys and racking to meet the maximum specified production throughput. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Confirm the floor structure/finish can accommodate the maximum weight of trolleys to be moved through the area. Sufficient space for manoeuvring trolleys when at maximum capacity. Racking systems should have smooth surfaces to prevent damage to the stored products. Adequate space is required between the lowest storage shelf and the floor to enable access to floor cleaning equipment as required. Controlled access is required to area. Where loaded trolleys or carriages are to be dispatched 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. Consideration of protection from wildlife, birds, cats, rodents etc. should be undertaken. An air curtain may be required at the exit to the loading bay (36e). If a roller door is chosen for the exit door suitable protection (from fully laden transport carts) of the door mechanism should be in place. Refer to Vehicle Loading Bay (36) for the specification of the loading bay connected to Dispatch (9).	
Adjacencies (as Figure 1)	Direct access to the Processed Products Store (24). Direct access to the Vehicle Loading Bay (36e).	

9 Room Data - Finishes

Room: Dispatch

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be in-situ resin bonded flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant. Suitable door protection required.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), protective corners, durable materials on lower part of walls and splayed skirting. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved. Suitable door and door frame protection should be in place.	

9 Room Data – M+E

Room: Dispatch

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Negative pressure with respect to the Processed Products Store (24).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	An air curtain may be required at the exit. Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70 (audible but not intrusive).
	Mechanical Services-Noise Rating (NR) noise level	35
	Intrusive noise – NR noise level	40
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

9 Room Data – Equipment/Furniture/Fittings

Room: Dispatch

	Transport carts.
	Transport containers.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Pressure differential meter, wall mounted.
	Stainless steel storage racking.
	Desk.
	Chair.
	Filing cabinet.
	Computer.
	Data scanner.
	Telephone.
	Wall mounted marker board.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

10	Room Data - Design	

Room: Entrance: Staff / Visitors

Function	To provide controlled secure access for staff and visitors. May provide a waiting area for a defined number of visitors.	
Occupancy	Personnel	State the number of personnel working at reception. Specify the number of seats to be provided for visitors at reception.
Activities	Access for staff. Access for visitors to reception. Receiving post. Staff time recording.	
Design Notes	Secure entrance door to outside with CCTV to view in office reception. Secure door into the General Corridor (14). Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Connects to General Corridor (14). Adjacent to Office (23). Close to Managers' offices (4, 8 and 25).	
Other Notes	Entrance should be ramp-approached.	

10 Room Data - Finishes

Room: Entrance Staff / Visitors

Wall	Wall Finish	Surface Finish (SHTM 56): performance category 5. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): performance category 4. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) N/A
Wall Hatch	Hatch	Sliding, glazed, secure and lockable.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.	

10 Room Data – M+E

Room: Entrance Staff / Visitors

Air	Winter deg C	16-24
	Summer deg C	16-24
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	200
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Standby Lighting Notes: Lighting of the level and quality one third to one half that provided by normal lighting.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

10 Room Data – Equipment/Furniture/Fittings

Room: Entrance Staff / Visitors

	Telephone operator console.
	Coffee Machine.
	Security card reader / writer.
	Fire alarm indicator panel.
	Clock battery operated and wall mounted.
	Security Alarm, push button and wall mounted.
	Cupboard/Drawer Unit, 2 drawers, lockable and on castors.
	Table, occasional, coffee, modular unit.
	Chair, stacking, polypropylene, with seat & back pads.
	Magazine rack for information.
	Rack, security cards.
	Dispenser- drinking water, wall mounted.
	Door mat.
	Fire extinguishers.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

11 Room Data - Design

Room: Estate Manager's Office

Function	This is an area used to provide an appropriate environment to undertake management of the Estate.	
Occupancy	Personnel	Specify the maximum number of personnel in this room, i.e. the Estate manager and the maximum number of persons during a meeting.
Activities	Discussion and meetings with staff/management. Discussion and meetings with visitors/contractors. Storing files and records.	
Design Notes	Define storage requirements. Privacy and security of contents. Depending on the Estate manager's requirements there may be a requirement for computers displaying some elements of the building management system. These systems may be on more than one computer. The validation of the BMS should include verification that it is compatible with the automated controls and systems within the building services package. Ensure the ventilation system design can deliver the specified room temperature limits, given the equipment planned to be in the room and the maximum number of people during a meeting. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies	Direct access to the General Corridor (14) if the design team determine an Estate Manager's Office is required within the CDU.	

11 Room Data - Finishes

Room: Estate Manager's Office

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required, to be in line with ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

11 Room Data – M+E

Room: Estate Manager's office

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14) if the design team determine an Estate Manager's office is required within the CDU.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

11	Room Data – Equipment/Furniture/Fittings	

Room: Estate Manager's Office

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table.
	Desk.
	Chairs.
	Filing cabinet.
	Computer.
	Telephone.
	Wall mounted marker board.
	Computer for floor management system and or building management system.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

12 Room Data - Design

Room: First Aid Room

Function	This is an area used to provide a dedicated private area for First Aid.	
Occupancy	Personnel	Specify the number of personnel to be accommodated-first aider and patient(s).
Activities	Resting for staff that are unwell. Minor First Aid treatment. Hand hygiene.	
Design Notes	This should be a quiet private environment for carrying out minor First Aid and resting of staff that are unwell. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies	Direct access to the General Corridor (14) if the design team determine there is a requirement for a First Aid Room. Easy access from the Entrance Staff/Visitors (10) and to the production areas.	

12 Room Data - Finishes

Room: First Aid Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	n/a
Internal glazing	Glazing	n/a.
Ceiling Hatch	Hatch	If required to be in line with ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

12 Room Data – M+E

Room: First Aid Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14) if the design team determines there is a requirement for a First Aid Room.
	Final Filtration	Minimum F5.
	Relative Humidity(%RH)	< 70
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

12 Room Data – Equipment/Furniture/Fittings

Room: First Aid Room

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Couch, examination/treatment with cover dispenser.
	Chairs.
	Wash hand basin - no tap holes, no overflow, no plug concealed as SHTM 64.
	IPS Panel.
	Hands free waste bin.
	Wall mounted First Aid cabinet.
	Wall mounted paper towel dispenser.
	Wall mounted soap solution dispenser.
	Wall mounted eye wash station with mirror.
	Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

13 Room Data - Design

Room: General / Clinical Waste Disposal Area

Function	This is an area for storing clinical and general waste awaiting collection.	
Occupancy	Personnel	Specify the maximum number of staff working in this area.
Activities	Receiving & holding clinical and general waste. Hand hygiene.	
Design Notes	Specify the maximum number and dimensions of clinical waste and general waste bins required to be accommodated as required to achieve the specified production throughput. The floor should be clearly subdivided in zones for clinical waste and general waste, since this assists rapid collection and reduces porting costs. The size of the area should be determined by the ratio of the rate of accumulation of material for disposal to the frequency of collection Interlock between General Corridor (14), Contaminated Returns Lobby (5) and the Clinical/General Waste exit (36b). Doors should be sized to allow replacement of equipment to access from Wash Room (27) (removable transom preferred option with removable panel above doors). Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Controlled access is required to area. It should be recognised that CDUs will produce significant quantities of contaminated waste and domestic type waste. Waste from deliveries will include pallets, cardboard, polythene, plastic containers and shrink wrap. Waste recycling should be considered at the design stage. Refer to Vehicle Loading Bay (36) for the specification of the loading bay connected to the General/Clinical Waste Disposal Area.	
Adjacencies (as Figure 1)	Direct access (interlocked) to Clinical/General Waste exit (36b). Direct access (interlocked) to General Corridor (14). Direct access (interlocked) to Contaminated Returns Lobby (5).	
Other Notes	Design should take into account the flammability of stored materials and consider the fire protection guidance in SHTM81. **Note** for CDUs producing large quantities of waste there may be a need to place a sealed skip outside of the building for general waste (see Figure 2). This could take the form of a container with attached compactor in a secure cage. External power point would be required for the compactor. The container would be sited on a concrete base. It could be sited alongside the Vehicle Wash Area (37). Other types of general waste may be managed within the Materials Store (22).	

13 Room Data - Finishes

Room: General / Clinical Waste Disposal Area

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 3. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 5. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the waste containers), protective corners, durable materials on lower part of walls and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish should allow for the heavy traffic in this area. Edges where the wall meets the ceiling should be coved. The exit door will require suitable protection from fully laden waste bins.	

13 Room Data – M+E

Room: General / Clinical Waste Disposal Area

Air	Winter deg C	16 to 19
	Summer deg C	16 to 19
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	Min 10 (with no recirculation into the room supply).
	Relative Pressure	Negative pressure with respect to adjoining areas.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	50
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

13	Room Data – Equipment/Furniture/Fittings	

Room: General / Clinical Waste Disposal area

	General waste bins.
	Clinical waste bins.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Waste - flush, grated, metal, 32mm and no plug as SHTM64.
	Wash hand basin as SHTM64.
	Paper towel dispenser, wall mounted.
	Wall mounted dispenser of hand wash solution.
	Hands free clinical waste container.
	Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

14 Room Data - Design

Room: General Corridor

Function	To provide controlled secure access for staff and visitors. To provide access to rooms off the corridor. To allow controlled movement of materials/ equipment between the various areas. (Soiled goods and their transport carts would not enter this corridor).	
Occupancy	Personnel	State number of personnel able to pass through corridor. State equipment/ raw materials able to be moved through the corridor.
Activities	Access for visitors and staff. Movement of raw materials.	
Design Notes	Confirm the corridor can accommodate the safe movement of materials/equipment as required by the decontamination process, e.g. movement of chemicals from the Materials Store (22) to the Wash Room Materials Transfer Room (38). Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Note the pressure differential required to each room where specified. Individual Room Data Sheets will specify pressure difference with respect to this corridor when applicable.	
Adjacencies (as Figure 1 where applicable)	Provides access to; General/Clinical Waste Disposal Area (13), General Plant Room (16), Communications Room (7), Test Equipment Room (34), Staff Changing Rooms (31), Entrance Staff /Visitors (10), Office (23), Managers' Offices (4, 8 & 25), WC (39), Training Room (35), Staff Room (32), General Areas DSR (15), Wash Room Material Transfer Room (38), Materials Store (22), IAP Materials Transfer Room (20), Wash Room Gowning Room (26), IAP Gowning Room (18), Cooling Area (6) and First Aid Room (12).	

14 Room Data - Finishes

Room: General Corridor

Wall	Wall Finish	Surface Finish (SHTM 56): performance category 5. Recommended finish acrylic paint. Protection of wall finish against mechanical damage from mobile equipment such as trolleys/pallet trolleys should be considered. Refer to SHTM 69.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): performance category 4. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail, durable materials on lower part of walls and splayed skirting. Corner protection should also be considered.	

14 Room Data – M+E

Room: General Corridor

Air	Winter deg C	16-24
	Summer deg C	16-24
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Not specified-individual Room Data Sheets will specify pressure difference with respect to this corridor when applicable.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	200 at Floor level.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	N/a
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

14	Room Data – Equipment/Furniture/Fittings	

Room: General Corridor

	Fire Alarm indicator panel.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Dispenser drinking water, wall mounted.
	Notice Board, wall mounted.
	Pressure differential gauges, wall mounted.
	Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac, wall mounted for cleaning equipment etc.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

15 Room Data - Design

Room: General Areas Domestic Services Room (DSR)

Function	This is a controlled area used for storing equipment and supplies used for cleaning the general production areas and other support areas. This would include cleaning of the General Plant Room (16) and the General Corridor (14) through to the Cart Wash Unload Area (3).	
Occupancy	Personnel	Specify the maximum number of staff working in this area.
Activities	Preparation of cleaning solutions for cleaning activities. Disposal of waste cleaning materials and solutions. Cleaning and drying equipment (Specify the number and dimensions of each). Hand hygiene. Storage of cleaning solutions and equipment (specify storage requirements). Completion of cleaning records.	
Design Notes	More than one General Areas DSR may be required if supportive areas such as Estate Manager's Office (11), Maintenance Manager's Office (21) or Technicians Workshop (33) are located upstairs in the CDU. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access from the General Corridor (14). If a second General Areas: DSR is required this may be located on a different level to the production areas.	

15 Room Data - Finishes

Room: General Areas DSR

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential.
Internal glazing	Glazing	n/a.
Ceiling Hatch	Hatch	If required to be in line with ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail, durable materials on lower part of walls, splayed skirting and protective corners.	

15 Room Data – M+E

Room: General Areas DSR

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14)
	Final Filtration	Not specified.
	Relative Humidity%	Not specified.
Air notes		
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	50
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

15	Room Data – Equipment/Furniture/Fittings	

Room: General Areas DSR

	Dedicated cleaning equipment.
	Scrubbing/polishing machine.
	Dry suction machine.
	Warning cone.
	Cleaner's trolley 3 bucket system and floor mop.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Low level bucket sink.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Traps for the waste pipes should be accessible from outside of the gowning room. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Wall mounted cartridge soap dispenser.
	Storage facilities (wire rack) for equipment.
	Wall mounted easily cleaned paper towel dispenser.
	Stainless steel sink with drainer.
	Hands free clinical waste containers.
	Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

16 Room Data - Design

Room: General Plant Room

Function	Accommodating plant associated with the general equipment within the CDU (which may include equipment for compressed air, steam generation, clean steam generation, water treatment/storage, air handling units), sprinklers systems and electrical incomer and distribution board. The plant will include that required for emergency supplies and duplex systems where specified. Securely and safely storing water treatment chemicals. Accommodating workshop space to allow mechanical engineering work which will likely be dirty in nature.	
Occupancy	Personnel	State the maximum number of staff the room can accommodate.
Activities	Validation and routine testing/maintenance of plant and associated equipment. Movement/ storage of water treatment chemicals.	
Design Notes There are two pages on Design for this Room Data Sheet.	There may be more than one General Plant Room (16) required and these may be on different levels within the building. Internal/External plant room doors should be sized to accommodate plant access and bulk raw materials if applicable. These doors and associated operating mechanism (e.g. roller door) should have suitable damage protection. Sampling facilities for water, air and/or steam quality should be considered. Careful consideration should be given to incorporating thermal insulation within the construction of the walls, doors and ceilings between the General Plant Room and surrounding rooms. e.g. insulating a ceiling in a room containing boiler plant will add to heat build up within the room. Sufficient air cooling would be required to allow plant maintenance activities to be carried out. The rationale for the size of the water storage tank should be stated, e.g. 24 hour supply for the production area. Duplex systems should be considered for all critical plant. In some circumstances it may be preferable to have additional plant. For example with a lead and back up boiler there would still be one boiler out of use (possibly one month) for annual inspection. Therefore three suitably sized boilers may be a better option in ensuring continuity of production. Ensure non return valves are installed to allow isolation of individual boilers. Hot well tanks are required to receive water via waste heat recovery vessels. These tanks will feed the main boiler plant. Consideration of the rationale concerning the provision of clean steam will impact on space requirements in the plant room(s). Centralised generation of clean steam versus local dedicated clean steam generators at each sterilizer should be considered. Emergency generators and oil storage tanks may be located in external plant areas. The rationale for the sizing of these should be stated, e.g. the design load capacity should be capable of maintaining the full electrical load under normal conditions. Emergency generators can be supplied as a module placed in its own housing external to the CDU building (see Figure 2). The fuel storage requirements for the emergency generator should be assessed and specified. Water main- consider spigot tee connection on main incoming supply for hose connection of bulk tank delivery in the event of mains failure.	

16 Room Data – Design (continued)

Room: General Plant Room

	A secure closed off area to house the main electrical incomer and distribution board is required. Other distribution boards may require to be housed in other areas. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the Room Data Sheet. Consider the requirements for a maintenance workshop in this area including its storage requirements. Considerable storage space may be required for spare parts for example washer disinfectors, sterilizers, pumps, auto control components for air handling plant, water filtration plant and RO plant.
Adjacencies (as Figure 1)	Direct secure access to outside of building (36a). Direct access to General Corridor (14) or other if plant room on upper level.
Other Notes	Adequate space and electrical outlets 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 item of plant to facilitate ease of maintenance and installation without interruption to production. External doors should be sized to accommodate access of plant during installation and future planned upgrades.

16 Room Data - Finishes

Room: General Plant Room

Wall	Wall Finish	Surface Finish (SHTM 56): performance category 5: Recommended finish sealed block work. Exposed steelwork to be painted.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be sealed concrete, smooth and finished. A liquid membrane may be applied to the concrete to provide chemical resistance. Flooring in the first floor to accommodate ventilation plant/ducting may be galvanised steel open mesh grid.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): self finish roof cladding.
Doorsets	Doorsets	(SHTM 58) Compliant. Full width kick plates.
Windows	Windows Type	(SHTM 55) Not essential.
Internal glazing	Glazing	(SHTM 57) N/A
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. The floor should be designed with regard to the weight of plant/raw materials to which it will be exposed. The floor finish should also be compatible with any chemicals (such as water treatment chemicals) that are stored or used within the area.	

16 Room Data – M+E

Room: General Plant Room

Air	Winter deg C	< 30
	Summer deg C	< 30
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Negative with respect to adjoining areas.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 at floor.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	< 70
	Mechanical Services-Noise Rating (NR) noise level	Not specified.
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes		
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector. Located to avoid false alarms from humidity spikes.

16 Room Data – Equipment/Furniture/Fitting

Room: General Plant Room

	Water treatment Plant, RO Plant.
	Storage for chemicals.
	Water main, Water storage Tank with 24 hour (or other) capacity.
	Clean steam generator (local to equipment or central supply).
	Air handling units/ductwork/control panels.
	Boilers-dual fuel (gas/oil) & associated plant including hot well tanks. Automatic water treatment unit for feedwater for boiler.
	Chilled water plant.
	Emergency generator with fuel storage.
	Oil storage bunded tank.
	Gas meter housing secure, water tight on a concrete base with air vents.
	Mains incoming & distribution board-sealed secure watertight with fixed signage conforming to the IEE regulations.
	Air compressors.
	Phone.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Wash hand basin.
	Wall mounted dispenser, with non-refillable hand wash solution.
	Wall mounted, easily cleanable dispenser for single use paper towels.
	Hands free clinical waste container.
	Sink for discarding waste water during water/steam testing.
	Work bench.
	Desk.
	Storage rack.
	Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Sufficient number and suitably located to allow use of portable test equipment during testing of the plant.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

17	Room Data - Design	

Room: Inspection, Assembly and Packing (IAP) Room

Room Function	The IAP Room (17) is a cleanroom, a controlled environment that conforms to airborne particle classification ISO Class 8 in the 'operational' occupancy state, i.e. during production activities. The room provides a suitable controlled environment for the receipt, inspection, testing, assembly, packing and labelling of cleaned and disinfected reusable medical devices.	
Occupancy	Personnel	Specify the maximum number of persons to be permitted in the IAP Room (17) at any one time when at maximum production throughput (this is inclusive of visitors, contractors and maintenance personnel) and define the cleanroom attire to be worn, e.g. 100% polyester cleanroom gowns, mobcaps and dedicated cleanroom footwear.
Activities There are three pages on Design for this Room Data Sheet.	These may include: Receiving clean, dry, disinfected devices from the Wash Room (27) via washer disinfectors or clean dry manually cleaned devices via a transfer hatch or drying cabinet connecting the two rooms. Receiving packing materials from the IAP Materials Transfer Room (20). Inspecting, packing instruments into trays/packs. Prepare packs and heat seal pouches/bags. Inspecting and testing items requiring a light source/magnification/ medical compressed air. Diathermy + conductivity functionality testing of certain devices. Inspecting, testing and packing endoscopic equipment. Parking steriliser loading trolleys. Transfer checked trays/packs to carriers on steriliser loading trolleys to the sterilising loading area within the IAP Room (17). Moving/manoeuvring steriliser loading trolley. Receive empty carriers via returns hatch from Steriliser Unload Area (30). Returning empty containers to the Wash Room (27). Tracking processed equipment passing through the room. Other activities could include environmental testing, environmental cleaning and maintenance.	

17 Room Data – Design (continued)

Room: Inspection, Assembly and Packing (IAP) Room

Design Notes	The IAP Room (17) is a cleanroom in which the airborne particles are controlled, and which is constructed and used in a manner to minimize the introduction, generation and retention of particles inside the room, and in which other parameters such as temperature, relative humidity and pressure differentials are controlled. The IAP Room (17) is specified as ISO Class 8 for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1. The contamination, affecting product quality, to be controlled includes both viable and non-viable types. The room design including the layout of furniture/equipment, surface type/ quality of finishes and air handling systems along with appropriate cleanroom staff discipline will determine whether the room environment is suitable for its intended purpose within the production process (decontamination lifecycle). The maximum number and dimensions of workstations, trolleys and storage racking for each type of activity required to meet the maximum production throughput should be specified. Supply of electrical power to equipment at workstations should ensure the minimal length of power cables is specified to minimize build up of contamination and allow for effective surface cleaning. The number & size of transfer hatches, gravity/ powered conveyors and design of the washer disinfector drip tray drainage systems - to suit requirements should be specified. The ceiling should be, where possible, solid with no access hatches. The ceiling should be of "walk on standard" from within the plant room above. This should allow maintenance work to be carried out on cleanroom lights and air handling systems as required with minimal disturbance to production. The IAP Room (17) design should consider the impact of noise generated from mechanical services. Washer Disinfectors and Sterilizers connected to the IAP Room may generate significant noise during operation. If the original design plans for future installation of equipment such as pass-through washer disinfectors or pass-through sterilizers then consideration should be given to designing a suitable wall construction to minimize production downtime. This would apply to all areas where large equipment would be required to move through on route to the installation site. If medical grade air is required in the IAP Room it should be piped in and where it passes through the wall the fitting should be dust tight. Air cylinders should not be stored in the IAP Room. Loading systems/trolleys for washer disinfectors or sterilizers may have limited flexibility in adjusting their height. In these cases the floor datum level and finish should be clearly specified. Telephones to be wall mounted, recessed, hands free operation, voice switching and spray cleanable. Wall mounted cleanroom grade intercoms to seek attention from the Wash Room (27), Quality Manager's office (25) and Sterilizer Unload Area (30) should be installed.

17 Room Data – Design (continued)

Room: Inspection, Assembly and Packing (IAP) Room

	Public address system with facility for piped music should be considered. The fire prevention officer will need to agree the staff means of escape from this area. Fire detection systems, e.g. VESDA that can be maintained externally to the cleanroom environment would be preferable providing the room integrity, i.e. the room airborne particle classification and pressure differential regime is not adversely effected. Standard ceiling mounted smoke detectors require to have smoke introduced into the cleanroom for testing purposes resulting in production downtime. Sprinkler systems are not recommended with respect to contamination control principles. The local Fire Officer will have to approve fire control measures. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Pressure gauge monitoring of pressure differential with respect to the Gowning Room (18), Materials Transfer Room (20), Wash Room (27) and the Sterilizer Unload Area (30) required.
Adjacencies (as Figure 1)	Adjacent to the Sterilizer unload Area (30) via pass through sterilizers. Adjacent to the Wash Room (27) connected via pass through washer disinfectors and transfer hatch. May also connect to the Wash Room (27) via an interlocked heated drying cabinet. Direct access to the IAP DSR (19). Direct access to the IAP Materials Transfer Room (20). Direct access to IAP Gowning Room (18).

17 Room Data - Finishes

Room: Inspection, Assembly and Packing (IAP) Room

Wall	Wall Finish	Surface Finish SHTM 56: performance category 3. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints or in-situ resin bonded flooring.
Ceiling	Ceiling Finish	Surface finish (SHTM 60): performance category 1.
Doorsets	Doorsets	(SHTM 58) Compliant. The interlocked door from the IAP Room (17) into its gowning room (18) should have a flush fitting smooth vision panel.
Windows	Windows Type	(SHTM 55) Not essential. If provided- clear, solar control, without opening, airtight.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Hatch	Hatch	Built-in, pass through, sliding interlocking doors
Finish Notes	There should be no exposed wooden finishes in the IAP Room. Ceiling to be solid. No access hatches in the ceiling. Walls may be subject to potential damage from mobile equipment such as transport trolleys and dedicated room cleaning equipment. In this room the use of buffer rails for protection is not appropriate as they provide an unwanted surface that can allow the build up of contamination. The same rationale applies to electrical trunking. This would require to be recessed and flush with wall surface if required. Electrical power to work stations located away from the walls could be from pendants from the ceilings or power cables from ceiling electrical sockets. Door frames if used should be flush with wall surfaces. The flooring should be turned up at the junction with the walls in an integral coved skirting. There should be no expansion joints in this room. Edges where the wall meets the ceiling should be coved. Coving should be suitable for heat exposure where it is directly above heat producing equipment such as washer disinfectors or sterilizers. The “cut outs” and “in fill panels” around equipment such as pass through-washer disinfectors and pass-through sterilizers will need to be demountable where required to facilitate service access. The design of the panels should allow them to be re-sealed, post maintenance work, to the level required to maintain the specified room pressure differential regime. To minimize ingress of contamination the room fabric/sealing must give a room integrity that will enable the room airborne classification to be achieved. Fittings/fixtures to the fabric of the cleanroom should be dust tight and or recessed if possible to minimize ledges, e.g. fire exit signage. The emergency exit door seals must be appropriate for the cleanroom environment of the IAP Room.	

17 Room Data – M+E

Room: Inspection, Assembly and Packing (IAP) Room

	Winter deg C	16 to 21
	Summer deg C	16 to 21
There are two pages on M+E for this Room Data Sheet.	Supply Air Change per hour (ac/hr)	That required to deliver the specified room conditions, i.e. airborne particle classification (at occupancy status "Operational"), temperature, relative humidity and pressure differential. Nominal 20 (rate set to meet airborne particle classification in the 'operational' occupancy state) through ceiling diffusers (spiral or four-way).
	Extract ac/hr	That required to deliver the specified room conditions. Low level extract grills to be used.
	Relative Pressure(Pa)	IAP Room (17) to be: +10 with respect to (wrt) its gowning room (18). +ve wrt its DSR (19). +10 wrt its material transfer room (20). +25 wrt the General Corridor (14). +30 wrt the Wash Room (27). (min.of +15) +10 wrt the Sterilizer Plant Room (29). +15 minimum wrt the Sterilizer Unload Area (30). These are suggested minimum pressure differentials based on a minimum of 15Pa between adjoining controlled/uncontrolled rooms and 10Pa between two adjoining controlled rooms. There are no maximum specifications of pressure differentials given.
	Final Filtration	Primary coarse filter grade G4 and secondary fine filter grade F9 as filter standard BS EN 779. Terminal HEPA filters (grade H12) may be considered. If used these would be protected by a secondary filter grade of less than F9.
	Relative Humidity (% RH)	40 to 60
Air notes	Mechanical ventilation (supply): ISO Class 8 for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1. Ceiling air supply diffusers to be 'four-way' or spiral type. There should be both an adequate number and suitably located ceiling supply and low level extract grills to achieve the airborne particle classification in the operational occupancy state. Some form of duplex air handling systems should be considered to minimize disruption to production during maintenance activities. Note the room air change rate directly effects the recovery time to satisfactory room conditions after an event that has compromised the room environment.	

17 Room Data – M+E (continued)

Room: Inspection, Assembly and Packing (IAP) Room

Lighting	Lighting Level during production (Lux)	500 at each workstation surface.
	Lighting Level Night (Lux)	Not specified.
	Lighting Level floor (Lux)	300
	Colour Rendering	Consider the potential effects of glare from the stainless steel workstations.
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Dust Tight Light Fittings/enclosures protected against splashing water – IP 64 rated.	
Noise	Privacy Factor	< 70
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector – The selection, type and placement of smoke detection systems must also take account of contamination control issues within the controlled environments.

17	Room Data – Equipment/Furniture/Fittings	

Room: Inspection, Assembly and Packing (IAP) Room

	Illuminated magnifier.
	Video microscope.
	Pouch reel holder.
	IT terminals and printer(s) and associated sundry items.
	Tape dispensers.
	Heat sealer.
	Mobile, height-adjustable dedicated workstations (for inspection, function testing, heat sealing, packing and administration).
	Specialist cabinet for product lubrication and air testing (if required)- this cabinet is designed to protect both the staff and the product. If the air extract is directly into the IAP Room it must be via a HEPA Filter (grade H12 minimum).
	Interlocked drying cabinet fitted in wall to Wash Room (27).
	Paper wrap trolley.
	Mobile stainless steel storage racks (including a quarantine area).
	Mobile, height-adjustable chair/stool.
	Stainless steel trolleys.
	Fixed roller/conveyor system for unloading WDs and returning empty carriages.
	Conveyor system for packed product transfer.
	Ventilation system status indicators/alarm.
	Phones/intercom to each connecting area.
	Fire exit signage suitable for the IAP Room cleanroom environment. Fire extinguishers.
	Socket outlet switched 13 Amp double, AC, wall or ceiling mounted and IP 64 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider. Note- all equipment/furniture/fittings in this room should be of cleanroom quality. There should be no exposed wooden surfaces in this room.

18 Room Data - Design

Room: IAP Room: Gowning Room

Function	To provide controlled entry and exit of personnel in line with good cleanroom discipline thereby minimizing the introduction of contamination into the IAP Room (17). Provide staff/supervised visitors with a facility for changing into and out of cleanroom overgarments, dedicated footwear and carry out hand hygiene.	
Occupancy	Personnel	State the maximum number of staff the room can accommodate. This includes the number of staff entering from the General Corridor (14) and from the IAP Room (17). Note- the number of wash hand basins will limit the number of staff that can carry out the gowning procedure for entry into the IAP Room (17) at the same time.
Activities	Hand hygiene using touch free fittings on the wash hand basins located on the dirty side of the room divided by the step-over bench. Changing into/out of cleanroom overgarments. Using transfer bench to change into/out of dedicated footwear. Holding new cleanroom overgarments & both types of foot wear, i.e. cleanroom footwear and general footwear. Hanging partially used cleanroom overgarments during staff breaks. Disposing of used cleanroom overgarments into appropriate bins.	
Design Notes There are two pages on Design for this Room Data Sheet.	The IAP Room Gowning Room (18) acts as an airlock between the IAP Room (17) and the General Corridor (14). The IAP Room Gowning Room (18) environment requires to be a controlled environment in its own right and is specified as ISO Class 9 for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1. Contamination to be controlled in this room includes both viable and non-viable types. Pressure differential monitoring between this room and the IAP Room (17) and the General Corridor (14) required. Specify the space required for storage of cleanroom overgarments, wall hooks, overgarment bin and footwear storage based on the maximum production throughput. There should be no exposed wooden finishes in the IAP Room Gowning Room (18). To facilitate change between the dirty side (corridor side of the gowning room) and the clean side (IAP Room side of the gowning room) a demarcation step-over bench barrier should be provided. The barrier should clearly divide the gowning room into a clean side and a dirty side. This controlled access into and out of the IAP Room (17) is one of a number of measures intended to minimize the introduction of contamination into the IAP Room. The barrier may be designed to enable wheelchair access. In this case an assessment of the contamination risks to the decontamination process from the use of wheelchairs should be carried out. Wheelchair use may present an increased risk of both introducing and generating contamination in the cleanroom environment of the IAP Room. There should be adequate wall space on each side of the step-over	

18 Room Data – Design (continued)

Room: IAP Room: Gowning Room

	bench. Wall space on the clean side of the step over is required to accommodate the number of wall hooks for hanging cleanroom garments (one hook per garment) and the full length mirror for checking satisfactory cleanroom attire. Wall space on the dirty side of the step-over bench must accommodate the wash hand basins, paper towel dispensers, cartridge soap dispenser and storage of new cleanroom overgarments. Location of the storage of the new cleanroom overgarments should be such that hand hygiene activity will not splash water onto them. Floor space is also required for foot operated waste containers and suitable storage bins for used cleanroom overgarments. Pipework associated with wash hand basins should be concealed. Traps for their waste pipes should be accessible from outside of the gowning room. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.
Adjacencies (as Figure 1)	Direct access (interlocked) to IAP Room (17). Direct access (interlocked) to General Corridor (14).
Other Notes	State rationale for the number of wash hand basins/ paper towel dispensers required with respect to the planned maximum number of staff working in the IAP Room (17). Hand hygiene carried out on entering the gowning room is one of a number of contamination control measures intended to primarily protect the product.

18 Room Data - Finishes

Room: IAP Room: Gowning Room

Wall	Wall Finish	Surface Finish (SHTM 56): performance category 3: Recommended finish elastomeric vinyl compound or epoxy coating/ acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): performance category 3 Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant. Both interlocked doors should have vision panels which are flush fitting and smooth.
Windows	Windows Type	(SHTM 55) Not essential. If provided - clear, without opening, airtight.
Internal glazing	Glazing	(SHTM 57) N/A.
Finish Notes	No exposed wooden surfaces. Ceiling to be solid if possible. No access hatches in the ceiling if possible. If access hatches are required they should be dust tight and be of a design that will remain so after use. Walls may be subject to potential damage from mobile equipment such as transport trolleys and dedicated room cleaning equipment. In this room the use of buffer rails for protection is not appropriate as they provide an unwanted surface that can allow the build up of contamination. The same rationale applies to electrical trunking. This would require to be recessed and flush with wall surface if required. Door frames should be flush with wall surfaces. Protective corners should be employed. The flooring should be turned up at the junction with the walls in an integral coved skirting. Edges where the wall meets the ceiling should be coved. To minimize ingress of contamination the room fabric/sealing must give a room integrity that will enable the room airborne classification to be achieved. Fittings/fixtures secured to the fabric of the gowning room should be dust tight.	

18 Room Data – M+E

Room: IAP Room: Gowning Room

	Winter deg C	16 to 21
	Summer deg C	16 to 21
There are two pages on M+E for this Room Data Sheet.	Supply ac/hr	That required to deliver the specified room conditions, i.e. airborne particle classification (at occupancy status "Operational"), temperature, relative humidity and pressure differential.
	Extract ac/hr	That required to deliver the specified room conditions. Low level extract grills to be used.
	Relative Pressure	-10Pa with respect to the IAP Room (17). +15Pa with respect to the General Corridor (14).
	Final Filtration	Primary filter grade G4 and secondary filter grade F8 Filter standard BS EN 779.
	Relative Humidity%	Not specified.
Air notes	Mechanical ventilation (supply): ISO Class 9 for considered particle sizes 0.5 and 5 micron tested in the "operational" occupancy state as BS EN ISO 14644-1.	
Lighting	Lighting Level during production (lux)	300 at floor.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Dust Tight Light Fittings/enclosures protected against splashing water – IP64. Design as SHTM 2011.	
Noise	Privacy Factor	< 70
	Mechanical Services-Noise Rating (NR) noise level	Not specified.
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.

18 Room Data – M+E (continued)

Room: IAP Room: Gowning Room

Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector – The selection, type and placement of smoke detection systems must also take account of contamination control issues within the controlled environments.

18	Room Data – Equipment/Furniture/Fittings	

Room: IAP Room: Gowning Room

	Wash hand basin (installed on the floor at the General Corridor side of step-over bench) vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Traps for the waste pipes should be accessible from outside of the gowning room. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Wall mounted dispenser, with non-refillable hand wash solution (General Corridor side).
	Wall mounted, easily cleanable dispenser for single use paper towels (General Corridor side).
	Fire alarm.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Secure entry unit wall mounted both sides of each door.
	Hands free general waste container (corridor side).
	Wall hooks for hanging partially used cleanroom overgarments. (hooks positioned on clean side of step-over bench)
	Stainless steel rack for storage of new cleanroom overgarments. (corridor side)
	Used cleanroom overgarments bin (corridor side).
	Foot operated waste container.
	Dedicated footwear storage – stainless steel rack (both for IAP Room footwear and general footwear) – sized according to design rationale for staff moving in/out of the area.
	Step over bench- stainless steel.
	Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. (sockets positioned on walls on both sides of the stepover bench).

No exposed wooden surfaces for any equipment/furniture or fittings in this room.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

19	Room Data - Design	

Room: IAP Room: Domestic Services Room (DSR)

Function	This is a controlled area used for storing approved dedicated equipment and supplies used for cleaning the IAP Room (17), the clean side of the step-over bench in the IAP Gowning Room (18) and the clean side of the barrier in the IAP Materials Transfer Room (20).	
Occupancy	Personnel	Specify the maximum number of staff working in this room.
Activities	Preparation of cleaning solutions for cleaning activities. Disposal of waste cleaning materials and solutions. Hand hygiene. Storage of cleaning solutions and dedicated equipment (Specify storage requirements and dimensions of equipment to be accommodated).	
Design Notes	The IAP Room DSR (19) connects directly only to the IAP Room (17). This DSR environment requires to be a controlled environment in its own right and is specified as ISO Class 8 for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1. It should have minimal impact with respect to the controlled environment of the IAP Room to which it is connected. Contamination to be controlled in this DSR includes both viable and non-viable types. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access from the IAP Room (17) only.	

19 Room Data - Finishes

Room: IAP Room: DSR

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 3. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints or in-situ resin bonded flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound-attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Finish Notes	There should be no exposed wooden surfaces in this room. Ceiling to be solid if possible. No access hatches in the ceiling if possible. If access hatches are required they should be dust tight and be of a design that will remain so after the hatch has been opened and closed. Walls may be subject to potential damage from mobile equipment such as the dry suction machine and cleaner's trolley that are stored in this room. In this room the use of buffer rails for protection is not appropriate as they provide an unwanted surface that can allow the build up of contamination. The same rationale applies to electrical trunking. This would require to be recessed and flush with wall surface if required. Protective corners should be employed. Door frames should be flush with wall surfaces. The flooring should be turned up at the junction with the walls in an integral coved skirting. Edges where the wall meets the ceiling should be coved. To minimise ingress of contamination the room fabric/sealing must give a room integrity that will enable the room airborne classification to be achieved. Fittings/fixtures secured to the fabric of the DSR should be dust tight.	

19 Room Data – M+E

Room: IAP Room: DSR

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
There are two pages on M+E for this Room Data Sheet.	Supply ac/hr	That required to deliver the specified room conditions, i.e. airborne particle classification (at occupancy status "Operational"), temperature, relative humidity and pressure differential
	Extract ac/hr	That required to deliver the specified room conditions. Low level extract grills to be used.
	Relative Pressure	Negative with respect to IAP Room (17).
	Final Filtration	Primary filter grade G4 and secondary filter grade F9 Filter standard BS EN 779. Terminal HEPA filters (minimum grade H12) may be considered.
	Relative Humidity%	Not specified
Air notes	Mechanical ventilation (supply): ISO Class 8 for considered particle sizes 0.5 and 5 micron tested in the "operational" occupancy state as BS EN ISO 14644-1. Ceiling air supply diffusers to be "four-way" or spiral type. Storage of equipment in this room should not interfere with the air extract grills.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Dust Tight Light Fittings/enclosures protected against splashing water – IP64. Design as SHTM 2011.	
Noise	Privacy Factor	Not specified.
	Mechanical Services-Noise Rating (NR) noise level	Not specified.
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.

19	Room Data – M+E (continued)	

Room: IAP Room: DSR

Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector – The selection, type and placement of smoke detection systems must also take account of contamination control issues within the controlled environments.

19	Room Data – Equipment/Furniture/Fittings	

Room: IAP Room: DSR

	Dedicated cleaning equipment. Scrubbing/polishing machine. Dry suction machine. Warning cone. Cleaner's trolley 3 bucket system and floor mop.
	Fire alarm & Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Low level bucket sink, stainless steel.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Traps for the waste pipes should be accessible from outside of the gowning room. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Wall mounted cartridge soap dispenser.
	Storage facilities (wire rack) for equipment.
	Wall mounted easily cleaned paper towel dispenser.
	Stainless steel sink with drainer.
	Hands free clinical waste containers.
	Socket outlet switched 13 Amp double, ac, wall mounted and IP 65 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 65 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

Note: All equipment/furniture/fittings in this room should be of cleanroom quality. There should be no exposed wooden surfaces in this room.

20 Room Data - Design

Room: IAP Materials Transfer Room

Function	This room is used to control the movement of materials into (and out) of the IAP Room (17). This room provides an air lock between the IAP Room and the General Corridor (14) in order that the level of contamination introduced and generated within the IAP Room is minimized.	
Occupancy	Personnel	Specify the maximum number of personnel working in this room.
Activities	Transfer of raw materials from the Material Store (22) to the IAP Room (17). Inspecting incoming goods. Remove waste from the IAP Room (17). Short term storage.	
Design Notes	State the space requirements needed for transfer of materials to meet the maximum specified production throughput. The IAP Materials Transfer Room provides an air-lock between the IAP Room (17) and the General Corridor (14). The IAP Materials Transfer Room is specified as ISO Class 9 for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1. A transfer barrier divides the room. This barrier will prevent the movement of personnel through this room into the IAP Room. Pressure gauge recording pressure differential with respect to the IAP Room (17) and the General Corridor (14) required. Controlled interlocked access is required to area. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Note-an alternative design could involve the use of an interlocked transfer hatch connecting the IAP Materials Transfer Room (20) and the IAP Room (17).	
Adjacencies (as Figure 1)	The room adjoins the IAP Room (17). The room adjoins the General Corridor (14).	
Other Notes	Entrance doors must accommodate bulk handling activities if required.	

20 Room Data - Finishes

Room: IAP Materials Transfer Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 3. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Transfer Hatch	Hatch	An interlocked transfer hatch could be considered as an alternative to dividing the room with a transfer barrier.
Finish Notes	No exposed wooden surfaces. Ceiling to be solid if possible. No access hatches in the ceiling if possible. If access hatches are required they should be dust tight and be of a design that will remain so. Walls may be subject to potential damage from the use of mobile equipment such as the dry suction machine and cleaner's trolley during room cleaning activities. In this room the use of buffer rails for protection is not appropriate on the IAP Room side of the transfer barrier as they provide an unwanted surface that can allow the build up of contamination. The same rationale applies to electrical trunking which would require to be recessed and flush with the wall surface if required. Protective corners should be employed. Door frames should be flush with wall surfaces. The flooring should be turned up at the junction with the walls in an integral coved skirting. Edges where the wall meets the ceiling should be coved. To minimise ingress of contamination the room fabric/sealing must give a room integrity that will enable the room airborne classification to be achieved. Fittings/fixtures secured to the fabric of the room should be dust tight.	

20 Room Data – M+E

Room: IAP Materials Transfer Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room conditions, i.e. airborne particle classification (at occupancy status 'Operational'), temperature, relative humidity and pressure differential.
	Extract ac/hr	That required to deliver the specified room conditions. Low level extract grills to be used.
	Relative Pressure	+15Pa with respect to General Corridor (14). -10 Pa with respect to IAP Room (17).
	Final Filtration	Primary filter grade G4 and secondary filter grade F8 Filter standard BS EN 779.
	Relative Humidity%	30-60
Air notes	Mechanical ventilation (supply): ISO Class 9 for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	< 70
	Mechanical Services-Noise Rating (NR) noise level	Not specified.
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

20 Room Data – Equipment/Furniture/Fittings

Room: IAP Materials Transfer Room

	Computer.
	Data scanner.
	Fire alarm.
	Clock battery operated and wall mounted.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Intercom wall mounted.
	Transfer barrier.
	Waste container on corridor side of barrier.
	Storage racking metal.
	Telephone.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted IP 54 rated and positioned on both sides of transfer barrier. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

No exposed wooden surfaces in this room.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

21 Room Data - Design

Room: Maintenance Manager's Office

Function	This is an area used to provide an appropriate environment to undertake management of the facility maintenance.	
Occupancy	Personnel	Specify the maximum number of personnel in this room, i.e. the Maintenance Manager and the maximum number of persons during a meeting.
Activities	Discussion and meetings with staff/management. Discussion and meetings with visitors/contractors. Storing files and records.	
Design Notes	Define storage requirements. Privacy and security of contents should be considered. Ensure the ventilation system design can deliver the specified room temperature limits, given the equipment planned to be in the room and the maximum number of people during a meeting. The validation of the BMS should include verification that it is compatible with the automated controls and systems within the building services package. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies	Direct access to the General Corridor (14) or other if the office is on a different level from the production areas.	

21 Room Data - Finishes

Room: Maintenance Manager's office

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Not essential. If provided should be clear.
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.	

21 Room Data – M+E

Room: Maintenance Manager's office

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

21	Room Data – Equipment/Furniture/Fittings	

Room: Maintenance Manager's office

	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table.
	Desk.
	Chairs.
	Filing cabinet.
	Computer.
	Telephone.
	Wall mounted marker board.
	Computer for floor management system and or building management system.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

22 Room Data - Design

Room: Materials Store

Function	This is a secure area used to receive and store instruments, raw materials and consumables used in the decontamination process. Also used to distribute goods.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	Receiving goods, opening cartons and inspecting incoming goods. Recording details on computer. Storing goods. Quarantine goods failing inspection/waiting for further documentation. Distribution of materials to specified areas. Hand hygiene. Disposal of packaging/pallets.	
Design Notes	Specify the space required to accommodate the storage of instruments and materials sufficient to meet the maximum specified production throughput. The space requirements will also be determined by the rationale for the number of days of supplies to be held at any given time. Determine whether there is a requirement to have a stockpile of single use instruments for use in an emergency. A separate space may be required in the Material Store (22) for cardboard compactors, shrinkwrap/polythene compactors and chemical drum compactors as applicable. This will form part of the waste handling policy for the site. Note that space will also be required for the subsequent baled waste products. A secure metal cabinet may be required for flammable chemicals. If bulk handling is required an allowance for forklift movement between racking should be considered. The racking should be protected from potential damage from forklifts. An area for storage of empty pallets should be assigned if appropriate. This may be external to the building in a secure cage (see Figure 2). Fork Lift storage may be appropriate in this area. If so facilities for battery charging should be considered or gas cylinder storage if required for powering the forklifts. (gas cylinders would be stored externally in secure cages) Controlled access is required to area. Refer to Vehicle Loading Bay (36) data sheet for the specification of the loading bay connected to the Material Store. If the loading bay serving this area is not able to allow unwrapping and unpacking of bulk products an ante room should be considered and located within the Materials Store. This is intended to prevent unnecessary dust contamination of stored goods. An air curtain to maintain room temperature may be considered at the entrance of the loading bay. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Direct secure access to Vehicle Loading Bay (36d)	
Other Notes	Entrance doors must accommodate bulk handling activities if required.	

22 Room Data - Finishes

Room: Materials Store

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear
Internal glazing	Glazing	(SHTM 57) Not essential. If provided should be clear
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), durable materials on lower part of walls, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish should allow for the heavy traffic in this area. Edges where the wall meets the ceiling should be coved. If appropriate protection of storage racking from forklift damage should be considered.	

22 Room Data – M+E

Room: Materials Store

Air	Winter deg C	16 to 19
	Summer deg C	16 to 19
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same pressure as General Corridor (14) and positive pressure with respect to outside environment.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	70 audible but not intrusive.
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

22 Room Data – Equipment/Furniture/Fittings

Room: Materials Store

	Computer.
	Data scanner.
	Trolleys.
	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Intercom wall mounted.
	Steps, 3 tread, 4 sprung wheels.
	Battery charger.
	Forklift.
	Pallet truck.
	Cardboard and polyfilm baler/compactors.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Wall mounted dispenser, with non-refillable hand wash solution.
	Wall mounted, easily cleanable dispenser for single use paper towels.
	Waste container.
	Workbench.
	Admin desk and filing cabinet.
	Flammables storage cabinet.
	PPE storage, e.g. hard hats, visibility jackets.
	Storage racking metal- adequate space is required between the lowest storage shelf and the floor to facilitate floor cleaning.
	Pallet racking.
	Secure Quarantine cupboard or cage.
	Telephone.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

23	Room Data - Design	

Room: Office

Function	This is an area used to provide an appropriate environment to undertake administrative and clerical work to support the CDU's activities. It provides the reception to control the access of visitors within the CDU and onto the site if a dedicated site.	
Occupancy	Personnel	Specify the maximum number of staff working in the office.
Activities	Controlling visitor access internally and at site entrance gate (see Figure 2) if applicable. Administrative work. Financial management. Supporting the Quality Management System- production documentation, purchasing and stock management. Storing files and records.	
Design Notes	Define storage requirements. Privacy and security of contents should be considered. Provides a secure reception point for managing visitor movement on site. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Adjacent to the Entrance Staff/Visitors (10). Direct access to the General Corridor (14).	

23 Room Data - Finishes

Room: Office

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Reception point could consist of horizontal sliding glass with locking device.
Internal glazing	Glazing	(SHTM 57) Clear.
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Consideration of protection (SHTM 69) of the walls may be required dependent on the activities planned for the room.	

23 Room Data – M+E

Room: Office

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	75 (normal speech audible but not intelligible).
	Mechanical Services - Noise Rating (NR) noise level	35
	Intrusive noise - NR noise level	40
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

23 Room Data – Equipment/Furniture/Fittings

Room: Office

	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table.
	Desk.
	Chairs.
	Filing cabinet.
	Photocopier.
	Computer.
	Telephone.
	Fax.
	CCTV and remote control of site entrance gates.
	Wall mounted marker board.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

24	Room Data - Design	

Room: Processed Products Store

Function	This is an area used for:- Storage of processed products released for distribution.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	Receiving processed goods from Cooling Area (6). Placing trays/packs into transport carts/ containers. Short term storage of sterile trays & packs. Selecting trays/packs for transferring to customers.	
Design Notes	Define the maximum number and dimensions of products to be accommodated in this area including transport carts/ containers and racking to achieve the specified maximum production throughput. Confirm the floor structure/finish can accommodate the maximum weight of trolleys to be moved through the area. There should be sufficient space for manoeuvring transport carts when at maximum capacity. Racking systems should have smooth surfaces to prevent damage to the stored products. Adequate space is required between the lowest storage shelf and the floor to enable access to floor cleaning equipment as required. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. To be positive pressure with respect to Dispatch (9). Controlled access is required to area.	
Adjacencies (as Figure 1)	Direct access to the Cooling Area (6). Direct access to Dispatch (9). Direct access to the Sterilizer Unload Area (30).	

24 Room Data – Finishes

Room: Processed Products Store

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be in situ- resin bonded flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), durable materials on lower part of walls, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved.	

24 Room Data – M+E

Room: Processed Products Store

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature & RH limits.
	Extract ac/hr	That required to deliver the specified room temperature & RH limits.
	Relative Pressure	Positive pressure with respect to Dispatch (9).
	Final Filtration	Minimum F5.
	Relative Humidity (%RH)	30-60
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	Intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

24 Room Data – Equipment/Furniture/Fittings

Room: Processed Products Store

	Transport carts.
	Transport containers.
	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Stainless steel storage racking for released product.
	Desk.
	Chair.
	Filing cabinet.
	Computer.
	Data scanner.
	Telephone.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

25 Room Data - Design

Room: Quality Manager's Office

Function	This is an area used to provide an appropriate environment to undertake management of the quality system.	
Occupancy	Personnel	Specify the maximum number of personnel in this room, i.e. the Quality Manager and the maximum number of persons during a meeting.
Activities	Managing the Quality Management System in compliance with BS EN ISO 13485. Discussion and meetings with staff/management. Discussion and meetings with visitors/contractors. Storing files and records.	
Design Notes	Define storage requirements. Privacy and security of contents should be considered. Allow direct viewing and communication into both the Wash Room (27) and the IAP Room (17). Ensure the ventilation system design for the office can deliver the specified room temperature limits, given the equipment planned to be in the room and the maximum number of people during a meeting. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Located adjacent and with viewing windows to both the Wash Room (27) and the IAP Room (17).	

25 Room Data - Finishes

Room: Quality Manager's Office

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Essential to view into the Wash Room (27) and the IAP Room (17).
Internal glazing	Glazing	(SHTM 57) Clear
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

25 Room Data – M+E

Room: Quality Manager's Office

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the General Corridor (14).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

25	Room Data – Equipment/Furniture/Fittings	

Room: Quality Manager's Office

	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table.
	Desk.
	Chairs.
	Filing cabinet.
	Computer.
	Telephone.
	Wall mounted marker board.
	Computer for floor management system and or building management system.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

26	Room Data - Design	

Room: Wash Room Gowning Room

Function	To provide controlled entry and exit of personnel. Provide staff with a facility for changing into and out of personal protective equipment required for Wash Room activities and hand hygiene.	
Occupancy	Personnel	State the maximum number of staff the room can accommodate.
Activities	Hand hygiene. Changing into/out of personal protective equipment (PPE). Using transfer bench to change into dedicated Wash Room footwear. Holding PPE & dedicated Wash Room footwear. Hanging PPE during breaks if applicable. Disposing of used PPE as applicable.	
Design Notes	Specify the storage space required for PPE and footwear storage. Specify the number of wall hooks required. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access to Wash Room (27). Direct access to the General Corridor (14).	
Other Notes	State rationale for number of wash hand basins required with respect to the planned maximum number of staff working in the Wash Room (27). The two doors of the Wash Room Gowning Room (26) to be interlocked.	

26 Room Data - Finishes

Room: Wash Room Gowning Room

Wall	Wall Finish	Surface Finish (SHTM 56): performance category 5: Recommended finish elastomeric vinyl compound or epoxy coating/ acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): performance category 3 Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided - clear, without opening, airtight.
Internal glazing	Glazing	(SHTM 57) N/A
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.	

26 Room Data – M+E

Room: Wash Room Gowning Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits and pressure differential level.
	Relative Pressure	Not positive with respect to adjoining areas.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 at floor.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

26	Room Data – Equipment/Furniture/Fittings	

Room: Wash Room Gowning Room

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Wash hand basin (installed on gowning room floor on the General Corridor side of the step over bench) - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste-flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel
	Wall mounted dispenser, with non-refillable hand wash solution (General Corridor side of the step over bench).
	Wall mounted, easily cleanable dispenser for single use paper towels (General Corridor side of the step over bench).
	Full length mirror (both sides of the step over bench).
	Hands free clinical waste container (General Corridor side of the step over bench).
	PPE storage (General Corridor side of the step over bench).
	Hanging facilities for reusable PPE (Wash Room side of the step over bench)-could be wall mounted hooks.
	Footwear storage to accommodate dedicated Wash Room footwear and General Production footwear. (both sides of step over bench)
	Step over bench- could be a barrier bench with footwear storage incorporated on each side of the bench.
	Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. (Both sides of the step over bench).

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

27 Room Data - Design

Room: Wash Room

Function	This is a controlled area used in the disassembly and preparation of reusable medical devices and associated equipment before cleaning, disinfecting and drying.	
Occupancy	Personnel	Specify the maximum number of personnel to be accommodated in this room.
Activities	Unloading of medical devices located within the contaminated returns holding area within the Wash Room (27). Sorting and loading of medical devices into washer disinfectors and other cleaning equipment such as ultrasonic cleaners. Segregation and streaming/batching of high CJD risk instruments and devices into dedicated cleaning/disinfection facilities. Checking contaminated returns. Selective manual cleaning of medical devices and accessories deemed unsuitable for automated cleaning. Collecting waste materials. Transfer processed items to the IAP Room (17). Receiving empty washer disinfector baskets from the IAP Room (17). Receiving unsatisfactorily processed medical devices back from the IAP Room (17) via the transfer hatch. Tracking of medical devices through the room.	
Design Notes There are two pages on Design for this Room Data Sheet.	Specify the maximum number and dimensions of containers to be held in the contaminated returns holding area within the Wash Room. Specify the number and dimensions of sorting or other workstations required to meet the specified maximum production throughput levels stated in the design rationale. Specify the number and size of admin workstations. Specify the requirements for storage racking. Ensure sufficient operational floor space is allowed around the transfer hatch and the drying cabinet if installed. Controlled staff access is required to the Wash Room (27) via the Wash Room- Gowning Room (26). Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. If the original design plans for future installation of equipment such as pass-through washer disinfectors then consideration should be given to suitable wall configuration, e.g. removable walls/panels, to minimize disruption of production. This would apply to all areas where large equipment would be required to move through on route to the installation site. Pressure gauge recording pressure differential with respect to the General Corridor (14) and to the IAP Room (17) required.	

27	Room Data – Design (continued)	

Room: Wash Room

Adjacencies (as Figure 1)	Direct access to Contaminated Returns Lobby (5). Direct access to the Wash Room- Gowning Room (26). Direct access to the Wash Room DSR (28). Adjacent to IAP Room (17) with pass through facilities. Adjacent to Quality Manager's Office (25) with viewing window. Adjacent to Wash Room Materials Transfer Room (38) with pass through facilities.

27 Room Data – Finishes

Room: Wash Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 2. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), durable materials on lower part of walls, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved. Coving should be suitable for heat exposure where it is directly above heat producing equipment such as washer disinfectors. The 'cut outs' and 'in fill panels' around equipment such as washer disinfectors will need to be demountable where required to facilitate service access. The design of the panels should allow them to be re-sealed, post maintenance work, to the level required to maintain the specified room pressure differential regime.	

27 Room Data – M+E

Room: Wash Room

Air	Winter deg C	16 to 19
	Summer deg C	16 to 19
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	Min 10 (with no recirculation into the room supply).
	Relative Pressure	-5Pa wrt General Corridor (14), not positive with respect to surrounding areas. -30Pa wrt the IAP Room (17). Note the minimum to be -15Pa with respect to IAP Room (17).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	Consider the potential effects of glare from the stainless steel workstations.
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Lighting enclosures IP 54 rated.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	Intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

27	Room Data – Equipment/Furniture/Fittings	

Room: Wash Room

There are two pages on Equipment/Furniture/Fittings for this Room Data Sheet.	Thermal washer-disinfectors for surgical instruments compliant with SHTM 2030: 'Washer-disinfectors', European and International standards BS EN ISO15883 Parts 1 & 2 and MES C30: 'Washer-disinfectors for surgical instruments'; Consider waste water heat recovery systems.
	Container/trolley washer-disinfectors compliant with SHTM 2030 and European and International standards BS EN ISO 15883 Parts 1 & 2.
	Accessories and associated equipment and fittings for washer-disinfectors.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Pressure differential gauge.
	Clock battery operated and wall mounted.
	Conveyor systems (these may be required).
	Security Alarm with push button and wall mounted.
	Ultrasonic cleaners/irrigators in compliance with SHTM 2030 and European and International standards BS EN ISO 15883 Parts 1 & 2.
	Accessories and associated equipment for ultrasonic cleaners/irrigators.
	Accessories and associated cleaning equipment for specialised medical devices, for example Phaco and dental hand-pieces.
	Double stainless steel sink(s) for manual cleaning –one wash sink and one rinse sink. See 3.52 for specification
	Storage facilities (wire rack) for baskets and associated carriages not in use.
	Loading trolleys.
	Stainless steel inspection tables.
	Instrument baskets.
	Cold-water spray-guns in manual wash sink.
	Medical devices transfer facilities – return carriages and medical devices from IAP Room; manually cleaned items to IAP Room
	Materials transfer facility – detergents, raw materials etc to Wash Room (27) from the Wash Room Materials Transfer Room (38).
	Short-term storage facilities for wash-room consumables, for example detergents, cleaning brushes etc.

27	Room Data – Equipment/Furniture/Fittings (continued)	

Room: Wash Room

	Drench shower (if required after COSHH assessment).
	Eye-wash station with mirror wall mounted.
	Computer.
	Stainless steel workbench for admin purposes.
	Data scanner.
	Hands free clinical waste containers.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 55 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 55 rated. Outlet isolator, wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

28 Room Data - Design

Room: Wash Room Domestic Services Room (DSR)

Function	This is a controlled area used for storing equipment and supplies used for cleaning the Wash Room (27), Contaminated Returns Lobby (5), the Wash Room side of its Gowning Room (26) and the Cart Wash Load Area (1).	
Occupancy	Personnel	Specify the maximum number of staff working in this room.
Activities	Preparation of cleaning solutions for cleaning activities. Disposal of waste cleaning materials and solutions. Cleaning and drying equipment. Hand hygiene. Storage of cleaning solutions and equipment.	
Design Notes	Specify the storage space required for cleaning solutions& other related consumables. Specify the cleaning equipment (with sizes) to be accommodated in this room, e.g. scrubbing machine and dry suction machine etc. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access from the Wash Room (27) only.	

28 Room Data - Finishes

Room: Wash Room DSR

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish tiles factory finished with acrylic paint.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential.
Internal glazing	Glazing	(SHTM 57) Not essential
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall with splayed skirting and protective corners.	

28 Room Data – M+E

Room: Wash Room DSR

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits and pressure differential level.
	Relative Pressure	Same as the Wash Room (27).
	Final Filtration	Not specified.
	Relative Humidity%	Not specified.
Air notes		
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Lighting enclosures IP54 rated.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

28	Room Data – Equipment/Furniture/Fittings	

Room: Wash Room DSR

	Dedicated cleaning equipment. Scrubbing/polishing machine. Dry suction machine. Warning cone. Cleaner's trolley 3 bucket system and floor mop.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Low level stainless steel bucket sink.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Wall mounted cartridge soap dispenser.
	Storage facilities (wire rack) for equipment.
	Stainless steel sink with drainer.
	Hands free clinical waste containers.
	Socket outlet switched 13 Amp double, ac, wall mounted and IP 55 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 55 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

29	Room Data - Design	

Room: Sterilizer Plant Room

Function	Accommodating sterilizers and associated plant (which may include equipment for clean steam generation)	
Occupancy	Personnel	State the maximum number of staff the room can accommodate.
Activities	Maintenance and repair of sterilizers. Validation and routine testing of sterilizer and associated equipment. Sampling of steam and water quality.	
Design Notes	Sampling facilities for water, air and/or steam quality required. Careful consideration should be given to incorporating thermal insulation within the construction of the walls, doors and ceilings between the plantroom and surrounding rooms. The location should be positioned to provide for ease of installation and removal of equipment. It should have secure door(s) for authorized access. For pass through sterilizers the entrance into the Sterilizer Plant Room should be from the Sterilizer Unload Area (30) and **not** from the IAP Room (17). Sufficient space should be specified around each sterilizer and other items of plant to facilitate ease of maintenance and installation without interruption to production. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. This room to be -10Pa with respect to the IAP Room (17).	
Adjacencies (as Figure 1)	It should be adjacent to the Sterilizer Unload Area (30) and the IAP Room (17).	
Other Notes	Adequate space and electrical outlets around each item of plant for installation, maintenance and periodic testing is essential. Manufacturers' recommendations should be followed with regard to the access space required. External doors should be sized to accommodate access of plant during installation and future planned upgrades.	

29 Room Data - Finishes

Room: Sterilizer Plant Room

Wall	Wall Finish	Surface Finish (SHTM 56): performance category 5: Recommended finish elastomeric vinyl compound or epoxy coating/ acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be concrete, smooth and finished.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential.
Internal glazing	Glazing	(SHTM 57) N/A
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail, durable materials on lower part of walls and splayed skirting.	

29 Room Data – M+E

Room: Sterilizer Plant Room

Air	Winter deg C	< 30
	Summer deg C	< 30
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	-10Pa with respect to the IAP Room (17). Negative with respect to other adjoining areas.
	Final Filtration	Not specified.
	Relative Humidity%	Not specified.
Air notes	Air temperature and the relative pressure specification will not be achievable if there is no ceiling in the Sterilizer Plant Room.	
Lighting	Lighting Level Normal lux	300 at floor.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Lighting enclosures IP 56 rated.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

29	Room Data – Equipment/Furniture/Fittings	

Room: Sterilizer Plant Room

	Sterilizer, built in, 2 sliding doors and associated plant.
	Fire alarm.
	Fire extinguishers.
	Socket outlet computer data. Socket outlet switched 13 Amp double, ac, wall mounted and IP56 rated. Sufficient number and suitably located to allow use of portable test equipment during testing of the plant.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

30 Room Data - Design

Room: Sterilizer Unload Area

Function	This is an area used to:- Unload sterilizers after a satisfactory cycle.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	Unloading of the sterilizer. Validation/ routine testing and maintenance of sterilizer. Transfer loaded carriers to the Cooling Area (6). Parking the sterilizer unloading trolleys.	
Design Notes	Define the maximum number and dimensions of sterilizer unloading trolleys and carriages required in the area to meet the maximum specified production throughput. Allow for space to manoeuvre these trolleys when assigning the space required. Ensure space is allowed for the unrestricted movement of transport carts through this area into the Cooling Area (6). As there may be frequent movement of trolleys through the door connecting the Cooling Area (6) and the Sterilizer Unload Area (30) door opening sensors should be considered to assist this process in addition to adequate door protection. Specify an area for quarantine of product that has failed visual inspection after sterilization. A storage facility for PPE is required (heat resistant gloves etc.) Space to accommodate storage of routine sterilizer test materials. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Pressure gauge recording pressure to room required relative to IAP Room (17). Controlled access is required to this area.	
Adjacencies (as Figure 1)	Direct access to Cart Wash Unload Area (3). Direct access to the Cooling Area (6).	

30 Room Data - Finishes

Room: Sterilizer Unload Area

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), durable materials on lower part of walls, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved.	

30 Room Data – M+E

Room: Sterilizer Unload Area

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature & RH limits.
	Extract ac/hr	That required to deliver the specified room temperature & RH limits.
	Relative Pressure	Positive pressure with respect to Sterilizer Plantroom (29). -15Pa with respect to IAP Room (17).
	Final Filtration	Minimum F5.
	Relative Humidity (%RH)	30-60
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Lighting enclosures IP 54 rated.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector - The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

30	Room Data – Equipment/Furniture/Fittings	

Room: Sterilizer Unload Area

	Sterilizer unloading trolleys.
	Transport carts.
	Admin workbench.
	Computer/data scanner.
	Fire alarm.
	Fire extinguishers.
	Telephone.
	Intercom.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Smoke detector.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 55 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 55 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

30A Room Data - Design

Room: Sterilizer Load & Unload Area

Function	This is an area used to:- Load and unload sterilizers.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	Loading of the sterilizer. Unloading of the sterilizer. Validation/ routine testing and maintenance of sterilizer. Transfer loaded carriers to the Cooling Area (6). Parking the sterilizer loading trolleys.	
Design Notes	This room is not presented in the model layout as figure 1. It is intended to specify room requirements where single door sterilizers are in use. Define the maximum number and dimensions of sterilizer loading trolleys and carriages required in the area to meet the maximum specified production throughput. Allow for space to manoeuvre these trolleys when assigning the space required. Ensure space is allowed for the unrestricted movement of transport carts through this area into the Cooling Area (6). As there may be frequent movement of trolleys through the door connecting the Cooling Area (6) and the Sterilizer Load & Unload Area (30A) door opening sensors should be considered to assist this process in addition to adequate door protection. Specify an area for quarantine of product that has failed visual inspection after sterilization. A storage facility for PPE is required (heat resistant gloves etc.) Space to accommodate storage of routine sterilizer test materials. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Pressure gauge recording pressure to room required relative to IAP Room (17). Controlled access is required to this area.	
Adjacencies	Direct access to Cart Wash Unload Area (3). Direct access to the Cooling Area (6). Connects to the IAP Room (17) via a transfer hatch/system.	

30A Room Data - Finishes

Room: Sterilizer Load & Unload Area

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy Duty protection (SHTM 69) should be considered, i.e. mid height crash rail (taking account of the dimensions of the transports carts), durable materials on lower part of walls, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved.	

This room is not presented in the model layout as Figure 1. It is intended to specify room requirements where single door sterilizers are in use.

30A Room Data – M+E

Room: Sterilizer Load & Unload Area

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature & RH limits.
	Extract ac/hr	That required to deliver the specified room temperature & RH limits.
	Relative Pressure	Positive pressure with respect to Sterilizer Plantroom (29). -15Pa with respect to IAP Room (17).
	Final Filtration	Minimum F5.
	Relative Humidity (%RH)	30-60
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011. Lighting enclosures IP 54 rated.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	N/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector - The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

This room is not presented in the model layout as Figure 1. It is intended to specify room requirements where single door sterilizers are in use.

30A	Room Data – Equipment/Furniture/Fittings	

Room: Sterilizer Load & Unload Area

	Sterilizer loading trolleys.
	Transport carts.
	Admin workbench.
	Computer/data scanner.
	Fire alarm.
	Fire extinguishers.
	Telephone.
	Intercom.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Smoke detector.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 55 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 55 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

This room is not presented in the model layout as Figure 1. It is intended to specify room requirements where single door sterilizers are in use.

31 Room Data - Design

Room: Staff Changing Rooms

Function	This is an area used to provide an appropriate environment for changing clothing and security for personal valuables.	
Occupancy	Personnel	Specify the maximum number of personnel (production & maintenance) to be accommodated in both the male and female Staff Changing Rooms. Specify the provision for visitors and contractors.
Activities	Changing into production clothing if applicable. Changing into personal clothing. Hand hygiene. Storing personal items in locker. WC and shower facilities available.	
Design Notes	Full separate changing facilities for male and female staff. Individual lockers for all staff (including part time) and visitors/contractors. Hold & cold water required and drainage.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Easy access from the Entrance Staff/Visitors (10) and to the production areas.	

31 Room Data - Finishes

Room: Staff Changing Rooms

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant. Door kickplates recommended.
Windows	Windows Type	(SHTM 55) Not essential.
Internal glazing	Glazing	(SHTM 57) N/a
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.	

31 Room Data – M+E

Room: Staff Changing Rooms

Air	Winter deg C	19 to 23
	Summer deg C	19 to 23
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height)
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Lighting enclosures IP 54 rated. Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

31 Room Data – Equipment/Furniture/Fittings

Room: Staff Changing Rooms

	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Storage shelving for general production staff uniforms.
	Hair dryer.
	Clothes Locker.
	Bench seating.
	Mirror wall mounted.
	Shoe rack for dedicated general production footwear.
	Hands free waste bin.
	Water cooler.
	Trolley for soiled linen, stainless steel.
	Wall mounted notice board.
	WC suitable for use by disabled staff.
	Shower suitable for use by disabled staff.
	Towel rail for shower.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Hand-towel dispenser.
	Wall mounted dispenser with hand wash solution.
	Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

32 Room Data - Design

Room: Staff Room

Function	This is an area used to provide an appropriate environment for staff rest including preparation and consumption of food.	
Occupancy	Personnel	Specify the maximum number of staff to be accommodated in the room.
Activities	Rest. Preparing food. Consuming food. Holding dry goods. Holding food in refrigerator. Washing of dishes etc. Hand hygiene.	
Design Notes	A food preparation area, washing-up facilities, hand hygiene facilities and appropriate tables chairs for consumption of food and resting. Hold & cold water required and drainage. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Easy access from the Entrance Staff/Visitors (10) and to the production areas. Close to Staff Changing Rooms (31).	

32 Room Data - Finishes

Room: Staff Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear.
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.	

32 Room Data – M+E

Room: Staff Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	75 (audible but not intelligible).
	Mechanical Services- Noise Rating (NR) noise level	35
	Intrusive noise - NR noise level	45
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

32 Room Data – Equipment/Furniture/Fittings

Room: Staff Room

	Fire alarm.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Coat hooks.
	Shelving.
	Table, occasional.
	Chairs.
	Refrigerator.
	Microwave oven.
	Toaster (consider impact of setting off smoke detectors and fire alarm)
	Water cooler.
	Telephone.
	Hot water boiler, electric and wall mounted.
	Sink with drainer.
	Storage unit 2 door.
	Wall mounted notice board.
	Worktop, plain, stainless steel, cantilevered from wall as SHTM 63.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Hand-towel dispenser.
	Hands free waste bin.
	Wall mounted dispenser with hand wash solution.
	Vending machine.
	Dishwasher domestic.
	Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

33 Room Data - Design

Room: Technicians Room

Function	This is a secure area used to provide an appropriate environment to support the repair and maintenance of the CDU's decontamination equipment.	
Occupancy	Personnel	Specify the maximum number of personnel working in this room.
Activities	Repair of equipment, e.g. Transport carts. Storage of spare parts. Hand hygiene.	
Design Notes	Specify the items (and their dimensions) to be repaired in this area. This will ensure the floor space including that around any workbenches is sufficient to accommodate the items to be repaired and maintained, e.g. transport carts. If applicable, state the rationale for managing spare parts for decontamination equipment and plant in order that the storage space requirements can be specified. It may be decided that a separate dedicated spare parts store is required outwith the Technicians Room. Doors should be sized to accommodate access of the items to be repaired. It is likely that two leaf doors would be required. Ventilation design to achieve the temperature & relative humidity levels specified. Hot & cold water services required. Drainage required. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Sufficient electrical power sockets and data outlets should be specified for the number of technicians working in the room who require access to plant and equipment test records, Building Management Systems, electronic planned preventative maintenance systems and data loggers.	
Adjacencies	Direct access from the General Corridor (14) or it could be located on a different level to the production areas.	

33 Room Data - Finishes

Room: Technicians Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	n/a
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall with protective corners. Two leaf doors required with suitable door protection.	

33 Room Data – M+E

Room: Technicians Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature & RH limits.
	Extract ac/hr	That required to deliver the specified room temperature & RH limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity (%RH)	30-60
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	B
Lighting Notes	Design as SHTM 2011. Lighting enclosure IP 52 rated.	
Noise	Privacy Factor	70 audible but not intrusive.
	Mechanical Services	40
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

33 Room Data – Equipment/Furniture/Fittings

Room: Technicians Room

	Computer with A3 colour printer to facilitate printing of building services drawings.
	Admin Table.
	Workbench.
	Electrical test stations with outlets for single phase, three phase and low voltage bench testing and repair.
	Phone.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Intercom.
	Security Alarm with push button and wall mounted.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Wall mounted cartridge soap dispenser.
	Sink.
	Storage facilities (wire rack).
	Secure storage cupboard for spare parts.
	Wall mounted easily cleaned paper towel dispenser.
	Hands free clinical waste containers.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

34 Room Data - Design

Room: Test Equipment Room

Function	This is a secure area used to provide an appropriate environment to support the testing of the CDU's decontamination equipment.	
Occupancy	Personnel	Specify the maximum number of personnel working in this room.
Activities	Storage of documentation. Storage of test equipment/ consumables. Data analysis. Report preparation. Hand hygiene.	
Design Notes	Specify the storage space required for test equipment. Specify the storage space required for documentation. Ventilation design to achieve the temperature & relative humidity levels specified. This is a requirement for storage of electronic test and calibration equipment. Hot & cold water services required. Drainage required. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	Direct access from the General Corridor (14).	

34 Room Data - Finishes

Room: Test Equipment Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear.
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall.	

34 Room Data – M+E

Room: Test Equipment Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature & RH limits.
	Extract ac/hr	That required to deliver the specified room temperature & RH limits.
	Relative Pressure	Same as the corridor.
	Final Filtration	Minimum F5.
	Relative Humidity (%RH)	30-60
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	B
Lighting Notes	Design as SHTM 2011. Lighting enclosure IP 52 rated.	
Noise	Privacy Factor	70 audible but not intrusive.
	Mechanical Services-Noise Rating (NR) noise level	40
	Intrusive noise – NR noise level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

34 Room Data – Equipment/Furniture/Fittings

Room: Test Equipment Room

	Computer.
	Table.
	Phone.
	Worktop.
	Secure storage cupboard for equipment.
	Secure storage cupboard for documentation.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Security Alarm with push button and wall mounted.
	Low level stainless steel bucket sink.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM 64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel
	Wall mounted cartridge soap dispenser.
	Storage facilities (wire rack) for equipment.
	Wall mounted easily cleaned paper towel dispenser.
	Stainless steel sink with drainer.
.	Laboratory fridge/freezer for storage of test soils and residual protein test products.
	Hands free clinical waste containers.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac, wall mounted and IP 54 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

35 Room Data - Design

Room: Training Room

Function	This is an area used to provide an appropriate environment for staff training.	
Occupancy	Personnel	Specify the number of personnel to be accommodated.
Activities	In house training of staff. Training of staff by external contractors. Reading and study. Examinations.	
Design Notes	This should be a quiet environment for staff training and development. Suitable air conditioning is required that is capable of meeting the specifications for room temperature/relative humidity when the room is manned at maximum capacity at any time of the year. Specify the number of chairs and tables (with dimensions) to be accommodated in the Training Room (35). Fittings and furniture should permit flexibility of the seating layout. Sufficient visual aids and computer network connection points need to be considered for use of staff undertaking computer based training/study/examinations. Specify the storage space required for training/reference documentation and training equipment. Consideration of wall finish/colour and free of fixtures/fittings will allow projection of presentations directly onto the walls. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Note-this room data sheet is not applicable for training rooms which are intended for hands-on training with decontamination equipment such as washer disinfectors.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Easy access from the Entrance Staff/Visitors (10) and to the production areas.	

35 Room Data - Finishes

Room: Training Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint. (see design notes)
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be textile.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear.
Ceiling Hatch	Hatch	If required to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall. Note- keeping the wall finish above the buffer rail free of fixtures/fittings will allow projection of presentations directly onto the wall.	

35 Room Data – M+E

Room: Training Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature & RH limits.
	Extract ac/hr	That required to deliver the specified room temperature & RH limits.
	Relative Pressure	Same as the General Corridor (14).
	Final Filtration	Not specified.
	Relative Humidity (%RH)	< 70
Air notes		
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	B
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

35 Room Data – Equipment/Furniture/Fittings

Room: Training Room

	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Clock battery operated and wall mounted.
	Security Alarm with push button and wall mounted.
	Tables.
	Chairs.
	Computer.
	Computer printer.
	Water cooler.
	Hands free waste bin.
	Wall mounted notice board.
	Video projector.
	Projection screen.
	Secure storage.
	White board.
	Flip chart.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

36(a to e)	Data - Design	

Vehicle Loading Bay

Function	These are secure controlled access areas for movement of various materials & products required for the production process. There may be a number of Vehicle Loading Bays (identified as 36 a to e) required to service the following rooms: 36a - General Plant Room (16); 36b - General/Clinical Waste Disposal (13); 36c - Contaminated Returns Lobby (5); 36d - Materials Store (22); 36e - Dispatch (9).	
Occupancy	Personnel	Specify the maximum number of personnel working in each of these areas.
Activities	Activities will vary between the different areas. Consult the individual room data sheet for full details of activities within the room. 36a-General Plant Room (16) - receipt of bulk chemicals. 36b-General/Clinical Waste Disposal (13) - collection of full waste containers and drop off of empty containers. 36c-Contaminated Returns Lobby (5) - drop off of soiled goods for reprocessing. 36d-Materials Store (22) - Receipt of raw materials. 36e-Dispatch (9) - Loading of transport carts/trolleys into vehicles.	
Design Notes There are two pages on Design for this Room Data Sheet.	Controlled access is required to each area to ensure product and staff safety. Closed circuit television (CCTV) intercoms and suitable external lighting should be provided. Roller shutter doors should be considered. The design of the approach ramp should account for the type(s) and number of transport vehicles to be used, e.g. lorry with tailgate lift. The method of approach of the transport vehicle into the loading bay may determine the need for a roof in the loading bay. The design of the loading bay should consider if the transport carts/trolleys need protection from strong wind conditions that could overturn them. The design of the loading bay should consider the need for demountable wall and door components to facilitate large machinery access or removal. The design should consider measures to prevent bird/rodent access. Other points to consider with regard to the external door and its approach include: Is the entrance door at ground floor level? Does the door form part of the final exit route in the event of fire? Is disabled-wheelchair access a requirement? Are auto-opening devices a requirement? Is additional extended headroom a requirement in regard to movement of goods? Is there a requirement for vision panels? Are hold open devices required?	

36(a to e)	Data – Design (continued)	

Vehicle Loading Bay

	Will rain water ingress present a risk of slip hazard to users? Suitable space in front of loading bays is required to allow vehicles to manoeuvre while not disrupting other traffic on site. See Figures 1 and 2. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. Suitable fire detection systems should be in place as security of bulk flammable items/waste products stored externally to the loading bays can present operational challenges. Fire Officers should be consulted.
Adjacencies (as Figure 1)	Depending on which loading bay: Direct access to the General Plant Room (16); Direct access to the General/Clinical Waste Disposal (13); Direct access to Contaminated Returns Lobby (5); Direct access to the Materials Store (22); Direct access to Dispatch (9).
Other Notes	none

36(a to e) Data - Finishes

Vehicle Loading Bay

Wall	Wall Finish	Surface Finish (SHTM 56): Smooth finished brick, block, plastered cement render with spray or brush resin or acrylic paint. Wall protection is essential.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be a concrete ramp.
Ceiling	Ceiling Finish	Need to determine if the loading bay is covered.
Doorsets	Doorsets	n/a
Windows	Windows Type	(SHTM 55) n/a
Internal glazing	Glazing	(SHTM 57) n/a
Hatch	Hatch	N/A
Finish Notes	Heavy Duty protection (SHTM 69) is essential, i.e. mid height crash rail, durable materials on lower part of walls. Posts should be installed to protect the building fabric, including doors and door frames where fork lifts or pallet trolleys are in use.	

36(a to e)	Data – M+E	

Vehicle Loading Bay

Air	Winter deg C	n/a
	Summer deg C	n/a
	Supply ac/hr	n/a
	Extract ac/hr	n/a
	Relative Pressure	n/a
	Final Filtration	n/a
	Relative Humidity (%RH)	n/a
Air notes		
Lighting	Lighting Level Normal lux	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	B
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	n/a
	Mechanical Services	n/a
	intrusive noise NR Level	n/a
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	n/a
Noise Notes	Design as SHTM 2045 part2.	
Safety	Hot Surface Temperature deg C	n/a
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

36(a to e) Data – Equipment/Furniture/Fittings

Vehicle Loading Bay

	Door bell.
	External lighting (high wattage with proximity sensor).
	CCTV & Intercom.
	Security Alarm, push button, wall mounted.
	Socket outlet intercom, wall mounted.
	Concrete posts (to protect building fabric from vehicle damage).
	Door/ Roller shutter door.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

37 Data - Design

Vehicle Wash Area

Function	This is a secure on site area for washing of transport vehicles. This area could have other functions such as siting of waste containers.	
Occupancy	Personnel	Specify the maximum number of personnel working in this area.
Activities	External cleaning of transport Vehicles. Internal Cleaning of vehicles. Collection/delivery waste containers. Filling of waste container.	
Design Notes	Suitable space in front of this area is required to allow vehicles to manoeuvre whilst not disrupting other traffic on site. Flood lighting if cleaning/waste management required at night. Define the number, type and location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies- see Figure 2	On site external to the CDU building.	
Other Notes	The electrical switch supply should be isolated from within the main building when not in use.	

37 Data - Finishes

Vehicle Wash Area

Wall	Wall Finish	n/a
Floor	Floor Finish	Concrete base
Ceiling	Ceiling Finish	n/a.
Doorsets	Doorsets	n/a
Windows	Windows Type	n/a
Internal glazing	Glazing	n/a
Hatch	Hatch	N/A
Finish Notes	Drain in centre of concrete base. Area sized to accommodate the vehicles to be cleaned and the management of waste containers if they are sited in this location.	

37	Data – M+E	

Vehicle Wash Area

Air	Winter degC	n/a
	Summer degC	n/a
	Supply ac/hr	n/a
	Extract ac/hr	n/a
	Relative Pressure	n/a
	Final Filtration	n/a
	Relative Humidity (%RH)	n/a
Air notes		
Lighting	Lighting Level Normal lux	Flood lighting if cleaning/waste management required at night.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	B
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	n/a
	Mechanical Services	n/a
	intrusive noise NR Level	n/a
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes		
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	n/a
	Fire Detection	n/a

37 Data – Equipment/Furniture/Fittings

Vehicle Wash Area

	External lighting.
	Outlet, cold water.
	Outlet, hot water if required.
	Washer, high pressure, electrical, single phase and defined hose length required.
	Socket outlet switched, 13 Amp double and IP 56 rated. Switch supply should be isolated from within the main building.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

38 Room Data - Design

Room: Wash Room Materials Transfer Room

Function	This room is used to control the movement of materials into (and out) of the Wash Room (27).	
Occupancy	Personnel	Specify the maximum number of personnel working in this room.
Activities	Transfer of raw materials from the Wash Room Material Transfer Room (38) to the Wash Room (27) via a transfer hatch. Inspecting incoming goods. Short term storage.	
Design Notes	Space requirements for material storage to meet the maximum specified production throughput must be stated. The Wash Room Materials Transfer Room (38) provides an air-lock by way of a transfer hatch between the Wash Room (27) and the General Corridor (14). Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet.	
Adjacencies (as Figure 1)	The room adjoins the Wash Room (27). The room adjoins the General Corridor (14).	
Other Notes	Entrance doors must accommodate bulk handling activities if required.	

38 Room Data - Finishes

Room: Wash Room Materials Transfer Room

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 3. Recommended finish acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be slip resistant PVC sheet with welded joints or slip resistant resin based flooring.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	(SHTM 55) Not essential. If provided should be clear.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.	

38 Room Data – M+E

Room: Wash Room Materials Transfer Room

Air	Winter deg C	16 to 21
	Summer deg C	16 to 21
	Supply ac/hr	That required to deliver the specified room temperature limits.
	Extract ac/hr	That required to deliver the specified room temperature limits.
	Relative Pressure	+ve with respect to the Wash Room (27).
	Final Filtration	Minimum F5.
	Relative Humidity%	Not specified.
Air notes	Filter standard BS EN 779.	
Lighting	Lighting Level during production (lux)	300 (bench height).
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	Not specified.
	Mechanical Services	Not specified.
	intrusive noise NR Level	Not specified.
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	No
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	n/a
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

38	Room Data – Equipment/Furniture/Fittings	

Room: Wash Room Materials Transfer Room

	Computer.
	Data scanner.
	Fire alarm.
	Smoke detector.
	Fire extinguishers.
	Hands free general waste bin.
	Security Alarm with push button and wall mounted.
	Intercom wall mounted.
	Transfer hatch, interlocked (manual or electrical operation).
	Storage racking – stainless steel.
	Socket double outlet computer data. Socket outlet telephone, wall mounted. Socket outlet intercom, wall mounted. Socket outlet switched 13 Amp double, ac and wall mounted. Socket outlet switched 13 Amp single, ac and wall mounted.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.

39	Room Data - Design	

Room: WC

Function	This is an area used to provide toilets facilities for visitors.	
Occupancy	Personnel	Single person
Activities	Hand hygiene. Use of WC.	
Design Notes	Ensure there is wheel chair access. Hold & cold water required and drainage. Define the number, type and room location of each item of equipment/furniture/fittings as selected from the room data sheet. These items to be suitable for disabled use. Pipework for the wash hand basin to be boxed in. A fire alarm may not be required to be installed within the WC if an external sounder is fitted locally and is audible within the WC.	
Adjacencies (as Figure 1)	Direct access to the General Corridor (14). Controlled access from the Entrance Staff/Visitors (10).	

39 Room Data - Finishes

Room: WC

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 6. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): a performance category system is not in use in this guidance document. Choice of floor finish is based on a risk assessment. Recommended finish would be PVC sheet with welded joints.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 6. Recommended finish mineral fibre tiles.
Doorsets	Doorsets	(SHTM 58) Compliant.
Windows	Windows Type	N/a
Internal glazing	Glazing	N/a
Ceiling Hatch	Hatch	If required, to be in line with the ceiling finish.
Finish Notes	Medium Duty protection (SHTM 69) should be considered, i.e. mid height buffer rail and /or durable finish on middle or lower part of the wall with protective corners.	

39 Room Data – M+E

Room: WC

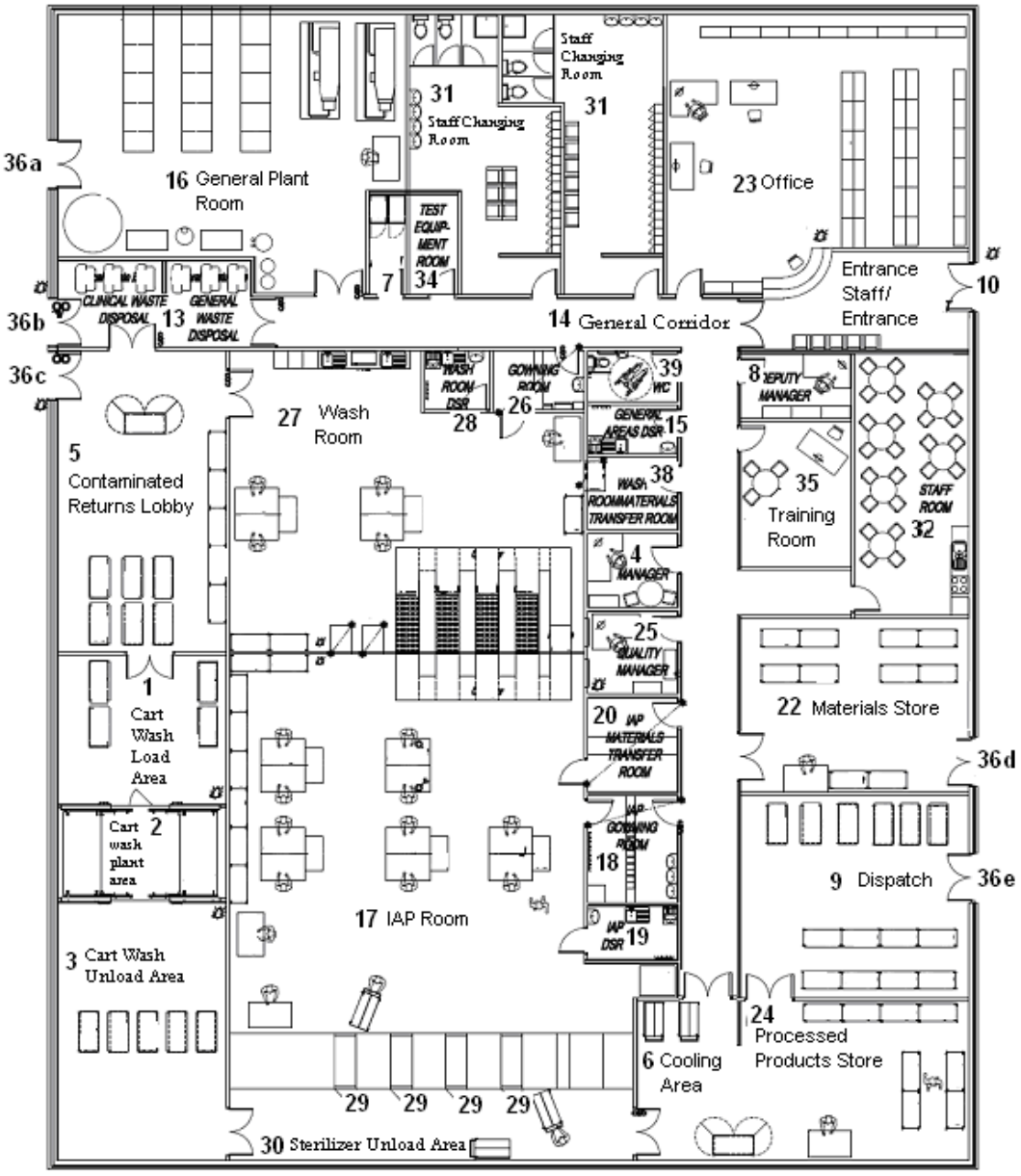
Air	Winter deg C	19 to 23
	Summer deg C	19 to 23
	Supply ac/hr	That required to meet the building regulations.
	Extract ac/hr	10
	Relative Pressure	Negative to the General Corridor (14).
	Final Filtration	That required to meet the building regulations.
	Relative Humidity%	Not Specified.
Air notes	Filter standard BS EN 779	
Lighting	Lighting Level (lux)	That required to meet the building regulations.
	Lighting Level Night lux	Not specified.
	Lighting Level Local lux	Not specified.
	Colour Rendering	No
	Standby Lighting Grade	A
Lighting Notes	Design as SHTM 2011.	
Noise	Privacy Factor	80 (normal speech inaudible).
	Mechanical Services - Noise Rating (NR) noise level	30
	Intrusive noise - NR noise level	35
	Acceptable Sound Level	As specified in the Control of Noise at Work Regulations 2005.
	Speech Privacy	Yes
Noise Notes	Design as SHTM 2045 Part2.	
Safety	Hot Surface Temperature deg C	43 maximum.
	Hot Water Temperature deg C	41 maximum.
Safety Notes		
Fire	Fire Enclosure	Fire risk assessment in line with SHTM 86 including review of fire-resisting construction (integrity and insulation).
	Fire Detection	Smoke Detector.

39	Room Data – Equipment/Furniture/Fittings	

Room: WC

	Fire alarm.
	Smoke detector.
	Mirror wall mounted.
	WC and associated fittings suitable for use by disabled person.
	Wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM64. Waste- flush, grated, metal and no plug. Tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls. IPS panel.
	Hand-towel dispenser.
	Hands free waste bin.
	Wall mounted dispenser with hand wash solution.

This Equipment/Furniture/Fittings data sheet is an informative list only. It is intended to be a list for the design team to consider.



Pressure Differential regime as applicable to CDU model Figure 1 (refer to Appendix 1 Figure 1 - note drawing not to scale)

Relative Areas	Minimum pressure differential (Pa)
Wash Room (27) to General Corridor (14)	-5
IAP Room (17) to Wash Room (27)	+15
IAP Room (17) to IAP Materials Transfer Room (20)	+10
IAP Materials Transfer Room (20) to General Corridor (14)	+15
IAP Room (17) to IAP Gowning Room (18)	+10
IAP Gowning Room (18) to General Corridor (14)	+15
IAP Room (17) to Sterilizer Unload Area (30)	+15

Refer to each room data sheet to confirm the required pressure differential between areas.

Appendix 2: Glossary of terms

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

Business Case: Business Cases are a mandatory part of the planning, approval, procurement and delivery of investments within NHSScotland.

Refer to http://www.scim.scot.nhs.uk/index.htm for full details.

The purpose of the **Outline Business Case** (OBC) is to:

- identify the option which optimises value for money (VFM) and overall sustainability;
- prepare the scheme for procurement;
- put in place the necessary funding and management arrangements for the successful delivery of the scheme.

The purpose of the **Full Business Case** (FBC) is to:

- identify the 'market place opportunity' which offers optimum VFM;
- set out the negotiated commercial and contractual arrangements for the deal;
- demonstrate that it is 'unequivocally' affordable;
- put in place the detailed management arrangements for the successful delivery of the scheme.

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.

Cart washer: Machine intended to clean and disinfect transportation carts.

Central Decontamination Unit: A Central Decontamination Unit (CDU) is characterized by the following features- it operates with appropriately segregated decontamination processes and effective environmental control to protect both staff and product. The CDU operates in compliance with the Quality Management System BS EN 13485 and the Medical Device Regulations. It has dedicated management and operational staff. The unit can supply third party legal entities.

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

Design Team: A multi disciplined team of relevant experts including those involved in decontamination, engineering, building and design (including

cleanroom design), and service users. These individuals will require to be 'approved suppliers' as stated in the quality management system BS EN 13485. They have the responsibility for approving the Validation Master Plan for delivery of the CDU.

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

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

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

ISO Classification number: A number of rooms within the CDU 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. The IAP Room (17) and the IAP Domestic Services Room (19) are specified as ISO Class 8 in the 'operational' occupancy state. The IAP Room: Gowning Room (18) and the IAP Materials Transfer Room (20) are specified as ISO Class 9 in the 'operational' occupancy state.

ISO Classification number	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below.					
				= 0.5 µm	= 1 µm	= 5.0 µm
ISO Class 7				352,000	83,200	29,300
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

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 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.

Occupancy states:

- **As-built**: condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present;
- **At-rest**: condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present;
- **Operational**: condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon.

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.

Production throughput: The CDU's annual output of product.

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

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

- Design;
- Finish;
- Mechanical & Electrical;
- Equipment/Furniture/Fittings.

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.

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

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

- the replacement or introduction of additional major decontamination equipment such as washer disinfectors or sterilizers;
- modification of the IAP Room to increase packing table capacity;
- replacement of air ventilation systems serving production areas.

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

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

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 and pharmaceutical practice.

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

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